

**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, 2017

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**  
(State or other jurisdiction of  
incorporation or organization)

**Connaught House  
1 Burlington Road  
Dublin 4, Ireland**  
(Address of principal executive offices)

**98-1007018**  
(I.R.S. Employer  
Identification No.)

(Zip code)

**+353-1-772-8000**

(Registrant's telephone number, including area code)

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

Ordinary shares, \$0.01 par value  
Title of each class

Nasdaq Global Select Market  
Name of each exchange on which registered

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 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   
(Do not check if a smaller reporting  
company)

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 \$8,819,125,952.

As of February 2, 2018, 156,144,366 ordinary shares were issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement for our 2018 Annual General Meeting of Shareholders are incorporated by reference into Part III of this report.

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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,” “intend,” or other similar words. These statements discuss future expectations, and contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward-looking information. Forward-looking statements in this Annual Report on Form 10-K (“Annual Report”) include, without limitation, statements regarding:

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;
- our expectations regarding our products, including the development, regulatory (including expectations about regulatory filing, regulatory approval and regulatory timelines), therapeutic and commercial scope and potential of such products and the costs and expenses related thereto;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the competitive landscape, and changes therein, related to our products, including our development programs, and our industry generally;
- our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;
- our expectations regarding future amortization of intangible assets;
- our expectations regarding our collaborations, licensing arrangements and other significant agreements with third parties relating to our products, including our development programs;
- our expectations regarding the impact of new legislation and related regulations, including the Tax Cuts and Jobs Act of 2017, 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; 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 the estimates included in this Annual Report.

**NOTE REGARDING COMPANY AND PRODUCT REFERENCES**

Use of the terms such as “us,” “we,” “our,” “Alkermes” or the “Company” in this Annual Report is meant to refer to Alkermes plc and its consolidated subsidiaries. Except as otherwise suggested by the context, (a) references to

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“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®, CODAS®, IPDAS®, LinkeRx®, MXDAS®, NanoCrystal®, SECA™, SODAS®, VERELAN® and VIVITROL®.

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

**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 products that address central nervous system (“CNS”) disorders such as schizophrenia, depression, addiction and multiple sclerosis (“MS”). Headquartered in Dublin, Ireland, Alkermes has a research and development (“R&D”) center in Waltham, Massachusetts; an R&D and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio.

**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:

<b>Product</b>	<b>Indication(s)</b>	<b>Licensee</b>	<b>Territory</b>
 <p><b>ARISTADA</b><sup>®</sup> aripiprazole lauroxil extended-release injectable suspension <b>441 mg · 662 mg · 882 mg · 1064 mg</b></p>	Schizophrenia	None	Commercialized by Alkermes in the U.S.
 <p><b>Vivitrol</b><sup>®</sup> (maltrexone for extended-release injectable suspension) 380 mg/vial</p>	Alcohol dependence and Opioid dependence	None  Cilag GmbH International (“Cilag”)	Commercialized by Alkermes in the U.S.  Russia and Commonwealth of Independent States (“CIS”)

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Summary information regarding products that use our proprietary technologies:

<b>Product</b>	<b>Indication(s)</b>	<b>Licensee</b>	<b>Territory</b>
<i>RISPERDAL CONSTA</i>	Schizophrenia and Bipolar I disorder	Janssen Pharmaceutica Inc. (“Janssen, Inc.”) and Janssen Pharmaceutica International, a division of Cilag International AG (“Janssen International”)	Worldwide
<i>INVEGA SUSTENNA</i>	Schizophrenia and Schizoaffective disorder	Janssen Pharmaceutica N.V. (together with Janssen, Inc., Janssen International and their affiliates “Janssen”)	U.S.
<i>XEPLION</i>	Schizophrenia	Janssen	All countries outside of the U.S. (“ROW”)
<i>INVEGA TRINZA</i>	Schizophrenia	Janssen	U.S.
<i>TREVICTA</i>	Schizophrenia	Janssen	ROW
<i>AMPYRA</i>	Treatment to improve walking in patients with MS, as demonstrated by an increase in walking speed	Acorda	U.S.
<i>FAMPYRA</i>		Biogen, under sublicense from Acorda	ROW
<i>BYDUREON and BYDUREON BCise</i>	Type 2 diabetes	AstraZeneca plc (“AstraZeneca”)	Worldwide

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### Proprietary Products

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

#### **ARISTADA**

ARISTADA (aripiprazole lauroxil) is an extended-release intramuscular injectable suspension approved in the U.S. for the treatment of schizophrenia. ARISTADA is the first of our products to utilize our proprietary LinkRx technology. ARISTADA is a prodrug; once in the body, ARISTADA is likely converted by enzyme-mediated hydrolysis to N-hydroxymethyl aripiprazole, which is then hydrolyzed to aripiprazole. ARISTADA is the first atypical antipsychotic with once-monthly, once-every-six-weeks and once-every-two-months dosing options to deliver and maintain therapeutic levels of medication in the body. ARISTADA has four dosing options (441 mg, 662 mg, 882 mg and 1064 mg) and is packaged in a ready-to-use, pre-filled product format. ARISTADA 1064 mg, our two-month dosing option, was approved by the U.S. Food and Drug Administration (the “FDA”) in June 2017. We developed ARISTADA and manufacture and commercialize it in the U.S.

#### *What is schizophrenia?*

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

#### **VIVITROL**

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

#### *What are opioid dependence and alcohol dependence?*

Opioid dependence is a serious and chronic brain disease characterized by compulsive, prolonged self-administration of opioid substances that are not used for a medical purpose. According to the 2016 U.S. National Survey on Drug Use and Health, nearly 2 million people aged 18 or older in the U.S. had an opioid use disorder.

Alcohol dependence is a serious and chronic brain disease characterized by cravings for alcohol, loss of control over drinking, withdrawal symptoms and an increased tolerance for alcohol. According to the 2016 U.S. National Survey on Drug Use and Health, an estimated 8 million people aged 12 or older had alcohol dependence. Adherence to medication is particularly challenging with this patient population.

### Products Using Our Proprietary Technologies

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

#### **INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA**

INVEGA SUSTENNA/XEPLION (paliperidone palmitate), INVEGA TRINZA (paliperidone palmitate)/TREVICTA (paliperidone palmitate 3-monthly injection) and RISPERDAL CONSTA (risperidone long-acting injection) are long-acting atypical antipsychotics owned and commercialized worldwide by Janssen that incorporate our proprietary technologies.

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

In January 2018, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (“Teva”), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of United States Patent No. 9,439,906. The Company is not a party to these proceedings. For further discussion of the legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 16, Commitments and Contingencies in the “Notes to Condensed Consolidated Statements” and “Item 3—Legal Proceedings” in this Annual Report and for information about risks relating to the INVEGA SUSTENNA Paragraph IV litigation, see “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 is an atypical antipsychotic injection for the treatment of schizophrenia used in people who have been treated with INVEGA SUSTENNA for at least four months. INVEGA TRINZA is the first schizophrenia treatment to be taken once every three months. TREVICTA is approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION. INVEGA TRINZA/TREVICTA uses our proprietary technology and is manufactured by Janssen.

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

Revenues from Janssen accounted for approximately 33%, 36% and 40% of our consolidated revenues for the years ended December 31, 2017, 2016 and 2015, respectively. See “Collaborative Arrangements” in Part I of this Annual Report for information about our relationship with Janssen.

### *What is bipolar I disorder?*

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

### *What is schizoaffective disorder?*

Schizoaffective disorder is a condition in which a person experiences a combination of schizophrenia symptoms, such as delusions, hallucinations or other symptoms characteristic of schizophrenia, and mood disorder symptoms, such as mania or depression. Schizoaffective disorder is a serious mental illness that affects about one in 100 people.

## **AMPYRA/FAMPYRA**

AMPYRA (dalfampridine)/FAMPYRA (fampridine) is believed to be the first treatment approved in the U.S. and in over 50 countries across Europe, Asia and the Americas to improve walking in adults with MS who have walking disability, as demonstrated by an increase in walking speed. Extended-release dalfampridine tablets are marketed and sold by Acorda in the U.S. under the trade name AMPYRA and by Biogen outside the U.S. under the trade name FAMPYRA. In July 2011, the European Medicines Agency (“EMA”) conditionally approved FAMPYRA in the EU, and in May 2017, the EMA granted FAMPYRA a standard marketing authorization in the EU for the improvement of



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walking in adults with MS. AMPYRA and FAMPYRA incorporate our oral controlled-release technology. AMPYRA and FAMPYRA are manufactured by us.

We and/or Acorda have received notices of ANDA filings for AMPYRA asserting that a generic form of AMPYRA would not infringe AMPYRA's Orange Book-listed patents and/or those patents are invalid. In response, we and/or Acorda filed lawsuits against certain of the ANDA filers in the U.S. District Court for the District of Delaware (the "Delaware Court") asserting infringement of U.S. Patent No. 5,540,938 (the "938 Patent"), which we own, and U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which are owned by Acorda. On March 31, 2017, the Delaware Court upheld the '938 Patent, which pertains to the formulation of AMPYRA and is set to expire in July 2018, and invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which pertain to AMPYRA (the "Delaware Court Decision"). In May 2017, Acorda filed its appeal of the Delaware Court Decision with the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") with respect to the findings on U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. In June 2017, certain of the ANDA filers filed a cross-appeal of the Delaware Court Decision with the Federal Circuit with respect to the validity of the '938 Patent. We and Acorda filed an opening brief in August 2017 and the ANDA filers responded in October 2017. Each side subsequently filed a response and reply brief in November 2017. A date for oral argument before the Federal Circuit has not yet been set. For further discussion of the legal proceedings related to the patents covering AMPYRA, see Note 16, *Commitments and Contingencies* in the "Notes to Condensed Consolidated Statements" and "Item 3—Legal Proceedings" in this Annual Report and for information about risks relating to the AMPYRA 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."

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

### *What is multiple sclerosis?*

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

### **BYDUREON and BYDUREON BCise**

BYDUREON (exenatide extended-release for injectable suspension) is approved in the U.S. and the EU for the treatment of type 2 diabetes. AstraZeneca is responsible for the development and commercialization of BYDUREON worldwide. BYDUREON, a once-weekly formulation of exenatide, uses our polymer-based microsphere injectable extended-release technology. BYDUREON is manufactured by AstraZeneca. BYDUREON Pen 2 mg, a pre-filled, single-use pen injector that contains the same formulation and dose as the original BYDUREON single-dose tray, is available in the U.S., certain countries in the EU and Japan.

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

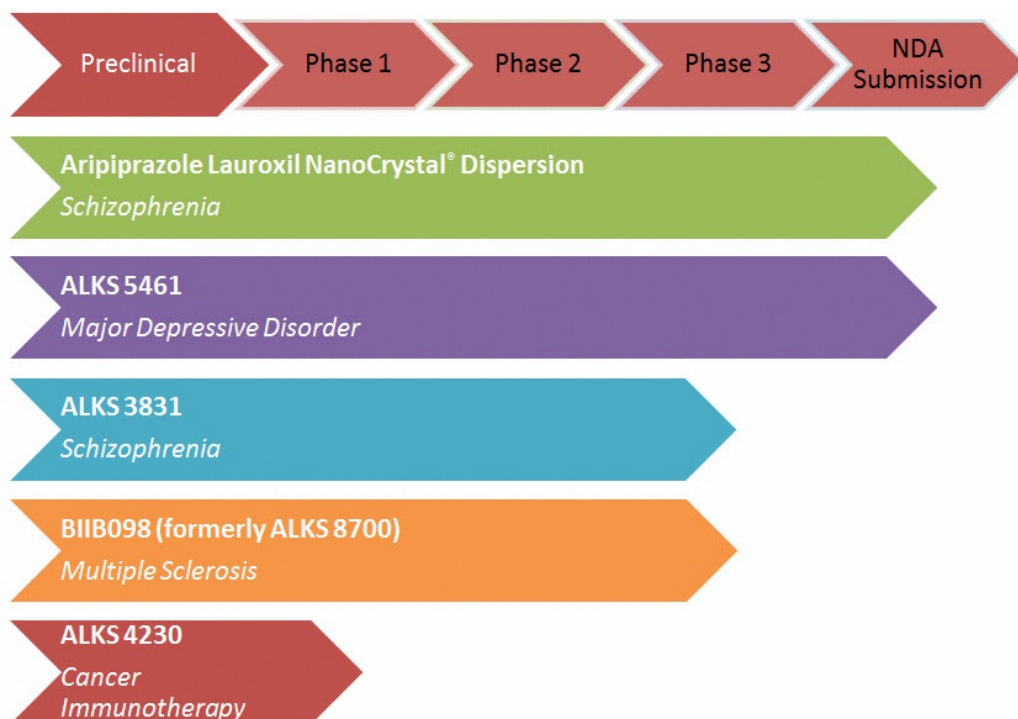
### *What is type 2 diabetes?*

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

## Key Development Programs

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

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



### *Aripiprazole Lauroxil NanoCrystal Dispersion*

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

### *ALKS 5461*

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

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antagonist, and samidorphan, a mu-opioid receptor antagonist. In October 2013, the FDA granted Fast Track status for ALKS 5461 for the adjunctive treatment of MDD in patients with inadequate response to standard antidepressant therapies.

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

In January 2016, we announced the topline results of FORWARD-3 and FORWARD-4. Neither study met the primary efficacy endpoint, which compared ALKS 5461 to placebo on the change from baseline on the 10-item Montgomery—Åsberg Depression Rating Scale (“MADRS-10”) total scores. FORWARD-4, which tested two dose levels of ALKS 5461 (2 mg/2 mg and 0.5 mg/0.5 mg) compared to placebo, showed a clear trend toward efficacy with the 2 mg/2 mg dose of ALKS 5461 on the primary endpoint, and post hoc analyses achieved statistical significance for the 2 mg/2 mg dose group on the MADRS-10 endpoint. Based on these analyses, we believe that FORWARD-4 provides supportive evidence of the efficacy of ALKS 5461 for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressant therapies. FORWARD-3 tested ALKS 5461 (2 mg/2 mg) compared to placebo. Placebo response was greater than that observed in FORWARD-4 and no treatment effect of ALKS 5461 was observed.

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

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

### **ALKS 3831**

ALKS 3831 is a novel, proprietary, oral investigational medicine designed as a broad-spectrum antipsychotic for the treatment of schizophrenia. ALKS 3831 is composed of samidorphan in combination with the established antipsychotic drug olanzapine, which is generally available under the name ZYPREXA. ALKS 3831 is designed to provide the strong antipsychotic efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties.

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

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

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showed that olanzapine achieved similar improvements from baseline PANSS scores as compared to placebo. Results from ENLIGHTEN-2 are expected in the fall of 2018.

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

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

### *BIIB098 (formerly ALKS 8700)*

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

The pivotal clinical program for BIIB098 consists of pharmacokinetic bridging studies comparing BIIB098 and TECFIDERA and a two-year, multicenter, open-label study designed to assess the safety of BIIB098, which we initiated in December 2015. During the third quarter of 2017, we completed the clinical registration requirements for BIIB098. We expect to complete the required non-clinical studies in 2018 and file a 505(b)(2) NDA in the second half of 2018. For more information about 505(b)(2) NDAs, see “Part 1, Item 1—Business, Regulatory, Hatch-Waxman Act” of this Annual Report.

In November 2017, we entered into an exclusive license and collaboration agreement with Biogen relating to BIIB098. For more information about the license and collaboration agreement with Biogen, see “Part 1, Item 1—Business, Collaborative Arrangements” of this Annual Report. We expect to have initial results to share with Biogen in the first half of 2018 from the head-to-head phase 3 study.

### *ALKS 4230*

ALKS 4230 is an engineered fusion protein designed to preferentially bind and signal through the intermediate affinity interleukin-2 (“IL-2”) receptor complex, thereby selectively activating and increasing the number of immunostimulatory tumor-killing immune cells while avoiding the expansion of immunosuppressive cells that interfere with anti-tumor response. The selectivity of ALKS 4230 is designed to leverage the proven anti-tumor effects while overcoming limitations of existing IL-2 therapy, which activates both immunosuppressive and tumor-killing immune cells. Our phase 1 study for ALKS 4230 is being conducted in two stages: a dose-escalation stage followed by a dose-expansion stage. The first stage of the study is designed to determine a maximum tolerated dose, and to identify the optimal dose range of ALKS 4230 based on measures of immunological-pharmacodynamic effects. Following the identification of the optimal dose range of ALKS 4230 in the first stage of the study, the dose-expansion stage of the study will evaluate ALKS 4230 in patients with selected solid tumor types. Initial data from the first stage of the phase 1 study are expected in 2018.

## **Other Programs**

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

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

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

## **Our Research and Development Expenditures**

Please see “Management’s Discussion and Analysis of Financial Condition and Results of Operations” for our R&D expenditures for the years ended December 31, 2017, 2016 and 2015.

## **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

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twentieth anniversary of the first commercial sale of the product in each such country, with the exception of Canada, France, Germany, Italy, Japan, Spain and the United Kingdom, in each case, where the fifteen-year minimum shall pertain regardless. After expiration, Janssen retains a non-exclusive, royalty-free license to manufacture, use and sell RISPERDAL CONSTA.

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

### *Acorda*

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

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

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

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



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the commercial manufacturing supply agreement terminates upon the expiry or termination of the amended and restated license agreement.

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

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

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

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

### *AstraZeneca*

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

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

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

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

### *Biogen*

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

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

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

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

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



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

### **Proprietary Product Platforms**

Our proprietary product platforms, which include technologies owned and exclusively licensed to us, address several important development opportunities. We have used these technologies as platforms to establish drug development, clinical development and regulatory expertise.

#### *Injectable Extended-Release Microsphere Technology*

Our injectable extended-release microsphere technology allows us to encapsulate small-molecule pharmaceuticals, peptides and proteins in microspheres made of common medical polymers. The technology is designed to enable novel formulations of pharmaceuticals by providing controlled, extended release of drugs over time. Drug release from the microsphere is controlled by diffusion of the drug through the microsphere and by biodegradation of the polymer. These processes can be modulated through a number of formulation and fabrication variables, including drug substance and microsphere particle sizing and choice of polymers and excipients.

#### *LinkeRx Technology*

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

#### *NanoCrystal Technology*

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

#### *Oral Controlled Release Technology*

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

- SODAS Technology: SODAS (“Spheroidal Oral Drug Absorption System”) technology involves producing uniform spherical beads of 1 mm to 2 mm in diameter containing drug plus excipients and coated with product-specific modified-release polymers. Varying the nature and combination of polymers within a selectively permeable membrane enables varying degrees of modified release depending upon the required product profile.
- CODAS Technology: CODAS (“Chronotherapeutic Oral Drug Absorption System”) technology enables the delayed onset of drug release incorporating the use of specific polymers, resulting in a drug release profile that more accurately complements circadian patterns.
- IPDAS Technology: IPDAS (“Intestinal Protective Drug Absorption System”) technology conveys gastrointestinal protection by a wide dispersion of drug in a controlled and gradual manner, through the use of numerous high-density controlled-release beads compressed into a tablet form. Release characteristics are modified by the application of polymers to the micro matrix and subsequent coatings, which form a rate-limiting semi-permeable membrane.

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

## **Manufacturing and Product Supply**

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

Although some materials and services for our products are currently available from a single source or a limited number of qualified sources, we attempt to acquire an adequate inventory of such materials, establish alternative sources and/or negotiate long-term supply arrangements. We believe we do not have any significant issues in finding suppliers. However, we cannot be certain that we will continue to be able to obtain long-term supplies of our manufacturing materials.

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

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

We manufacture microspheres for RISPERDAL CONSTA and VIVITROL, polymer for BYDUREON and BYDUREON BCise, and ARISTADA in our Wilmington, Ohio facility. We are currently operating one RISPERDAL CONSTA line, two VIVITROL lines and two ARISTADA lines at commercial scale. In 2018, we expect to qualify a dedicated fill line for the commercial production of VIVITROL diluent. We source our packaging operations for VIVITROL and ARISTADA to a third-party contractor. Janssen is responsible for packaging operations for RISPERDAL CONSTA and, in Russia and certain countries of the CIS, VIVITROL. Our Wilmington, Ohio facility has been inspected by U.S., European (including the Medicines and Healthcare Products Regulatory Agency), Chinese, Japanese, Brazilian, Turkish and Saudi Arabian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

We manufacture AMPYRA/FAMPYRA and other products in our Athlone, Ireland facility. This facility has been inspected by U.S., Irish, Brazilian, Turkish, Saudi Arabian, Korean, Belarusian and Chinese regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing. The FDA recently completed a pre-approval inspection and recommended the Athlone, Ireland facility for approval to manufacture commercial supplies of bulk intermediate NanoCrystal Dispersion of Meloxicam.

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.

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### *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, 2017, 2016 and 2015.

### **Permits and Regulatory Approvals**

We hold various licenses in respect of our manufacturing activities conducted in Wilmington, Ohio and Athlone, Ireland. The primary licenses held in this regard are FDA Registrations of Drug Establishment; and Drug Enforcement Administration of the U.S. Department of Justice (“DEA”). We also hold a Manufacturers Authorization (No. M1067), an Investigational Medicinal Products Manufacturers Authorization (No. IMP074) and Certificates of Good Manufacturing Practice Compliance of a Manufacturer (Ref. 2014/7828/IMP074 and 2014/7828/M1067) from the Health Products Regulatory Authority in Ireland (“HPRA”) in respect of our Athlone, Ireland facility, and a number of Controlled Substance Licenses granted by the HPRA. Due to certain U.S. state law requirements, we also hold state licenses to cover distribution activities through certain states and not in respect of any manufacturing activities conducted in those states.

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

### **Marketing, Sales and Distribution**

We are responsible for the marketing of VIVITROL and ARISTADA in the U.S. We focus our sales and marketing efforts on specialist physicians in private practice and in public treatment systems. We believe that we use customary pharmaceutical company practices to market our product and to educate physicians. Our practices include, the education of individual physicians, nurses, social workers, counselors and other stakeholders involved in the treatment of opioid dependence, advertisements, professional symposia, selling initiatives and other methods. We provide, or contract with third-party vendors to provide, customer service and other related programs for our products, such as product-specific websites, insurance research services and order, delivery and fulfillment services.

Our sales force for VIVITROL in the U.S. consists of approximately 100 individuals. VIVITROL is sold to pharmaceutical wholesalers, pharmacies, specialty distributors and treatment providers. Product sales of VIVITROL during the year ended December 31, 2017 to Cardinal Health, McKesson Corporation, AmerisourceBergen Corporation (“AmerisourceBergen”) and CVS Caremark Corporation represented approximately 19%, 18%, 18% and 11%, respectively, of total VIVITROL sales.

Our sales force for ARISTADA in the U.S. consists of approximately 220 individuals. ARISTADA is primarily sold to pharmaceutical wholesalers. Product sales of ARISTADA during the year ended December 31, 2017 to Cardinal Health, McKesson Corporation and AmerisourceBergen represented approximately 45%, 24% and 20%, respectively, of total ARISTADA sales.

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

Under our license agreements with Janssen, AstraZeneca, Acorda and other licensees and sublicensees, they are each responsible for the commercialization of any products developed under their respective agreement if and when regulatory approval is obtained.

## Competition

We face intense competition in the development, manufacture, marketing and commercialization of our products from many and varied sources, such as academic institutions, government agencies, research institutions and biopharmaceutical companies, including other companies with similar technologies. Some of these competitors are also our licensees, who control the commercialization of products from which we receive manufacturing and royalty revenues. These competitors are working to develop and market other systems, products and other methods of preventing or reducing disease, and new small-molecule and other classes of drugs that can be used with or without a drug delivery system.

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

There are other companies developing extended-release product platforms. In many cases, there are products on the market or in development that may be in direct competition with our products. In addition, we know of new chemical entities that are being developed that, if successful, could compete against our products. These chemical entities are being designed to work differently than our products and may turn out to be safer or to be more effective than our products. Among the many experimental therapies being tested around the world, there may be some that we do not now know of that may compete with our proprietary product platforms or products. Our licensees could choose a competing technology to use with their drugs instead of one of our product platforms and could develop products that compete with our products.

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

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products, including, but not limited to Luye Pharma Group Ltd. (“Luye Pharma”), which is developing risperidone formulated as extended release microspheres for intramuscular injection for the treatment of schizophrenia and/or schizoaffective disorders, and Indivior plc, which is developing a once-monthly injectable risperidone for the treatment of schizophrenia. In the treatment of schizophrenia, ARISTADA, INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERSDAL CONSTA compete with each other and a number of other injectable products including ZYPREXA RELPREVV (olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly; ABILIFY MAINTENA (aripiprazole for extended release injectable suspension), a once-monthly injectable formulation of ABILIFY (aripiprazole) developed by Otsuka Pharm. Co.; oral compounds currently on the market; and generic versions of branded oral and injectable products. In the treatment of bipolar disorder, RISPERSDAL CONSTA competes with antipsychotics such as oral aripiprazole, REXULTI, LATUDA, ABILIFY MAINTENA, risperidone, olanzapine, ziprasidone and clozapine.

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

In the treatment of opioid dependence, VIVITROL competes with SUBOXONE (buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE (buprenorphine/naloxone) Sublingual Film, SUBUTEX (buprenorphine HCl sublingual tablets) and, once launched, will compete with SUBLOCADE (once-monthly buprenorphine extended-release

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injection), each of which is, or will be, marketed and sold by Indivior plc, and BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences, PROBUPHINE (buprenorphine) from Titan Pharmaceuticals, Inc., and ZUBSOLV (buprenorphine and naloxone) marketed by Orexo US, Inc. VIVITROL also competes with methadone, oral naltrexone and generic versions of SUBUTEX and SUBOXONE sublingual tablets. Other pharmaceutical companies are developing products that have shown promise in treating opioid dependence that, if approved by the FDA, would compete with VIVITROL.

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

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

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

## **Patents and Proprietary Rights**

Our success will be dependent, in part, on our ability to obtain and maintain patent protection for our products, including those marketed and sold by our licensees, to maintain trade secret protection and to operate without infringing upon the proprietary rights of others. We have a proprietary portfolio of patent rights and exclusive licenses to patents and patent applications. In addition, our licensees may own issued patents that cover certain of our products. We have filed numerous patent applications in the U.S. and in other countries directed to compositions of matter as well as processes of preparation and methods of use, including patent applications relating to each of our delivery technologies. As of December 31, 2017, we owned more than 200 issued U.S. patents. In the future, we plan to file additional patent applications in the U.S. and in other countries directed to new or improved products and processes, and we intend to vigorously defend our patent positions.

### **ARISTADA**

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

- U.S. Patent No. 8,431,576, having claims to a class of compounds that includes aripiprazole lauroxil, expiring in 2030;
- U.S. Patent No. 8,796,276, having claims to methods of treating schizophrenia using a class of compounds that includes aripiprazole lauroxil, expiring in 2030;
- U.S. Patent No. 9,034,867, having claims to pharmaceutical compositions, expiring in 2032;
- U.S. Patent No. 9,193,685, having claims to pharmaceutical compositions that confer long-term stability, expiring in 2033;
- U.S. Patent No. 9,452,131, having claims to methods of treatment for schizophrenia, expiring in 2035; and
- U.S. Patent No. 9,526,726, having claims to kits comprising pharmaceutical compositions of aripiprazole lauroxil and instructions for intramuscular injection, expiring in 2035.

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

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

We have a significant number of patents and certain pending patent applications covering our microsphere technology throughout the world, which, to some extent, cover VIVITROL, RISPERDAL CONSTA, BYDUREON and BYDUREON BCise. The latest of our patents covering VIVITROL, RISPERDAL CONSTA, BYDUREON and BYDUREON BCise expire in 2029, 2023, 2025 and 2025 in the U.S., respectively, and 2021, 2021, 2024 and 2024 in the EU, respectively, and we own 16, 4, 11 and 10 unexpired Orange-Book listed U.S. patents covering VIVITROL, RISPERDAL CONSTA, BYDUREON and BYDUREON BCise, respectively.

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

Our NanoCrystal technology patent portfolio contains a number of patents granted throughout the world, including the U.S. and countries outside of the U.S. We also have a number of pending patent applications covering our NanoCrystal technology which, to some extent, cover INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. The latest of the patents subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expire in 2019 in the U.S. and 2022 in the EU, and, in certain countries, in 2030. The latest of the patents covering INVEGA TRINZA/TREVICTA expired in 2017 in the U.S. (with regulatory exclusivity in the U.S. until May 2018) and will expire in 2022 in the EU. In addition, the latest of the patents not subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expires in 2031 in the U.S. For a discussion of legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 16, *Commitments and Contingencies* in the “Notes to Condensed Consolidated 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). AMPYRA/FAMPYRA incorporates our OCR technology, and the latest of the patents covering AMPYRA/FAMPYRA expires in 2027 in the U.S. and 2025 in the EU (with regulatory exclusivity in the EU until 2021). For a discussion of legal proceedings related to the patents covering AMPYRA, see Note 16, *Commitments and Contingencies* in the “Notes to Condensed Consolidated Statements” and “Item 3—Legal Proceedings” in this Annual Report.

### *ALKS 5461 and ALKS 3831*

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

<b>U.S. Patent No.</b>	<b>Product Candidate(s) Covered</b>	<b>Expiration Date</b>
7,956,187	ALKS 5461 ALKS 3831	2021
8,252,929	ALKS 5461 ALKS 3831	2021
7,262,298	ALKS 5461 ALKS 3831	2025
8,680,112	ALKS 5461 ALKS 3831	2030
9,119,848	ALKS 5461 ALKS 3831	2031
9,126,977	ALKS 3831	2031
9,517,235	ALKS 3831	2031
8,778,960	ALKS 3831	2032
8,822,488	ALKS 5461	2032
9,498,474	ALKS 5461	2032



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### *BIIB098*

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

- U.S. Patent No. 8,669,281, having claims to a composition of matter that covers BIIB098, expiring in 2033; and
- U.S. Patent No. 9,090,558, having claims to methods of treating MS, expiring in 2033.

### *ALKS 4230*

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

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

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

There may be patents issued to third parties that relate to our products. The manufacture, use, offer for sale, sale or import of some of our products might be found to infringe on the claims of these patents. A third party might file an infringement action against us. The cost of defending such an action is likely to be high, and we might not receive a favorable ruling. There may also be patent applications filed by third parties that relate to some of our products if issued in their present form. The patent laws of the U.S. and other countries are distinct, and decisions as to patenting, validity of patents and infringement of patents may be resolved differently in different countries.

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

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

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

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

## Revenues and Assets by Region

For the years ended December 31, 2017, 2016 and 2015, our revenue and assets by geographic area are presented below:

(In thousands)	Year Ended December 31.		
	2017	2016	2015
Revenue by region:			
U.S.	\$ 700,090	\$ 557,312	\$ 448,639
Ireland	9,706	4,407	3,902
Rest of world	193,578	183,975	175,794
Assets by region:			
Current assets:			
U.S.	\$ 402,481	\$ 382,168	\$ 360,154
Ireland	403,167	407,761	394,281
Rest of world	3,196	749	527
Long-term assets:			
U.S.:			
Other	\$ 360,641	\$ 236,175	\$ 294,158
Ireland:			
Intangible assets	\$ 256,168	\$ 318,227	\$ 379,186
Goodwill	92,873	92,873	92,873
Other	278,701	288,470	334,565

## 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.

*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



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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 the supplemental information.

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

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

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

In reviewing a BLA or NDA, the FDA may grant marketing approval, or issue a complete response letter to communicate to the applicant the reasons the application cannot be approved in the current form and provide input on the changes that must be made before an application can be approved. Even if such additional information and data are submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval. The receipt of regulatory approval often takes a number of years, involves the expenditure of substantial resources and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, potential safety signals observed in pre-clinical or clinical tests, and the risks and benefits demonstrated in clinical trials. It is impossible to predict with any certainty whether and when the FDA will grant marketing approval. Even if a product is approved, the approval may be subject to limitations based on the FDA’s interpretation of the data. For example, the FDA may require, as a condition of approval,

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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.

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 controlled substance must undergo scheduling by the DEA, which is a separate process that may delay the commercial launch of a pharmaceutical product even after FDA approval of the NDA. Companies with a scheduled pharmaceutical product are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess ongoing compliance with the DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal, of any DEA registration and injunctions, or civil or criminal penalties.

### *Outside the United States*

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

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recognition procedure, where applicants submit an application to one country for review and other countries may accept or reject the initial decision. Regardless of the approval process employed, various parties share responsibilities for the monitoring, detection and evaluation of adverse events post-approval, including national authorities, the EMA, the EC and the marketing authorization holder.

### *Good Manufacturing Processes*

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

### *Good Clinical Practices*

The FDA, the EMA and other regulatory agencies promulgate regulations and standards, commonly referred to as Good Clinical Practices (“GCP”), for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the trial participants are adequately protected. The FDA, the EMA and other regulatory agencies enforce GCP through periodic inspections of trial sponsors, principal investigators, trial sites, contract research organizations (“CROs”) and institutional review boards. If our studies fail to comply with applicable GCP, 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

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

### *Sales and Marketing*

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

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and healthcare providers and require disclosure to the government and public of such interactions. The laws include federal "sunshine" provisions enacted in 2010 as part of the comprehensive federal healthcare reform legislation. The sunshine provisions apply to pharmaceutical manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government (for re-disclosure to the public) certain payments made to, or at the request of, or on behalf of, physicians or to teaching hospitals. Certain state laws also require disclosure of pharmaceutical pricing information and marketing expenditures. Given the ambiguity found in many of these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

### *Pricing and Reimbursement*

#### *United States*

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

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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.

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”).

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

### *Outside the United States*

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

### *Other Regulations*

*Foreign Corrupt Practices Act:* We are subject to the U.S. Foreign Corrupt Practices Act (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



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

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

## **Employees**

As of February 2, 2018, we had approximately 2,000 full-time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biopharmaceutical or medical product companies. We believe that we have been successful in attracting skilled and experienced scientific and senior management personnel; however, competition for such personnel is intense. None of our employees is covered by a collective bargaining agreement. We consider our relations with our employees to be good.

## **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](http://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. You may read and copy materials we file with the SEC at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at [www.sec.gov](http://www.sec.gov).

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](http://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.*

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

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

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

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

In addition, most of our licensees can terminate their agreements with us without cause, and we cannot guarantee that any of these relationships will continue. Failure to make or maintain these arrangements or a delay in, or failure of, a licensee's performance, or factors that may affect a licensee's sales, may materially adversely affect our business, financial condition, cash flows and results of operations.

*We receive substantial revenues from our key products.*

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

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

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

- the perception of physicians and other members of the healthcare community as to our products' safety and efficacy relative to that of competing products and the willingness or ability of physicians and other members of the healthcare community to prescribe or dispense, and patients to use, our products, including those that may be scheduled by the DEA (if and when approved);
- unfavorable publicity concerning us or our products, similar classes of drugs or the industry generally;
- the cost-effectiveness of our products;
- patient and physician satisfaction with our products;
- the successful manufacture of our products on a timely basis;
- the cost and availability of raw materials necessary for the manufacture of our products;
- the size of the markets for our products;
- reimbursement policies of government and third-party payers;



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- the introduction, availability and acceptance of competing treatments, including treatments marketed and sold by our licensees;
- the reaction of companies that market competitive products;
- adverse event information relating to our products or to similar classes of drugs;
- changes to the product labels of our products, or of products within the same drug classes, to add significant warnings or restrictions on use;
- our continued ability to access third parties to vial, package and/or distribute our products on acceptable terms;
- the unfavorable outcome of litigation or proceedings before the U.S. Patent and Trademark Office's (the "USPTO") Patent Trial and Appeal Board (the "PTAB"), including so-called "Paragraph IV" litigation, inter partes reviews ("IPR") and other patent litigation, related to any of our products, including Paragraph IV litigation relating to INVEGA SUSTENNA and AMPYRA;
- regulatory developments related to the manufacture or continued use of our products, including the issuance of a REMS by the FDA;
- the extent and effectiveness of the sales and marketing and distribution support our products receive, including from our licensees;
- our licensees' decisions as to the timing of product launches, pricing and discounting;
- disputes with our licensees relating to the marketing and sale of products from which we receive revenue;
- exchange rate valuations and fluctuations; and
- any other material adverse developments with respect to the commercialization of our products.

Our revenues will also fluctuate from quarter to quarter based on a number of other factors, including the acceptance of our products in the marketplace, our licensees' orders, the timing of shipments, and our ability to manufacture products successfully, including our yield and our production schedule. The unit costs to manufacture our products may be higher than anticipated if certain volume levels are not achieved. In addition, we may not be able to supply the products in a timely manner or at all.

*We have less experience in the commercialization of long-acting atypical antipsychotics and oral antidepressants than our competitors.*

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

We lack experience commercializing products in markets with multiple branded and generic competitors, including schizophrenia and depression, and will face competition from companies with more experience and resources than we have. If we are not able to attract and retain qualified personnel to serve in our sales and marketing organization, to maintain effective distribution networks and reimbursement for our products, or to otherwise effectively and efficiently support our commercialization activities, we may not be able to successfully commercialize our products and such events could materially adversely affect our business, financial condition, cash flows and results of operations.

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

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

In addition, regulation is not static, and regulatory agencies, including the FDA, evolve in their staff, interpretations and practices and may impose more stringent requirements than currently in effect, which may adversely affect our planned drug development and/or our commercialization efforts. The approval procedure and the time required to obtain approval also varies among countries. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory agency does not ensure approval by regulatory agencies in other jurisdictions. In addition, the FDA or regulatory agencies outside the U.S. may choose not to communicate with or update us during clinical testing

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and regulatory review periods. The ultimate decision by the FDA or other regulatory agencies regarding drug approval may not be consistent with prior communications.

This product approval process can last many years, be very costly and still be unsuccessful. Regulatory approval by the FDA or regulatory agencies outside the U.S. can be delayed, limited or not granted at all for many reasons, including:

- a product may not demonstrate safety and efficacy for each target indication in accordance with the FDA's or regulatory agencies' standards;
- data from pre-clinical testing and clinical trials may be interpreted by the FDA or other regulatory agencies in different ways than we or our licensees interpret it;
- the FDA or other regulatory agencies may not agree with our or our licensees' regulatory approval strategies, components of our or our licensees' filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of our or our licensees' submitted data;
- the FDA or other regulatory agencies might not approve our or our licensees' manufacturing processes or facilities;
- the FDA or other regulatory agencies may not approve accelerated development timelines for our products;
- the failure of our clinical investigational sites and the records kept at such sites, including the clinical trial data, to be in compliance with the FDA's GCP, or EU legislation governing GCP, including the failure to pass FDA, EMA or EU member state inspections of clinical trials;
- the FDA or other regulatory agencies may change their approval policies or adopt new regulations; and
- adverse medical events during the trials could lead to requirements that trials be repeated or extended, or that a program be terminated or placed on clinical hold, even if other studies or trials relating to the program are successful.

Failure to obtain regulatory approval for products will prevent their commercialization. Any delay in obtaining regulatory approval for products could adversely affect our ability to successfully commercialize such products. In addition, share prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a product or where the timing of FDA approval is delayed. If the FDA's or any other regulatory agency's response to any application for approval is delayed or not favorable for any of our products, our share price could decline significantly and could materially adversely affect our business, financial condition, cash flows and results of operations.

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

Before obtaining regulatory approvals for the commercial sale of any products, we or our licensees must demonstrate, through pre-clinical testing and clinical trials, that our products are safe and effective for use in humans. Conducting clinical trials is a lengthy, time-consuming and expensive process. We have incurred, and we will continue to incur, substantial expense for pre-clinical testing and clinical trials.

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

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

In addition, we are currently conducting and enrolling patients in clinical studies in a number of countries where our experience is more limited. For example, phase 3 efficacy studies of ALKS 3831 are being conducted in many countries around the world, including in Europe and Israel. We depend on independent clinical investigators, CROs and other third-party service providers and our collaborators in the conduct of clinical trials for our products and in the accurate

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reporting of results from such clinical trials. We rely heavily on these parties for successful execution of our clinical trials but do not control many aspects of their activities. For example, while the investigators are not our employees, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols.

The outcome of our clinical trials is uncertain. The results from pre-clinical testing and early clinical trials often have not predicted results of later clinical trials. A number of products have shown promising results in early clinical trials but subsequently failed to establish sufficient safety and efficacy data in later clinical trials to obtain necessary regulatory approvals.

If a product fails to demonstrate safety and efficacy in clinical trials, or if third parties fail to conduct clinical trials in accordance with their obligations, the development, approval and commercialization of our products may be delayed or prevented, and such events could materially adversely affect our business, financial condition, cash flows and results of operations.

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

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

We rely solely on our manufacturing facility in Wilmington, Ohio for the manufacture of RISPERDAL CONSTA, VIVITROL, ARISTADA, polymer for BYDUREON and BYDUREON BCise and certain of our other development products. We rely on our manufacturing facility in Athlone, Ireland for the manufacture of AMPYRA/FAMPYRA and some of our other products using our NanoCrystal and OCR technologies.

Due to regulatory and technical requirements, we have limited ability to shift production among our facilities or to outsource any part of our manufacturing to third parties. If we cannot produce sufficient commercial quantities of our products to meet demand, there are currently very few, if any, third-party manufacturers capable of manufacturing our products as contract suppliers. We cannot be certain that we could reach agreement on reasonable terms, if at all, with those manufacturers. Even if we were to reach agreement, the transition of the manufacturing process to a third party to enable commercial supplies could take a significant amount of time and money, and may not be successful.

Our manufacturing facilities also require specialized personnel and are expensive to operate and maintain. Any delay in the regulatory approval or market launch of products, or suspension of the sale of our products, manufactured in our facilities, may cause operating losses as we continue to operate these facilities and retain specialized personnel. In addition, any interruption in manufacturing could result in delays in meeting contractual obligations and could damage our relationships with our licensees, including the loss of manufacturing and supply rights.

### *We rely on third parties to provide services in connection with the manufacture and distribution of our products.*

We rely on third parties for the timely supply of specified raw materials, equipment, contract manufacturing, formulation and packaging services, storage and product distribution services, customer service activities and product returns processing. These third parties must comply with federal, state and local regulations applicable to their business, including FDA and, as applicable, DEA regulations. Although we actively manage these third-party relationships to ensure continuity, quality and compliance with regulations, some events beyond our control could result in the complete or partial failure of these goods and services. Any such failure could materially adversely affect our business, financial condition, cash flows and results of operations.

The manufacture of products and product components, including the procurement of bulk drug product, packaging, storage and distribution of our products, requires successful coordination among us and multiple third-party providers. For example, we are responsible for the entire supply chain for both ARISTADA and VIVITROL, up to the sale of final product and including the sourcing of key raw materials and active pharmaceutical agents from third parties. Issues with our third-party providers, including our inability to coordinate these efforts, lack of capacity available at such third-party

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providers or any other problems with the operations of these third-party providers, could require us to delay shipment of saleable products, recall products previously shipped or could impair our ability to supply products at all. This could increase our costs, cause us to lose revenue or market share and damage our reputation and have a material adverse effect on our business, financial condition, cash flows and results of operations.

In addition, due to the unique nature of the production of our products, there are several single-source providers of our key raw materials. We endeavor to qualify and register new vendors and to develop contingency plans so that production is not impacted by issues associated with single-source providers. Nonetheless, our business could be materially and adversely affected by issues associated with single-source providers.

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

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

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

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

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

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

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our products.

In the U.S., federal and state legislatures, health agencies and third-party payers continue to focus on containing the cost of healthcare, including by comparing the effectiveness, benefits and costs of similar treatments. Any adverse findings for our products from such comparisons may reduce the extent of reimbursement for our products. Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs, including but not limited to price control initiatives, discounts and other pricing-related actions. For example, in 2017, the State of California enacted as law SB-17, a drug pricing transparency bill that requires, among other things, that manufacturers notify the state and health insurers, and justify, any time such manufacturers plan to increase the price of a medication by sixteen percent (16%) or more over a two-year period. We expect similar state drug pricing initiatives to be proposed in 2018. In addition, State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

In 2018, we may face uncertainties as a result of likely continued federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA and potential reforms and changes to government negotiation or regulation of drug pricing. There is no assurance that the PPACA, as currently enacted or as amended in the future, or such reforms and changes, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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

### *Patent protection for our products is important and uncertain.*

The following factors are important to our success:

- receiving and maintaining patent and/or trademark protection for our products, technologies and developing technologies, including those that are the subject of our licenses;
- maintaining our trade secrets;
- not infringing the proprietary rights of others; and
- preventing others from infringing our proprietary rights.

Patent protection only provides rights of exclusivity for the term of the patent. We are able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. In this regard, we try to protect our proprietary position by filing patent applications in the U.S. and elsewhere related to our proprietary product inventions and improvements that are important to the development of our business and products. Our pending patent applications, together with those we may file in the future, or those we may license to or from third parties, may not result in patents being issued. Even if issued, such patents may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar technology. The development of new technologies or products may take a number of years, and there can be no assurance that any patents which may be granted in respect of such technologies or products will not have expired or be due to expire or withstand challenge by the time such products are commercialized.

Although we believe that we make reasonable efforts to protect our intellectual property rights and to ensure that our proprietary technology does not infringe the rights of third parties, we cannot ascertain the existence of all potentially

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conflicting claims. Therefore, there is a risk that third parties may make claims of infringement against our products or technologies. There may be patents issued to third parties that relate to our products. There may also be patent applications filed by third parties that relate to some of our products. If patents exist or are issued that cover our products, we may not be able to manufacture, use, offer for sale, sell or import such products without first getting a license from the patent holder. The patent holder may not grant us a license on reasonable terms, or it may refuse to grant us a license at all. This could delay or prevent us from developing, manufacturing, selling or importing those of our products that would require the license. Claims of intellectual property infringement also might require us to redesign affected products, enter into costly settlement or license agreements or pay costly damage awards, or face a temporary or permanent injunction prohibiting us from marketing or selling certain of our products. Even if we have an agreement to indemnify us against such costs, the indemnifying party may be unable to uphold its contractual obligations. If we cannot or do not license the infringed technology at all, license the technology on reasonable terms or substitute similar technology from another source, our business, financial condition, cash flows and results of operations could be materially adversely affected.

Because the patent positions of biopharmaceutical companies involve complex legal and factual questions, enforceability of patents cannot be predicted with certainty. The ultimate degree of patent protection that will be afforded to products and processes, including ours, and those of our licensees, in the U.S. and in other important markets, remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. Patents, if issued, may be challenged, invalidated or circumvented. As more products are commercialized using our proprietary product platforms, or as any product achieves greater commercial success, our patents become more likely to be subject to challenge by potential competitors. The laws of certain countries may not protect our intellectual property rights to the same extent as do the laws of the U.S., and any patents that we own or license from others may not provide any protection against competitors. Furthermore, others may independently develop similar technologies outside the scope of our patent coverage.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our licensees, licensors, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information, or our competitors might learn of the information in some other way. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to, or independently developed by, a competitor, such event could materially adversely affect our business, financial condition, cash flows and results of operations.

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

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

In part as a result of this uncertainty, there has been, and we expect that there may continue to be, significant litigation and an increasing number of IPRs and administrative proceedings in the pharmaceutical industry regarding patents and other intellectual property rights. A patent holder might file an IPR, interference and/or infringement action against us claiming that certain claims of one or more of our issued patents are invalid or that the manufacture, use, offer for sale, sale or import of our products infringed one or more of such party's patents. We may have to expend considerable time, effort and resources to defend such actions. In addition, we may need to enforce our intellectual property rights against third parties who infringe our patents and other intellectual property or challenge our patents, patent applications or trademark applications (see “—We or our licensees may face claims against our intellectual property rights covering our products and competition from generic drug manufacturers” for additional information regarding litigation with generic drug manufacturers). We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Competitors may sue us as a way of delaying the introduction of our products.

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



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

As is typical in the pharmaceutical industry, we utilize pharmaceutical wholesalers in connection with the distribution of the products that we market and sell. A significant amount of our product is sold to end-users through the three largest wholesalers in the U.S. market, Cardinal Health Inc., AmerisourceBergen Corp. and McKesson Corp. If we are unable to maintain our business relationships with these major pharmaceutical wholesalers on commercially acceptable terms, if the buying patterns of these wholesalers fluctuate due to seasonality or if wholesaler buying decisions or other factors outside of our control change, such events could materially adversely affect our business, financial condition, cash flows and results of operations.

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

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

If our delivery technologies or product development efforts fail to result in the successful development and commercialization of products, if our licensees decide not to pursue development and/or commercialization of our products or if our products do not perform as anticipated, such events could materially adversely affect our business, financial condition, cash flows and results of operations (see “—Our revenues may be lower than expected as a result of failure by the marketplace to accept our products or for other factors” for factors that may affect the market acceptance of our products approved for sale).

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

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

Further, if a product for which we obtain regulatory approval is a controlled substance, it will not become commercially available until after the DEA provides its final schedule designation, which may take longer and may be more restrictive than we expect or may change after its initial designation. We currently expect ALKS 5461 and ALKS 3831 to require such DEA final schedule designation prior to commercialization. A restrictive designation could adversely affect our ability to commercialize such products and could materially adversely affect our business, financial condition, cash flows and results of operations.

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

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

We may be the subject of certain claims, including those asserting violations of securities and fraud and abuse laws and derivative actions. Following periods of volatility in the market price of a company’s securities, securities class action litigation has often been instituted against companies. In November 2017, a purported stockholder of ours filed a putative class action against us and certain of our officers on behalf of a putative class of purchasers of our securities during the period of February 24, 2015 to November 3, 2017. Such action alleges violations of Sections 10(b) and 20(a) of the Exchange Act based on allegedly false or misleading statements and omissions regarding our marketing practices

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related to VIVITROL, and seeks to recover unspecified damages for alleged inflation in the price of securities, and reasonable costs and expenses, including attorneys' fees. For further discussion of this putative class action, see Note 16, *Commitments and Contingencies* in the "Notes to Condensed Consolidated Statements" and "Item 3—Legal Proceedings" in this Annual Report. This punitive class action and any similar future litigation could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

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

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

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

Our activities, and the activities of our licensees and third-party providers, are subject to comprehensive government regulation. Government regulation by various national, state and local agencies, which includes detailed inspection of, and controls over, research and laboratory procedures, clinical investigations, product approvals and manufacturing, marketing and promotion, adverse event reporting, sampling, distribution, recordkeeping, storage, and disposal practices, and achieving compliance with these regulations, substantially increases the time, difficulty and costs incurred in obtaining and maintaining approvals to market newly developed and existing products. Government regulatory actions can result in delay in the release of products, seizure or recall of products, suspension or revocation of the authority necessary for the manufacture and sale of products, and other civil or criminal sanctions, including fines and penalties. Biopharmaceutical companies also have been the target of government lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of healthcare business, submission of false claims for government reimbursement, antitrust violations and violations related to environmental matters. In addition, we may be the subject of securities law claims and derivative actions.

While we have implemented numerous risk mitigation measures, we cannot guarantee that we, our employees, our licensees, our consultants or our contractors are, or will be, in compliance with all applicable U.S. federal and state regulations and/or laws or all applicable regulations and/or laws outside the U.S. and interpretations of the applicability of these laws to marketing practices. If we or our agents fail to comply with any of those regulations or laws, a range of actions could result, including the termination of clinical trials, the failure to approve a product, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation.



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Changes in laws affecting the healthcare industry, including new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to patent protection and enforcement, healthcare availability, and product pricing and marketing, could also adversely affect our revenues and our potential to be profitable. The enactment in the U.S. of healthcare reform and the promulgation of regulations, new legislation and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business. The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the U.S. and the current administration has stated that it will address such costs through new legislative and administrative measures. These measures, if adopted, could impact our ability to generate revenues from our products.

### *We face competition in the biopharmaceutical industry.*

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

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

There are other companies developing extended-release product platforms. In many cases, there are products on the market or in development that may be in direct competition with our products. In addition, we know of new chemical entities that are being developed that, if successful, could compete against our products. These chemical entities are being designed to work differently than our products and may turn out to be safer or more effective than our products. Among the many experimental therapies being tested around the world, there may be some that we do not now know of that may compete with our proprietary product platforms or products. Our licensees could choose a competing technology to use with their drugs instead of one of our product platforms and could develop products that compete with our products.

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products, including, but not limited to Luye Pharma, which is developing risperidone formulated as extended release microspheres for intramuscular injection for the treatment of schizophrenia and/or schizoaffective disorders and Indivior plc, which is developing a once-monthly injectable risperidone for the treatment of schizophrenia. In the treatment of schizophrenia, ARISTADA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA compete with each other and a number of other injectable products including ZYPREXA RELPREVV ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly; ABILIFY MAINTENA, (aripiprazole for extended release injectable suspension), a once-monthly injectable formulation of ABILIFY (aripiprazole) developed by Otsuka Pharm. Co.; oral compounds currently on the market; and generic versions of branded oral and injectable products. In the treatment of bipolar disorder, RISPERDAL CONSTA competes with antipsychotics such as oral aripiprazole, REXULTI, LATUDA, ABILIFY MAINTENA, risperidone, olanzapine, ziprasidone and clozapine.

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

In the treatment of opioid dependence, VIVITROL competes with SUBOXONE (buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE (buprenorphine/naloxone) Sublingual Film, SUBUTEX (buprenorphine HCl

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sublingual tablets) and, once launched, will compete with SUBLOCADE (once-monthly buprenorphine extended-release injection), each of which is, or will be, marketed and sold by Indivior plc, and BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences, PROBUPHINE (buprenorphine) from Titan Pharmaceuticals, Inc. and ZUBSOLV (buprenorphine and naloxone) marketed by Orexo US, Inc. It also competes with methadone, oral naltrexone and generic versions of SUBUTEX and SUBOXONE sublingual tablets. Other pharmaceutical companies are developing products that have shown promise in treating opioid dependence that, if approved by the FDA, would compete with VIVITROL.

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

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

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

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

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

In the U.S., generic manufacturers of innovator drug products may file ANDAs and, in connection with such filings, certify that their products do not infringe the innovator’s patents and/or that the innovator’s patents are invalid. This often results in litigation between the innovator and the ANDA applicant. This type of litigation is commonly known in the U.S. as “Paragraph IV” litigation.

We have received notices of ANDA filings for AMPYRA asserting that a generic form of AMPYRA would not infringe AMPYRA’s Orange-Book listed patents and/or those patents are invalid. We are currently engaged in Paragraph IV litigation disputing such claims. This litigation may be costly and time consuming. For a discussion of legal proceedings related to the patents covering AMPYRA, see Note 16, *Commitments and Contingencies* in the “Notes to Condensed Consolidated 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, 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 Contingencies* in the “Notes to Condensed Consolidated 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 our defense of our patent rights. Our and our licensees’ existing patents could be invalidated, found unenforceable or found not to cover generic forms of our or our licensees’ products. If an ANDA filer were to receive FDA approval to sell a generic version of our products and/or

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prevail in any patent litigation, our products would become subject to increased competition and our business, financial condition, cash flows and results of operations could be materially adversely affected.

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

We cannot predict whether the commercial use of our products will produce undesirable or unintended side effects that have not been evident in the use of, or in clinical trials conducted for, such products to date. The administration of drugs in humans carries the inherent risk of product liability claims whether or not the drugs are actually the cause of an injury. Our products may cause, or may appear to have caused, injury or dangerous drug interactions, and we may not learn about or understand those effects until the products have been administered to patients for a prolonged period of time. Additionally, incidents of product misuse may occur.

These events, among others, could result in product recalls, product liability actions or withdrawals or additional regulatory controls (including additional regulatory scrutiny, REMS programs, and requirements for additional labeling). Our product liability insurance coverage may not be sufficient to satisfy any liabilities that may arise. As our development activities progress and we continue to have commercial sales, this product liability insurance coverage may be inadequate, we may be unable to obtain adequate coverage at an acceptable cost or at all, or our insurer may disclaim coverage as to a future claim. This could prevent or limit our commercialization of our products. In addition, the reporting of adverse safety events involving our products and public rumors about such events could cause our product sales or share price to decline or experience periods of volatility. These types of events could have a material adverse effect on our business, financial condition, cash flows and results of operations.

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

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

### *We may not become profitable on a sustained basis.*

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

A major component of our revenue is dependent on our licensees' and our ability to commercialize, and our and our licensees' ability to manufacture economically, our products. Our ability to achieve sustained profitability in the future depends, in part, on our or our licensees', as applicable, ability to:

- successfully commercialize VIVITROL and ARISTADA in the U.S. and any other products that may be approved in the U.S. or in other countries;
- obtain and maintain regulatory approval for products both in the U.S. and in other countries;
- efficiently manufacture our products;
- support the commercialization of products by our licensees;
- enter into agreements to develop and commercialize our products;
- develop, have manufactured or expand our capacity to manufacture and market our products;
- obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third-party payers;
- obtain additional research and development funding for our proprietary products; and
- achieve certain product development milestones.

In addition, the amount we spend will impact our profitability. Our spending will depend, in part, on:

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- the progress of our research and development programs for our products, including clinical trials;
- the time and expense that will be required to pursue FDA and/or other regulatory approvals for our products and whether such approvals are obtained;
- the time that will be required for the DEA to provide its final scheduling designation for our products that are controlled substances;
- the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property rights;
- the cost of building, operating and maintaining manufacturing and research facilities;
- the cost of third-party manufacturers;
- the number of products we pursue, particularly proprietary products;
- how competing technological and market developments affect our products;
- the cost of possible acquisitions of technologies, compounds, product rights or companies;
- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise;
- the costs of potential litigation; and
- the costs associated with recruiting and compensating a highly skilled workforce in an environment where competition for such employees is intense.

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

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

Pursuant to an amendment to our credit agreement, dated as of October 12, 2016, we extended our \$288.0 million term loan with an interest rate at LIBOR plus 2.75% with a LIBOR floor of 0.75% by two years to September 25, 2021 (“Term Loan B-1”).

Our existing indebtedness is secured by a first priority lien on substantially all of the combined company assets and properties of Alkermes plc and most of its subsidiaries, which serve as guarantors. The agreements governing Term Loan B-1 include a number of restrictive covenants that, among other things, and subject to certain exceptions and baskets, impose operating and financial restrictions on us. Our level of indebtedness and the terms of these financing arrangements could adversely affect our business by, among other things:

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

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

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

We may require additional funds in the future to execute on our business strategy, and we may seek funds through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets, sale of royalty streams we receive on our products or other financing methods or structures. The source, timing and availability of any financings will depend on market conditions, interest rates and other factors. If we issue additional equity securities or securities convertible into equity securities to raise funds, our shareholders will suffer dilution of their investment, and it may adversely affect the market price of our ordinary shares. In addition, as a condition to providing additional funds to us, future investors or lenders may demand, and may be granted, rights

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superior to those of existing shareholders. If we issue additional debt securities in the future, our existing debt service obligations will increase further. If we are unable to generate sufficient cash to meet these obligations and need to use existing cash or liquidate investments in order to fund our debt service obligations or to repay our debt, we may be forced to delay or terminate clinical trials or curtail operations. We cannot be certain, however, that additional financing will be available from any of these sources when needed or, if available, will be on acceptable terms, if at all, particularly if the credit and financial markets are constrained at the time we require funding. If we fail to obtain additional capital when we need it, we may not be able to execute our business strategy successfully and may have to give up rights to our product platforms, and/or products, or grant licenses on terms that may not be favorable to us.

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

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

### *Currency exchange rates may affect revenues and expenses.*

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

### *We may not be able to attract and retain our key personnel.*

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

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

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

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

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

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

- uncertainties in assessing the value, strengths and potential profitability of, and identifying the extent of all weaknesses, risks, contingent and other liabilities of, the respective parties;
- the potential loss of key customers, management and employees of an acquired business;
- the consummation of financing transactions, acquisitions or dispositions and the related effects on our business;
- the ability to achieve identified operating and financial synergies from an acquisition in the amounts and within the timeframe predicted;
- problems that could arise from the integration of the respective businesses, including the application of internal control processes to the acquired business;
- difficulties that could be encountered in managing international operations; and
- unanticipated changes in business, industry, market or general economic conditions that differ from the assumptions underlying our rationale for pursuing the transaction.

Any one or more of these factors could cause us not to realize the benefits anticipated from a transaction. Moreover, any acquisition opportunities we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. Future acquisitions could also result in our assuming more long-term liabilities relative to the value of the acquired assets than we have assumed in our previous acquisitions.

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

At December 31, 2017, we have \$256.2 million of amortizable intangible assets and \$92.9 million of goodwill. Under accounting principles generally accepted in the U.S. (“GAAP”), we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite-lived intangible assets have been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders’ equity in future periods.

### *Our effective tax rate may increase.*

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

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

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



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*The business combination of Alkermes, Inc. and the drug technology business (“EDT”) of Elan Corporation, plc may limit our ability to use our tax attributes to offset taxable income, if any, generated from such business combination.*

On September 16, 2011, the businesses of Alkermes, Inc. and EDT were combined under Alkermes plc (this combination is referred to as the “Business Combination”). For U.S. federal income tax purposes, a corporation is generally considered tax resident in the place of its incorporation. Because we are incorporated in Ireland, we should be deemed an Irish corporation under these general rules. However, Section 7874 of the Internal Revenue Code of 1986, as amended (the “Code”) generally provides that a corporation organized outside the U.S. that acquires substantially all of the assets of a corporation organized in the U.S. will be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal income tax purposes if shareholders of the acquired U.S. corporation own at least 80% (of either the voting power or the value) of the stock of the acquiring foreign corporation after the acquisition by reason of holding stock in the domestic corporation, and the “expanded affiliated group” (as defined in Section 7874) that includes the acquiring corporation does not have substantial business activities in the country in which it is organized.

In addition, Section 7874 provides that if a corporation organized outside the U.S. acquires substantially all of the assets of a corporation organized in the U.S., the taxable income of the U.S. corporation during the period beginning on the date the first assets are acquired as part of the acquisition, through the date which is ten years after the last date assets are acquired as part of the acquisition, shall be no less than the income or gain recognized by reason of the transfer during such period or by reason of a license of property by the expatriated entity after such acquisition to a foreign affiliate during such period, which is referred to as the “inversion gain,” if shareholders of the acquired U.S. corporation own at least 60% (of either the voting power or the value) of the stock of the acquiring foreign corporation after the acquisition by reason of holding stock in the domestic corporation, and the “expanded affiliated group” of the acquiring corporation does not have substantial business activities in the country in which it is organized. If this rule was to apply to the Business Combination, among other things, Alkermes, Inc. would have been restricted in its ability to use the approximately \$274.0 million of U.S. federal net operating loss (“NOL”) carryforwards and \$38.0 million of U.S. state NOL carryforwards that it had as of March 31, 2011. We do not believe that either of these limitations should apply as a result of the Business Combination. However, the U.S. Internal Revenue Service (the “IRS”) could assert a contrary position, in which case we could become involved in tax controversy with the IRS regarding possible additional U.S. tax liability. If we were to be unsuccessful in resolving any such tax controversy in our favor, we could be liable for significantly greater U.S. federal and state income tax than we anticipate being liable for through the Business Combination, which would place further demands on our cash needs.

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

None.

### **Item 2. *Properties***

We lease approximately 14,600 square feet of corporate office space in Dublin, Ireland, which houses our corporate headquarters. This lease expires in 2022. 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. We entered into a second lease in Waltham, Massachusetts on January 31, 2017 for approximately 67,400 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 3,800 square feet of corporate office and administrative space in Washington, DC. On December 1, 2017 we amended the lease to provide for a relocation of the premises to certain space containing approximately 7,000 square feet. We gain access to this premises in September 2018. This amended lease expires in 2029 and includes a tenant option to extend the term for an additional five-year period.

We own a R&D and manufacturing facility in Athlone, Ireland (approximately 400,000 square feet) and a manufacturing facility in Wilmington, Ohio (approximately 314,800 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 Contingencies* in the “Notes to Condensed Consolidated Statements” in this Annual Report, which is incorporated into this Part I, Item 3 by reference.

### **Item 4. *Mine Safety Disclosures***

Not Applicable.

## **PART II**

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

#### ***Market and shareholder information***

Our ordinary shares are traded on the Nasdaq under the symbol “ALKS.” Set forth below for the indicated periods are the high and low closing sales prices for our ordinary shares.

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	Year Ended December 31, 2017		Year Ended December 31, 2016	
	High	Low	High	Low
1st Quarter	\$ 61.16	\$ 52.26	\$ 75.27	\$ 29.05
2nd Quarter	61.66	55.90	47.00	35.67
3rd Quarter	60.45	49.16	51.78	43.77
4th Quarter	55.39	47.69	59.50	42.30

There were 130 shareholders of record for our ordinary shares on February 2, 2018. In addition, the last reported sale price of our ordinary shares as reported on the Nasdaq on February 2, 2018 was \$63.42.

#### *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, 2017. As of December 31, 2017, we had purchased a total of 8,866,342 shares at a cost of \$114.0 million. Term Loan B-1 includes restrictive covenants that impose certain limitations on our ability to repurchase our ordinary shares.

During the three months ended December 31, 2017, we acquired 304 Alkermes ordinary shares, at an average price of \$51.48 per share related to the vesting of employee equity awards to satisfy withholding tax obligations. During the three months ended December 31, 2017, we acquired 365 Alkermes ordinary shares, at an average price of \$54.58 per share, tendered by employees as payment of the exercise price of stock options granted under our equity compensation plans.

#### *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 2, 2018, 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 Depository 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.

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

### *Income tax on dividends*

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

### *Irish tax on capital gains*

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

### *Capital acquisitions tax*

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

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

### *Stamp duty*

Irish stamp duty, if any, may become payable in respect of ordinary share transfers. However, a transfer of our ordinary shares from a seller who holds shares through DTC to a buyer who holds the acquired shares through DTC 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.

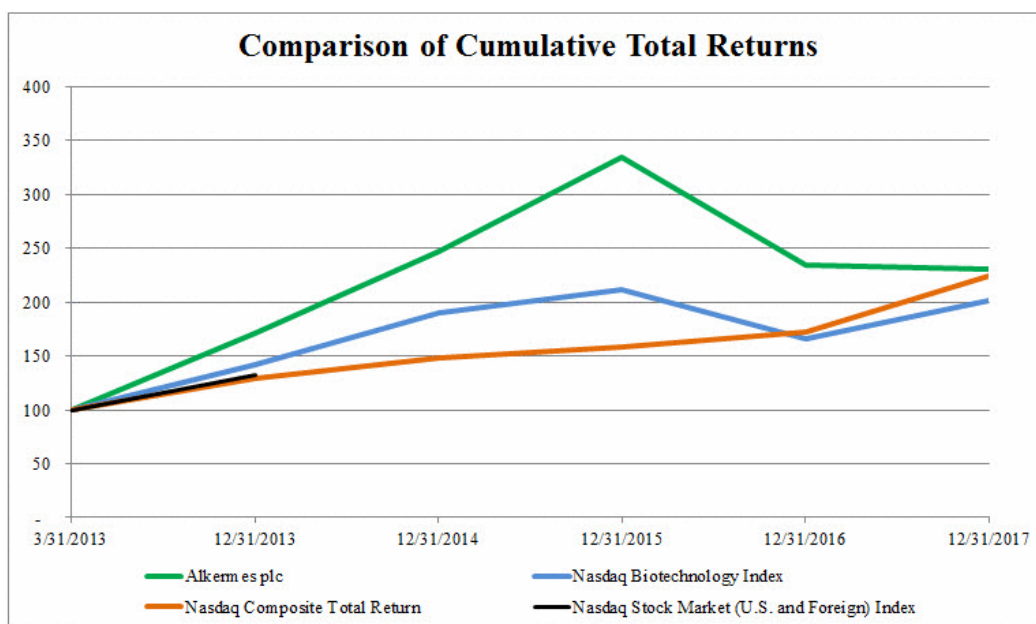
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*Stock performance graph*

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 March 31, 2013 through December 31, 2017 with the cumulative returns of the Nasdaq Composite Total Return Index and the Nasdaq Biotechnology Index. The comparison assumes \$100 was invested on March 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.

Please note that our stock performance graph previously compared the cumulative total shareholder returns on our ordinary shares with the cumulative total returns of the Nasdaq Biotechnology Index and the Nasdaq Stock Market (U.S. and Foreign) Index. However, December 31, 2013 was the last day that the Nasdaq Stock Market (U.S. and Foreign) Index data was made available to us by our third-party index provider. As a result of this change, for time periods following December 31, 2013, our performance graph uses information from the Nasdaq Composite Total Return Index in lieu of the Nasdaq Stock Market (U.S. and Foreign) Index. The Nasdaq Biotechnology Index was not affected by this change.



	Year Ended	Nine Months Ended	Year Ended December 31,			
	March 31,	December 31,	2014	2015	2016	2017
	2013	2013				
Alkermes	100	172	247	335	235	231
Nasdaq Composite Total Return	100	129	148	158	173	224
Nasdaq Biotechnology Index	100	142	190	212	166	201
Nasdaq Stock Market (U.S. and Foreign) Index	100	132	—	—	—	—

**Item 6. Selected Financial Data**

The selected historical financial data set forth below at December 31, 2017 and 2016 and for the years ended December 31, 2017, 2016 and 2015 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, 2015 and for the

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year ended and at December 31, 2014 and the nine months ended December 31, 2013 are derived from audited consolidated financial statements, which are not included in this Annual Report.

On May 21, 2013, our Audit and Risk Committee, with such authority delegated to it by our board of directors, approved a change to our fiscal year-end from March 31 to December 31. We have elected not to recast prior period amounts to conform to the change in our fiscal year.

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements, the related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included 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,				Nine Months Ended
	2017	2016	2015	2014	December 31, 2013
(In thousands, except per share data)					
<b>Consolidated Statements of Operations Data:</b>					
REVENUES:					
Manufacturing and royalty revenues	\$ 505,308	\$ 487,247	\$ 475,288	\$ 516,876	\$ 371,039
Product sales, net	362,834	256,146	149,028	94,160	57,215
License revenues	28,000	—	—	—	—
Research and development revenue	7,232	2,301	4,019	7,753	4,657
Total revenues	<u>903,374</u>	<u>745,694</u>	<u>628,335</u>	<u>618,789</u>	<u>432,911</u>
EXPENSES:					
Cost of goods manufactured and sold	154,748	132,122	138,989	175,832	134,306
Research and development	412,889	387,148	344,404	272,043	128,125
Selling, general and administrative	421,578	374,130	311,558	199,905	116,558
Amortization of acquired intangible assets	62,059	60,959	57,685	58,153	38,428
Total expenses	<u>1,051,274</u>	<u>954,359</u>	<u>852,636</u>	<u>705,933</u>	<u>417,417</u>
OPERATING (LOSS) INCOME	(147,900)	(208,665)	(224,301)	(87,144)	15,494
OTHER INCOME (EXPENSE), NET <sup>(1)</sup>	4,626	(5,722)	296	73,115	(10,097)
(LOSS) INCOME BEFORE INCOME TAXES	<u>(143,274)</u>	<u>(214,387)</u>	<u>(224,005)</u>	<u>(14,029)</u>	<u>5,397</u>
PROVISION (BENEFIT) FOR INCOME TAXES	14,671	(5,943)	3,158	16,032	(12,252)
NET (LOSS) INCOME	<u>\$ (157,945)</u>	<u>\$ (208,444)</u>	<u>\$ (227,163)</u>	<u>\$ (30,061)</u>	<u>\$ 17,649</u>
(LOSS) EARNINGS PER ORDINARY SHARE:					
BASIC	\$ (1.03)	\$ (1.38)	\$ (1.52)	\$ (0.21)	\$ 0.13
DILUTED	\$ (1.03)	\$ (1.38)	\$ (1.52)	\$ (0.21)	\$ 0.12
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:					
BASIC	<u>153,415</u>	<u>151,484</u>	<u>149,206</u>	<u>145,274</u>	<u>135,960</u>
DILUTED	<u>153,415</u>	<u>151,484</u>	<u>149,206</u>	<u>145,274</u>	<u>144,961</u>
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and investments	\$ 590,716	\$ 619,165	\$ 798,849	\$ 801,646	\$ 449,995
Total assets <sup>(2)</sup>	1,797,227	1,726,423	1,855,744	1,919,058	1,574,848
Long-term debt <sup>(2)</sup>	281,436	283,666	349,944	355,756	361,553
Shareholders’ equity	1,202,808	1,209,481	1,314,275	1,396,837	1,065,186

(1) 2015 includes a \$9.6 million gain on the Gainesville Transaction (as described and defined in Note 2, *Summary of Significant Accounting Policies*, in the accompanying “Notes to Consolidated Financial Statements” section of this Annual Report). 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.

(2) In 2015, the Company retrospectively adopted the Financial Accounting Standards Board (“FASB”)’s guidance, simplifying the presentation of debt issuance costs. As a result, deferred financing costs of \$2.2 million and \$2.7 million that were classified within “Other long-term assets” at December 31, 2014 and December 31, 2013, respectively, were reclassified to “Long-term debt” to conform to the then-current period presentation.

[Table of Contents](#)**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 and ARISTADA, which are proprietary products that we manufacture, market and sell in the U.S., and manufacturing and/or royalty revenues on net sales of products commercialized by our licensees. Our key marketed products are expected to generate significant revenues for us in the near- and medium-term and we believe are singular or competitively advantaged products in their classes. These key marketed products consist of VIVITROL; ARISTADA; INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA; AMPYRA/FAMPYRA; and BYDUREON. Revenues from these key products accounted for 91% of our total revenues during 2017, as compared to 92% and 88% during 2016 and 2015, respectively.

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

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

**Results of Operations****Manufacturing and Royalty Revenues**

Manufacturing revenues are earned from the sale of products under arrangements with our licensees when product is shipped to them at an agreed upon price. Royalties are generally earned on our licensees' net sales of products that incorporate our technologies and are recognized in the period the products are sold by our licensees. The following table compares manufacturing and royalty revenues earned in the years ended December 31, 2017, 2016 and 2015:

(In millions)	Year Ended December 31,			Change	
	2017	2016	2015	Favorable/(Unfavorable) 2017-2016	2016-2015
Manufacturing and royalty revenues:					
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	\$ 214.9	\$ 184.2	\$ 149.7	\$ 30.7	\$ 34.5
AMPYRA/FAMPYRA	117.0	114.2	104.7	2.8	9.5
RISPERDAL CONSTA	84.9	87.2	100.7	(2.3)	(13.5)
BYDUREON	45.7	45.6	46.1	0.1	(0.5)
Other	42.8	56.0	74.1	(13.2)	(18.1)
Manufacturing and royalty revenues	<u>\$ 505.3</u>	<u>\$ 487.2</u>	<u>\$ 475.3</u>	<u>\$ 18.1</u>	<u>\$ 11.9</u>

Under our INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA agreement with Janssen, we earn royalties on end-market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA of 5% up to the first \$250 million in calendar-year sales, 7% on calendar-year sales of between \$250 million and \$500 million, and 9% on calendar-year sales exceeding \$500 million. The royalty rate resets at the beginning of each calendar-year



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to 5%. Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earn manufacturing revenues of 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA and royalty revenues of 2.5% of end-market net sales.

The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues 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 \$2.6 billion, \$2.2 billion and \$1.8 billion, during the years ended December 31, 2017, 2016 and 2015, respectively.

The decrease in RISPERDAL CONSTA revenue in each period was primarily due to a decline in Janssen's end-market net sales of RISPERDAL CONSTA. Janssen's end-market net sales of RISPERDAL CONSTA were \$805.0 million, \$893.0 million and \$970.0 million, during the years ended December 31, 2017, 2016 and 2015, respectively. The decline in Janssen's end-market net sales led to a decrease in our royalty revenues of 10% in 2017, as compared to 2016 and 8% in 2016, as compared to 2015. The manufacturing revenue we earned on shipments of RISPERDAL CONSTA to Janssen in 2017 was consistent with the amount we earned in 2016. While the number of units shipped to Janssen increased by 6% in 2017, this was offset by a lower average net selling price on the units shipped to Janssen as Janssen receives a lower sales price for units sold outside the U.S. The number of units shipped for resale in the U.S. decreased by 17% and the number of units shipped for resale in the rest of the world increased by 11%. Manufacturing revenues declined by 15% in 2016, as compared to 2015, which was primarily due to a 13% decrease in the number of units shipped to Janssen. RISPERDAL CONSTA is covered by a patent until 2021 in the EU and 2023 in the U.S.

We expect revenues from our long-acting, atypical antipsychotic franchise to continue to grow as INVEGA SUSTENNA/XEPLION grows and INVEGA TRINZA/TREVICTA is launched around the world. A number of companies, including us, are working to develop products to treat schizophrenia and/or bipolar disorder that may compete with INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA. Increased competition may lead to reduced unit sales of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA, as well as increasing pricing pressure. The latest of the patents subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expire in 2019 in the U.S. and 2022 in the EU, and, in certain countries, in 2030. The latest of the patents covering INVEGA TRINZA/TREVICTA expired in November 2017 in the U.S. (with regulatory exclusivity in the U.S. until May 2018) and will expire in 2022 in the EU. In addition, the latest of the patents not subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expires in 2031 in the U.S.

In January 2018, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva, who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of United States Patent No. 9,439,906. For further discussion of the legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 16, *Commitments and Contingencies* in the "Notes to Condensed Consolidated 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."

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

The increase in AMPYRA/FAMPYRA revenues in 2017, as compared to 2016, was primarily due to a 4% increase in manufacturing revenue, which was due to an 11% increase in the amount of FAMPYRA shipped to Biogen, partially offset by an 8% decrease in the amount of AMPYRA shipped to Acorda. The increase in AMPYRA/FAMPYRA revenues in 2016, as compared to 2015, was due to a 10% increase in manufacturing revenue and an 8% increase in royalty revenue. The increase in manufacturing revenue was primarily due to a 12% increase in product shipped to Acorda and Biogen. The increase in royalty revenue was due to an increase in the end-market net sales of AMPYRA/FAMPYRA as end-market net sales of the products increased by 18% in 2016, as compared to 2015.

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On March 31, 2017, the Delaware Court upheld the '938 Patent, which pertains to the formulation of AMPYRA and is set to expire in July 2018, and invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which pertain to AMPYRA. If the Federal Circuit upholds the Delaware Court's findings with respect to U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685 and the validity of the '938 Patent, we can expect competition from generic forms of AMPYRA as early as July 2018 when the '938 Patent expires. If the Federal Circuit upholds the Delaware Court's findings with respect to U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685 and overturns the Delaware Court's upholding of the validity of the '938 Patent, competition from generic forms of AMPYRA may occur before the July 2018 expiry of the '938 Patent. We can expect that competition from generic forms of AMPYRA would impact our manufacturing and royalty revenues. We expect our manufacturing and royalty revenues to decline in advance of generic entry in anticipation of reduced demand for AMPYRA. For further discussion of the legal proceedings related to the patents covering AMPYRA, see Note 16, *Commitments and Contingencies* in the "Notes to Condensed Consolidated Statements" and "Part I, Item 3—Legal Proceedings" in this Annual Report and for information about risks relating to the AMPYRA 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."

Included in other manufacturing and royalty revenues in 2015 was \$18.8 million of revenue associated with certain products manufactured at our divested manufacturing facility in Gainesville, GA, including RITALIN LA, FOCALIN XR and VERELAN, which were sold in April 2015.

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 and, following its approval by the FDA in October 2015, ARISTADA in the U.S., primarily to wholesalers, specialty distributors and pharmacies. The following table presents the adjustments deducted from product sales, gross to arrive at product sales, net for sales of VIVITROL and ARISTADA in the U.S. during the years ended December 31, 2017, 2016 and 2015:

(In millions)	Year Ended December 31,					
	2017	% of Sales	2016	% of Sales	2015	% of Sales
Product sales, gross	\$ 657.7	100.0 %	\$ 444.6	100.0 %	\$ 227.0	100.0 %
Adjustments to product sales, gross:						
Medicaid rebates	(147.8)	(22.5)%	(94.2)	(21.2)%	(32.2)	(14.2)%
Product discounts	(51.0)	(7.8)%	(35.1)	(7.9)%	(13.2)	(5.8)%
Chargebacks	(47.9)	(7.3)%	(31.5)	(7.1)%	(17.8)	(7.8)%
Co-pay assistance	(9.5)	(1.4)%	(8.5)	(1.9)%	(6.5)	(2.9)%
Other	(38.7)	(5.8)%	(19.2)	(4.3)%	(8.3)	(3.7)%
Total adjustments	(294.9)	(44.8)%	(188.5)	(42.4)%	(78.0)	(34.4)%
Product sales, net	\$ 362.8	55.2 %	\$ 256.1	57.6 %	\$ 149.0	65.6 %

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

The increase in product sales, gross in 2016, as compared to 2015, was due to a 66% increase in the number of VIVITROL units sold and a 3% increase in the selling price of VIVITROL, as well as having a full year of ARISTADA sales as compared to a partial year in 2015.

The increases in Medicaid rebates as a percentage of sales in 2017, as compared to 2016, and in 2016, as compared to 2015, were primarily due to increases in the amount of VIVITROL sold under the Medicaid Drug Rebate Program.

Our product sales, net for VIVITROL were \$269.3 million, \$209.0 million and \$144.4 million in 2017, 2016 and 2015, respectively. Our product sales, net for ARISTADA were \$93.5 million, \$47.1 million and \$4.6 million in 2017,

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2016 and 2015, respectively. We expect our product sales, net will continue to grow as VIVITROL continues to penetrate the opioid dependence market in the U.S., and as ARISTADA sales continue to increase.

A number of companies, including us, are working to develop products to treat addiction, including alcohol and opioid dependence that may compete with, and negatively impact, future sales of VIVITROL. Increased competition and increased pricing pressure may lead to reduced unit sales of VIVITROL. VIVITROL is covered by a patent that will expire in the U.S. in 2029 and in Europe in 2021; and, as such, we do not anticipate any generic versions of this product in the near term. A number of companies, including us, currently market and/or are working to develop products to treat schizophrenia that may compete with and negatively impact future sales of ARISTADA. Increased competition and increased pricing pressure may lead to reduced unit sales of ARISTADA. ARISTADA is covered by a patent that will expire in the U.S. in 2035; and, as such, we do not anticipate any generic versions of this product in the near term.

### *License Revenue*

(In millions)	Year Ended December 31,			Change	
	2017	2016	2015	Favorable/(Unfavorable) 2017 - 2016	2016 - 2015
License revenue	\$ 28.0	\$ —	\$ —	\$ 28.0	\$ —

The increase in license revenue in 2017, as compared to 2016, was due to revenue earned under our license and collaboration agreement with Biogen for BIIB098, as discussed in further detail within the *Critical Accounting Estimates* section below.

### *Research and Development Revenue*

(In millions)	Year Ended December 31,			Change	
	2017	2016	2015	Favorable/(Unfavorable) 2017 - 2016	2016 - 2015
Research and development revenue	\$ 7.2	\$ 2.3	\$ 4.0	\$ 4.9	\$ (1.7)

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

## **Costs and Expenses**

### *Cost of Goods Manufactured and Sold*

(In millions)	Year Ended December 31,			Change	
	2017	2016	2015	Favorable/(Unfavorable) 2017 - 2016	2016 - 2015
Cost of goods manufactured and sold	\$ 154.7	\$ 132.1	\$ 139.0	\$ (22.6)	\$ 6.9

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

The decrease in cost of goods manufactured and sold in 2016, as compared to 2015, was primarily due to the Company's entry on March 7, 2015 into a definitive agreement with Recro Pharma, Inc. ("Recro") and Recro Pharma LLC to sell 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"). During the year ended December 31, 2015, the Gainesville facility had cost of goods manufactured of \$10.2 million. In addition, cost of goods manufactured at our Athlone facility decreased by \$8.2 million, which was primarily due to a reduction in manufacturing activity due to the restructuring program initiated in April 2013. These decreases were partially offset by an \$11.4 million increase in cost of goods manufactured and sold related to products produced at our Wilmington, Ohio manufacturing facility, which was primarily due to the increase in VIVITROL sales and a full year of ARISTADA sales compared to a partial year in 2015.

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*Research and Development Expenses*

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

The following table sets forth our external R&D expenses for the years ended December 31, 2017, 2016 and 2015 relating to our individual Key Development Programs and all other development programs, and our internal R&D expenses by the nature of such expenses:

(In millions)	Year Ended December 31,			Change	
	2017	2016	2015	Favorable/(Unfavorable) 2017 - 2016	2016 - 2015
<b>External R&amp;D Expenses:</b>					
Key development programs:					
ALKS 3831	\$ 91.9	\$ 71.0	\$ 26.1	\$ (20.9)	\$ (44.9)
BIIB098	47.4	26.9	17.9	(20.5)	(9.0)
ALKS 5461	42.2	46.2	108.4	4.0	62.2
ARISTADA and ARISTADA line extensions	13.7	36.3	38.1	22.6	1.8
ALKS 6428	10.6	16.3	7.0	5.7	(9.3)
ALKS 4230	7.0	4.8	4.6	(2.2)	(0.2)
Other external R&D expenses	27.8	42.4	14.9	14.6	(27.5)
Total external R&D expenses	240.6	243.9	217.0	3.3	(26.9)
<b>Internal R&amp;D expenses:</b>					
Employee-related	132.2	110.1	97.5	(22.1)	(12.6)
Occupancy	9.6	9.0	8.1	(0.6)	(0.9)
Depreciation	10.5	7.9	6.2	(2.6)	(1.7)
Other	20.0	16.2	15.6	(3.8)	(0.6)
Total internal R&D expenses	172.3	143.2	127.4	(29.1)	(15.8)
Research and development expenses	\$ 412.9	\$ 387.1	\$ 344.4	\$ (25.8)	\$ (42.7)

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

The increase in expenses related to ALKS 3831 in 2017, as compared to 2016, was primarily due to the timing of activity within the ENLIGHTEN-1 and ENLIGHTEN-2 pivotal trials, which were initiated in December 2015 and February 2016, respectively and activity for a supportive study in the ENLIGHTEN clinical development program for ALKS 3831, which was initiated in June 2017. The increase in expenses related to BIIB098 in 2017, as compared to 2016, was primarily due to further progression of the two-year, multicenter, open-label phase 3 study designed to assess the safety of BIIB098, which was initiated in December 2015 and is actively enrolling. We also initiated a phase 3 gastrointestinal tolerability study for BIIB098 in March 2017. The decrease in expenses related to ALKS 5461 in 2017, as compared to 2016, was primarily due to the completion of the three core phase 3 studies related to the program. We announced topline results of the FORWARD-3 and FORWARD-4 studies in January 2016 and topline results from FORWARD-5 were announced in October 2016. In January 2018, we completed our submission of an NDA to the FDA seeking marketing approval of ALKS 5461 for the adjunctive treatment of MDD. The decrease in expenses related to ARISTADA and ARISTADA line extensions in 2017, as compared to 2016, was primarily due to the timing of the phase 1 clinical study of extended dosing intervals of aripiprazole lauroxil in patients with schizophrenia. ARISTADA 1064 mg, our two-month dosing option, was approved by the FDA in June 2017 and we submitted an NDA to the FDA for AL<sub>NCD</sub> in October 2017, which was accepted by the FDA in November 2017. The decrease in expenses related to ALKS 6428 in 2017, as compared to 2016, was primarily due to the completion of a phase 3 clinical study initiated in September 2015 evaluating the safety, tolerability and efficacy of ALKS 6428 in patients with opioid dependence. Topline results were announced in February 2017. The increase in expenses related to ALKS 4230 in 2017, as compared to 2016, was primarily related to the timing of the phase 1 study which was initiated in May 2016. Initial data from the first stage of the phase 1 study is expected in 2018.

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The increase in expenses related to ALKS 3831 in 2016, as compared to 2015, was primarily due to the timing of the ENLIGHTEN-1 and ENLIGHTEN-2 pivotal trials. The decrease in expenses related to ARISTADA and ARISTADA line extensions in 2016, as compared to 2015, was primarily due to the timing of the phase 1 clinical study of extended dosing intervals of aripiprazole lauroxil in patients with schizophrenia. ARISTADA was approved by the FDA in October 2015. Also, in December 2014, we initiated a phase 1 clinical study of extended dosing intervals of ARISTADA in patients with schizophrenia. The increase in expenses related to ALKS 6428 was primarily due to the initiation of the phase 3 study evaluating the safety, tolerability and efficacy of ALKS 6428 in patients with opioid dependence in September 2015. The increase in expenses related to BIIB098 in 2016, as compared to 2015, was primarily due to the timing of study activity. We initiated the two-year, multicenter, open-label phase 3 study designed to assess the safety of BIIB098 in December 2015, following the completion of a phase 1 study of BIIB098 initiated in 2014.

The decrease in other external R&D expenses in 2017, as compared to 2016, and the increase in 2016, as compared to 2015, were 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 Reset Therapeutics, Inc. The remainder of the changes are due to activity related to our early-stage, pre-clinical development activity.

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.

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 9% in 2017, as compared to 2016, and 20% in 2016, as compared to 2015.

### *Selling, General and Administrative Expenses*

(In millions)	Year Ended December 31,			Change	
	2017	2016	2015	Favorable/(Unfavorable) 2017 - 2016	2016 - 2015
Selling, general and administrative expense	\$ 421.6	\$ 374.1	\$ 311.6	\$ (47.5)	\$ (62.5)

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 \$31.1 million and \$27.1 million, respectively, and were primarily due to additional brand investments in both VIVITROL and ARISTADA, as well as an increase in patient access support services, such as reimbursement and transition assistance, for both of these products. Employee-related expenses increased by \$13.4 million and \$28.9 million, respectively, and were primarily due to an increase in our SG&A-related headcount of 17% in 2017 and 15% in 2016.

### *Amortization of Acquired Intangible Assets*

(In millions)	Year Ended December 31,			Change	
	2017	2016	2015	Favorable/(Unfavorable) 2017 - 2016	2016 - 2015
Amortization of acquired intangible assets	\$ 62.1	\$ 61.0	\$ 57.7	\$ (1.1)	\$ (3.3)

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

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

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*Other Income (Expense), Net*

(In millions)	Year Ended December 31,			Change	
	2017	2016	2015	2017 - 2016	2016 - 2015
Interest income	\$ 4.6	\$ 3.8	\$ 3.3	\$ 0.8	\$ 0.5
Interest expense	(12.0)	(14.9)	(13.2)	2.9	(1.7)
Change in the fair value of contingent consideration	21.6	7.9	(2.3)	13.7	10.2
Gain on Gainesville Transaction	—	—	9.6	—	(9.6)
Gain on sale of property, plant and equipment	—	—	2.9	—	(2.9)
Other (expense) income, net	(9.6)	(2.5)	—	(7.1)	(2.5)
Total other income (expense), net	\$ 4.6	\$ (5.7)	\$ 0.3	\$ 10.3	\$ (6.0)

The decrease in interest expense in 2017, as compared to 2016 and the increase in interest expense in 2016, as compared to 2015, was due to the amendment of Term Loan B-1 in October 2016, pursuant to which, among other things, the due date of Term Loan B-1 was extended from September 25, 2019 to September 25, 2021 (the “Refinancing”). The interest rate under Term Loan B-1 was unchanged and remains at LIBOR plus 2.75% with a LIBOR floor of 0.75%. We incurred a charge of \$2.1 million in connection with the Refinancing, which is included in interest expense.

In April 2015, we completed the Gainesville Transaction and received \$54.0 million in cash, \$2.1 million in warrants to acquire Recro common stock and \$57.6 million in contingent consideration tied to low double digit royalties on net sales of the IV/IM and parenteral forms of Meloxicam and any other product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of our intellectual property to which Recro was provided a right of use, through license or transfer, pursuant to the Gainesville Transaction (the “Meloxicam Products”), and up to \$120.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products. We determined the fair value of the contingent consideration through three valuation approaches, which are described in greater detail in *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, 2017, 2016 and 2015, we determined that the fair value of the contingent consideration increased by \$21.6 million, \$7.9 million and decreased by \$2.3 million, respectively. The increases in 2017, as compared to 2016, and in 2016, as compared to 2015, were primarily due to the change in the structure of the development milestones, which 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 and a shorter time to payment and improved probability of success on the milestones and royalties included in the contingent consideration.

The increase in other (expense) income, net, in 2017, as compared to 2016, was primarily due to an impairment charge related to our investment in Reset, which was accounted for under the equity method. In September 2017, we recorded an other-than-temporary impairment charge of \$10.5 million, which represented our remaining investment in Reset, as we believe that Reset is unable to generate future earnings that justify the carrying amount of the investment.

*Provision (Benefit) for Income Taxes*

(In millions)	Year Ended December 31,			Change	
	2017	2016	2015	2017 - 2016	2016 - 2015
Income tax provision (benefit)	\$ 14.7	\$ (5.9)	\$ 3.2	\$ (20.6)	\$ 9.1

The income tax provisions in 2017 and 2015 and the income tax benefit in 2016 were primarily due to U.S. federal and state taxes. The unfavorable change in income taxes in 2017, as compared to 2016, was primarily due to the enactment of the Tax Cuts and Jobs Act (the “Act” or “Tax Reform”) and an increase in income earned in the U.S., partially offset by the recognition of excess tax benefits related to share-based compensation. The favorable change in income taxes in 2016, as compared to 2015, was primarily due to a reduction in income earned in the U.S.



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No provision for income tax has been provided on undistributed earnings of our foreign subsidiaries because such earnings may be repatriated to Ireland without incurring any tax liability. Cumulative unremitted earnings of overseas subsidiaries totaled approximately \$160.3 million at December 31, 2017.

In March 2016, the FASB issued guidance as part of its simplification initiative that involves several aspects of the accounting for share-based payment transactions including the requirement that all future excess tax benefits and tax deficiencies be recognized as income tax expense or benefit in the income statement. On January 1, 2017, we adopted this standard on a modified retrospective basis, which resulted in a favorable cumulative-effect adjustment of \$61.5 million to accumulated deficit due to the change in the accounting treatment of excess tax benefits and tax deficiencies.

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

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

At December 31, 2017, we maintained a valuation allowance of \$9.4 million against certain U.S. state deferred tax assets and \$163.4 million against certain Irish deferred tax assets as we determined that it is more-likely-than-not that these net deferred tax assets will not be realized. If we demonstrate consistent profitability in the future, the evaluation of the recoverability of these deferred tax assets may change and the remaining valuation allowance may be released in part or in whole.

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



[Table of Contents](#)**Liquidity and Capital Resources**

Our financial condition is summarized as follows:

(In millions)	December 31, 2017			December 31, 2016		
	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	\$ 114.7	76.6	\$ 191.3	\$ 81.2	105.2	\$ 186.4
Investments—short-term	127.5	114.7	242.2	184.4	126.5	310.9
Investments—long-term	108.9	48.3	157.2	60.1	61.8	121.9
Total cash and investments	\$ 351.1	\$ 239.6	\$ 590.7	\$ 325.7	\$ 293.5	\$ 619.2
Outstanding borrowings—short and long-term	\$ 281.4	\$ —	\$ 281.4	\$ 283.7	\$ —	\$ 283.7

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

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

**Sources and Uses of Cash**

We generated \$19.2 million and used \$63.8 million and \$40.4 million of cash from operating activities during the years ended December 31, 2017, 2016 and 2015, respectively. We expect that our existing cash and investments will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments on our long-term debt, for at least the twelve months following the date from which our financial statements were issued. Subject to market conditions, interest rates and other factors, we may pursue opportunities to obtain additional financing in the future, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures. In addition, Term Loan B-1 has an incremental facility capacity in an amount of \$140.0 million, plus additional amounts as long as we meet certain conditions, including a specified leverage ratio.

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

Information about our cash flows, by category, is presented in the accompanying consolidated statements of cash flows. The following table summarizes our cash flows for the years ended December 31, 2017, 2016 and 2015:

(In millions)	Year Ended December 31,		
	2017	2016	2015
Cash and cash equivalents, beginning of period	\$ 186.4	\$ 181.1	\$ 224.1
Cash provided by (used in) operating activities	19.2	(63.8)	(40.4)
Cash (used in) provided by investing activities	(18.4)	127.2	(43.5)
Cash provided by (used in) financing activities	4.1	(58.1)	40.9
Cash and cash equivalents, end of period	\$ 191.3	\$ 186.4	\$ 181.1

**Operating Activities**

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

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due to the increase in revenues in 2017, as compared to 2016. The increase in the amount of cash paid to our employees is primarily due to the increase in our headcount and the increase in the amount of cash paid to our suppliers is due to the increase in R&D and commercial activity, as previously discussed.

The increase in cash used in operating activities in 2016, as compared to 2015, was primarily due to a 26% increase in the amount of cash paid to our employees and a 21% increase in the amount of cash paid to our suppliers, partially offset by a 16% increase in the amount of cash we collected from our customers. The increase in the amount of cash paid to our employees is primarily due to the increase in our headcount and the increase in the amount of cash paid to our suppliers is due to the increase in R&D and commercial activity, as previously discussed.

### *Investing Activities*

The increase in cash used in investing activities in 2017, as compared to 2016, was primarily due to a 15% increase in property, plant and equipment additions and a 2% decrease in net sales of investments. This was partially offset by a \$15.0 million investment in Reset Therapeutics, Inc., that we made in 2016. The increase in capital spending was primarily due to the timing of our capital projects, primarily the construction of facilities and equipment at our Wilmington, Ohio location for the manufacture of products currently in development and existing proprietary products. Amounts included as construction in progress at December 31, 2017 primarily include capital expenditures at our manufacturing facility in Wilmington, Ohio. We expect to spend approximately \$85.0 million during the year ended December 31, 2018 for capital expenditures. We continue to evaluate our manufacturing capacity based on expectations of demand for our products and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service, or we determine we have sufficient existing capacity and the assets are no longer required, at which time we would recognize an impairment charge. We continue to periodically evaluate whether facts and circumstances indicate that the carrying value of these long-lived assets to be held and used may not be recoverable.

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

### *Financing Activities*

The increase in cash provided by financing activities in 2017, as compared to 2016, was primarily due to a \$60.9 million principal payment for a term loan which matured in September 2016, which had an original principal balance of \$75.0 million, bore interest at LIBOR plus 2.75%, with no LIBOR floor. In 2017, our financing activities consisted of \$7.1 million in cash received from our employees related to stock option exercises and \$3.0 million in principal payments we made under Term Loan B-1.

The increase in cash used in financing activities in 2016, as compared to 2015, was primarily due to the \$60.9 million principal payment, as previously mentioned. In addition, there was a \$12.2 million decrease in cash received from employee stock option exercises.

## **Borrowings**

At December 31, 2017, our borrowings consisted of \$284.3 million outstanding under Term Loan B-1. Please refer to Note 9, *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, 2017:

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

As interest on Term Loan B-1 is based on a one, three or six month LIBOR rate of our choosing, we are using the three-month LIBOR rate, which was 1.69% at December 31, 2017 as this exceeds the LIBOR rate floor under the terms of Term Loan B-1 and is the frequency in which we make interest payments. This table excludes any liabilities pertaining to uncertain tax positions as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities.

At December 31, 2017, we had \$5.5 million of net liabilities associated with uncertain tax positions. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months.

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

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

### Off-Balance Sheet Arrangements

At December 31, 2017, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

### 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.

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We have reviewed these critical accounting estimates and related disclosures with the Audit and Risk Committee of our board of directors.

### *Manufacturing and Royalty Revenue*

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

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

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

### *Product Sales, Net*

We recognize revenue from product sales of VIVITROL and ARISTADA when persuasive evidence of an arrangement exists, and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured. We sell VIVITROL and ARISTADA to pharmaceutical wholesalers, specialty distributors, pharmacies and treatment providers.

Product sales are recorded net of sales reserves and allowances. Sales of many pharmaceutical products in the U.S. are subject to increased pricing pressure from managed care groups, institutions, government agencies and other groups seeking discounts. We and other biopharmaceutical companies selling products in the U.S. market are required to provide statutorily defined rebates and discounts to various U.S. government and state agencies in order to participate in the Medicaid program and other government-funded programs. The sensitivity of our estimates can vary by program and type of customer. Estimates associated with Medicaid and other U.S. government allowances may become subject to adjustment in a subsequent period. We record product sales net of the following significant categories of product sales allowances:

- *Medicaid Rebates*—we record accruals for rebates to states under the Medicaid Drug Rebate Program as a reduction of sales when the product is shipped into the distribution channel. We rebate individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is based on our AMPs. We estimate expected unit sales and rebates per unit under the Medicaid program and adjust our rebate estimates based on actual unit sales and rebates per unit. To date, actual Medicaid rebates have not differed materially from our estimates;
- *Chargebacks*—chargebacks are discounts that occur when contracted indirect customers purchase directly from wholesalers and specialty distributors. Contracted customers generally purchase the product at its contracted price. The wholesaler or specialty distributor, in turn, then generally charges back to 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 based on actual and expected utilization of these programs. Chargebacks could exceed historical experience and our estimates of future

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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. To date, actual product discounts have not differed materially from our estimates;
- *Co-pay Assistance*— we have a program whereby a patient can receive monetary assistance each month toward their product co-payment, co-insurance or deductible, provided the patient meets certain eligibility criteria. Reserves for such co-pay assistance are recorded upon the product sale. To date, actual co-pay assistance has not differed materially from our estimates; and
- *Product Returns*—we record an estimate for product returns at the time our customer takes title to our product. We estimate the liability based on our historical return levels and specifically identified anticipated returns due to known business conditions and product expiry dates. Once product is returned, it is destroyed. At December 31, 2017, our product return reserve was estimated to be approximately 1.5% of each of our VIVITROL and ARISTADA gross product sales.

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

(In millions)	Medicaid Rebates	Chargebacks	Product Discounts	Co-Pay Assistance	Product Returns	Other	Total
<b>Balance, December 31, 2015</b>	\$ 17.2	\$ 0.6	\$ 2.9	\$ (0.2)	\$ 6.7	\$ 3.4	\$ 30.6
Provision:							
Current year	92.1	31.5	35.3	9.2	7.1	12.1	187.3
Prior year	2.1	—	(0.2)	(0.7)	—	—	1.2
Total	94.2	31.5	35.1	8.5	7.1	12.1	188.5
Actual:							
Current year	(48.7)	(30.6)	(30.6)	(8.9)	(1.0)	(10.8)	(130.6)
Prior year	(18.9)	(0.4)	(1.8)	—	0.7	(0.9)	(21.3)
Total	(67.6)	(31.0)	(32.4)	(8.9)	(0.3)	(11.7)	(151.9)
<b>Balance, December 31, 2016</b>	\$ 43.8	\$ 1.1	\$ 5.6	\$ (0.6)	\$ 13.5	\$ 3.8	\$ 67.2
Provision:							
Current year	153.5	47.9	51.2	9.9	7.5	31.9	301.9
Prior year	(5.7)	—	(0.2)	(0.4)	(0.8)	0.1	(7.0)
Total	147.8	47.9	51.0	9.5	6.7	32.0	294.9
Actual:							
Current year	(66.0)	(46.3)	(42.0)	(9.3)	(0.1)	(24.1)	(187.8)
Prior year	(35.7)	(0.8)	(6.0)	0.3	(1.3)	(3.1)	(46.6)
Total	(101.7)	(47.1)	(48.0)	(9.0)	(1.4)	(27.2)	(234.4)
<b>Balance, December 31, 2017</b>	\$ 89.9	\$ 1.9	\$ 8.6	\$ (0.1)	\$ 18.8	\$ 8.6	\$ 127.7

*Multiple Element Arrangements*

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

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

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Significant 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.

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

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

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 this agreement in November 2017, we received an up-front cash payment of \$28.0 million. We are also eligible to receive additional payments upon achievement of milestones, as follows: (i) a \$50.0 million option payment upon Biogen's decision to continue the collaboration after having reviewed certain data from our long-term safety clinical trial and part A of the head-to-head phase 3 gastrointestinal tolerability clinical trial comparing BIIB098 and TECFIDERA and (ii) a \$150.0 million payment upon an approval by the FDA on or before December 31, 2021 of a 505(b)(2) NDA (or, in certain circumstances, a 505(b)(1) NDA) for BIIB098. 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 royalty on worldwide net sales of BIIB098, subject to, under certain circumstances, minimum annual payments for the first five years following FDA approval of BIIB098, and worldwide net sales of products, other than BIIB098, covered by patents licensed to Biogen under the agreement. Biogen paid a portion of the BIIB098 development costs we incurred in 2017 and, beginning on January 1, 2018, Biogen will be responsible for all BIIB098 development costs we incur, subject to annual budget limitations. 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 ASC Subtopic 605-25, *Multiple Element Arrangements* (“ASC 605-25”). We determined that we had four initial performance obligations: (i) the grant of the license to Biogen, (ii) future development services, (iii) assuming we enter into a supply agreement with Biogen, clinical supply and (iv) participation on a joint steering committee with Biogen. The participation on the joint service committee was considered to be perfunctory and thus not recognized as a separate unit of accounting. The deliverables, aside from the participation in the joint steering committee which was considered to be perfunctory, were determined to be separate units of accounting as they each have value to Biogen on a stand-alone basis.

The consideration allocable to the delivered unit or units of accounting is limited to the amount that is not contingent upon the delivery of additional items or meeting other specified performance conditions. Therefore, we will exclude from the allocable consideration the milestone payments and royalties, regardless of the probability that such milestone and royalty payments will be made, until the events that give rise to such payments actually occur.

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

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

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

### *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



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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.

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, 2017, 2016 and 2015, the ranges in weighted-average assumptions were as follows:

	Year Ended December 31,		
	2017	2016	2015
Expected option term	5 - 8 years	5 - 7 years	5 - 7 years
Expected stock volatility	43 % - 47 %	39 % - 53 %	38 % - 46 %
Risk-free interest rate	1.69 % - 2.38 %	0.95 % - 2.14 %	1.29 % - 2.02 %
Expected annual dividend yield	—	—	—

In addition to the above, we apply judgment in developing estimates of award forfeitures. For the year ended December 31, 2017, 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

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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, 2017, is expected to be approximately \$65.0 million, \$55.0 million, \$50.0 million, \$40.0 million and \$35.0 million in the years ending December 31, 2018 through 2022, respectively. Although we believe such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying our expectations regarding such future revenues, there is the potential for our actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible asset will change in proportion to the change in revenue.

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

### *Goodwill*

We evaluate goodwill for impairment for our reporting units annually, as of October 31, and whenever events or changes in circumstances indicate its carrying value may not be recoverable. A reporting unit is an operating segment, as defined by the segment reporting accounting standards, or a component of an operating segment. A component of an operating segment is a reporting unit if the component constitutes a business for which discrete financial information is available and is reviewed by management. Two or more components of an operating segment may be aggregated and deemed a single reporting unit for goodwill impairment testing purposes if the components have similar economic characteristics. As of December 31, 2017, 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, 2017, we elected to first assess qualitative factors to determine whether it was necessary to perform the quantitative impairment test. Based on the weight of all available evidence, we determined that the fair value of the reporting unit more-likely-than-not exceeds its carrying value.

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### *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, 2017, our contingent consideration relates to consideration received as part of the Gainesville Transaction. We are eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and any other product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of our intellectual property to which Recro was provided a right of use, through license or transfer, pursuant to the Gainesville Transaction (together, the “Meloxicam Product(s)”) and up to \$125.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products.

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

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

### *Valuation of Deferred Tax Assets*

We evaluate the need for deferred tax asset valuation allowances based on a more-likely-than-not standard. The ability to realize deferred tax assets depends on the ability to generate sufficient taxable income within the carryback

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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.”

### *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 50% of our investments at December 31, 2017 are in debt securities issued by the U.S. government or its agencies, our exposure to liquidity and credit risk is not believed to be significant.

At December 31, 2017, our borrowings consisted of \$284.3 million outstanding under our Term Loan B-1. Term Loan B-1 bears interest at a LIBOR rate of our choosing (one, three or six months), plus 2.75% with a LIBOR floor of 0.75%. We are using the three-month LIBOR rate, which was 1.69% at December 31, 2017. A 10% increase in the three-month LIBOR rate would have increased the amount of interest we owe under this agreement during the year ended December 31, 2017 by approximately \$0.4 million.

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**Currency Exchange Rate Risk**

Manufacturing and royalty revenues we receive on certain of our products and services are a percentage of the net sales made by our licensees, and a portion of these sales are made in countries outside the U.S. and are denominated in currencies in which the product is sold, which is predominantly the Euro. The manufacturing and royalty payments on these non-U.S. sales are calculated initially in the currency in which the sale is made and are then converted into USD to determine the amount that our licensees pay us for manufacturing and royalty revenues. Fluctuations in the exchange ratio of the USD and these non-U.S. currencies will have the effect of increasing or decreasing our revenues even if there is a constant amount of sales in non-U.S. currencies. For example, if the USD weakens against a non-U.S. currency, then our revenues will increase given a constant amount of sales in such non-U.S. currency. For the year ended December 31, 2017, an average 10% strengthening of the USD relative to the currencies in which these products are sold would have resulted in revenues being reduced by approximately \$26.8 million.

We incur significant operating costs in Ireland and face exposure to changes in the exchange ratio of the USD and the Euro arising from expenses and payables at our Irish operations that are settled in Euro. The impact of changes in the exchange ratio of the USD and the Euro on our USD denominated revenues earned in countries other than the U.S. is partially offset by the opposite impact of changes in the exchange ratio of the USD and the Euro on operating expenses and payables incurred at our Irish operations that are settled in Euro. For the year ended December 31, 2017, an average 10% weakening in the USD relative to the Euro would have resulted in an increase to our expenses denominated in Euro of approximately \$6.9 million.

**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
<b>Year Ended December 31, 2017</b>					
<b>REVENUES:</b>					
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	<u>191,778</u>	<u>218,841</u>	<u>217,385</u>	<u>275,370</u>	<u>903,374</u>
<b>EXPENSES:</b>					
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	<u>262,648</u>	<u>263,350</u>	<u>255,741</u>	<u>269,535</u>	<u>1,051,274</u>
OPERATING (LOSS) INCOME	<u>(70,870)</u>	<u>(44,509)</u>	<u>(38,356)</u>	<u>5,835</u>	<u>(147,900)</u>
OTHER INCOME (EXPENSE), NET	<u>(1,720)</u>	<u>(1,171)</u>	<u>2,566</u>	<u>4,951</u>	<u>4,626</u>
(LOSS) EARNINGS BEFORE INCOME TAXES	<u>(72,590)</u>	<u>(45,680)</u>	<u>(35,790)</u>	<u>10,786</u>	<u>(143,274)</u>
INCOME TAX PROVISION (BENEFIT)	<u>(3,709)</u>	<u>(2,681)</u>	<u>486</u>	<u>20,575</u>	<u>14,671</u>
NET LOSS	<u>\$ (68,881)</u>	<u>\$ (42,999)</u>	<u>\$ (36,276)</u>	<u>\$ (9,789)</u>	<u>\$ (157,945)</u>
LOSS PER SHARE—BASIC AND DILUTED	<u>\$ (0.45)</u>	<u>\$ (0.28)</u>	<u>\$ (0.24)</u>	<u>\$ (0.06)</u>	<u>\$ (1.03)</u>

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	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
<b>Year Ended December 31, 2016</b>					
<b>REVENUES:</b>					
Manufacturing and royalty revenues	\$ 106,159	\$ 137,034	\$ 110,250	\$ 133,804	\$ 487,247
Product sales, net	49,374	57,519	69,802	79,451	256,146
Research and development revenue	1,241	612	189	259	2,301
Total revenues	<u>156,774</u>	<u>195,165</u>	<u>180,241</u>	<u>213,514</u>	<u>745,694</u>
<b>EXPENSES:</b>					
Cost of goods manufactured and sold	27,711	33,998	35,456	34,957	132,122
Research and development	101,072	97,006	99,444	89,626	387,148
Selling, general and administrative	89,719	96,121	91,145	97,145	374,130
Amortization of acquired intangible assets	15,156	15,157	15,323	15,323	60,959
Total expenses	<u>233,658</u>	<u>242,282</u>	<u>241,368</u>	<u>237,051</u>	<u>954,359</u>
OPERATING LOSS	(76,884)	(47,117)	(61,127)	(23,537)	(208,665)
OTHER EXPENSE, NET	(135)	(596)	(4,215)	(776)	(5,722)
LOSS BEFORE INCOME TAXES	<u>(77,019)</u>	<u>(47,713)</u>	<u>(65,342)</u>	<u>(24,313)</u>	<u>(214,387)</u>
INCOME TAX (BENEFIT) PROVISION	404	(520)	(2,655)	(3,172)	(5,943)
NET LOSS	<u>\$ (77,423)</u>	<u>\$ (47,193)</u>	<u>\$ (62,687)</u>	<u>\$ (21,141)</u>	<u>\$ (208,444)</u>
LOSS PER SHARE—BASIC AND DILUTED	<u>\$ (0.51)</u>	<u>\$ (0.31)</u>	<u>\$ (0.41)</u>	<u>\$ (0.14)</u>	<u>\$ (1.38)</u>

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.

**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, 2017. 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, 2017 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

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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, 2017. 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, 2017, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2017 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included in this Annual Report, on page F-1.

### **Item 9B. Other Information**

Our policy governing transactions in its securities by our directors, officers and employees permits our officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended December 31, 2017, Mr. Iain M. Brown, an executive officer of ours and Mr. Paul J. Mitchell, a director of ours, entered into trading plans in accordance with Rule 10b5-1, and our policy governing transactions in our securities by our directors, officers and employees. We undertake no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.



**PART III**

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

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2018 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 2018 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 2018 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 2018 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 2018 Annual General Meeting of Shareholders.

**PART IV**

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

- (a)(1) Consolidated Financial Statements—The consolidated financial statements of Alkermes plc, required by this item, are submitted in a separate section beginning on page F-1 of this Annual Report.
- (2) Financial Statement Schedules—All schedules have been omitted because the absence of conditions under which they are required or because the required information is included in the consolidated financial statements or notes thereto.
- (3) 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**

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
2.1 *	<a href="#">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.</a>	Exhibit 2.1 of the Alkermes plc Current Report on Form 8-K/A (File No. 001-35299)	April 16, 2015
2.1.1	<a href="#">First Amendment to Purchase and Sale Agreement, dated December 8, 2016 by and among Alkermes Pharma Ireland Limited, Daravita Limited, Eagle Holdings USA, Inc., Recro Pharma, Inc., and Recro Gainesville LLC.</a>	Exhibit 2.1.1 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 17, 2017
3.1	<a href="#">Memorandum and Articles of Association of Alkermes plc.</a>	Exhibit 3.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299)	May 26, 2016

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>	<u>Incorporated by reference herein</u>	
		<u>Form</u>	<u>Date</u>
10.1	<a href="#">Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of April 22, 2009.</a>	Exhibit 10.5 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 28, 2009
10.1.1	<a href="#">First Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009.</a>	Exhibit 10.2 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	August 6, 2009
10.1.2	<a href="#">Second Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of November 12, 2013.</a>	Exhibit 10.74 of the Alkermes plc Transition Report on Form 10-KT (File No. 001-35299)	February 27, 2014
10.1.3	<a href="#">Third Amendment to Lease Agreement between Alkermes, Inc. and PDM 850 Unit, LLC, dated as of May 15, 2014.</a>	Exhibit 10.2 of the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 31, 2014
10.1.4	<a href="#">Fourth Amendment to Lease Agreement between Alkermes, Inc. and GI TC 850 Winter Street, LLC, dated as of December 30, 2014.</a>	Exhibit 10.7 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 30, 2015
10.2	<a href="#">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).</a>	Exhibit 10.2 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.2.1 *	<a href="#">Third Amendment To Development Agreement, Second Amendment To Manufacturing and Supply Agreement and First Amendment To License Agreements by and between Janssen Pharmaceutica International Inc. and Alkermes Controlled Therapeutics Inc. II, dated April 1, 2000 (assigned to Alkermes, Inc. in July 2006).</a>	Exhibit 10.5 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.2.2 *	<a href="#">Second Amendment, dated as of August 16, 2012, to the License Agreement, dated as of February 13, 1996, as amended, by and between Alkermes, Inc. ("Alkermes") and Janssen Pharmaceutica, Inc. ("Janssen US") and the License Agreement, dated as of February 21, 1996, as amended, by and between Alkermes and JPI Pharmaceutica International, a division of Cilag GmbH International ("JPI") (Janssen US and JPI together, "Janssen"), and the Fifth Amendment, dated as of August 16, 2012, to the Manufacturing and Supply Agreement, dated as of August 6, 1997, as amended, by and between Alkermes and Janssen.</a>	Exhibit 10.3 of the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	November 1, 2012
10.3	<a href="#">License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except United States) (assigned to Alkermes, Inc. in July 2006).</a>	Exhibit 10.3 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
10.4	<a href="#">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).</a>	Exhibit 10.4 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.4.1 *	<a href="#">Fourth Amendment To Development Agreement and First Amendment To Manufacturing and Supply Agreement by and between Janssen Pharmaceutica International Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 20, 2000 (assigned to Alkermes, Inc. in July 2006).</a>	Exhibit 10.4 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.4.2	<a href="#">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.</a>	Exhibit 10.4.2 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.4.3	<a href="#">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).</a>	Exhibit 10.4.3 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.4.4 *	<a href="#">Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 22, 2003 (assigned to Alkermes, Inc. in July 2006).</a>	Exhibit 10.6 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 30, 2015
10.4.5 *	<a href="#">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).</a>	Exhibit 10.9 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.5 *	<a href="#">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).</a>	Exhibit 10.28 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 21, 2010
10.6 *	<a href="#">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).</a>	Exhibit 10.6 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.6.1 *	<a href="#">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).</a>	Exhibit 10.7 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.7	<a href="#">Amended and Restated License Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc.</a>	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

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Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.7.1 *	<a href="#">Supply Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc.</a>	Exhibit 10.22 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.7.2	<a href="#">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.</a>	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	<a href="#">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 Pharma Ireland Limited (as successor in interest to Elan Corporation, plc).</a>	Exhibit 10.46 of the Acorda Therapeutics, Inc. Annual Report on Form 10-K (File No.000-50513; film no. 13653677)	February 28, 2013
10.7.4	<a href="#">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).</a>	Exhibit 10.1 of the Acorda Therapeutics, Inc. Quarterly Report on Form 10-Q (File No. 000-50513; film No. 13831684)	May 10, 2013
10.7.5*	<a href="#">Development and Supplemental Agreement between Elan Pharma International Limited and Acorda Therapeutics, Inc. dated January 14, 2011.</a>	Exhibit 10.21 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.8 *	<a href="#">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.</a>	Exhibit 10.23 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.8.1	<a href="#">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.</a>	Exhibit 10.24 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.8.2 *	<a href="#">Agreement Amendment No. 2, dated as of July 31, 2009, to the License Agreement by and among Elan Pharmaceutical Research Corp., d/b/a Nanosystems and Elan Pharma International Limited and Janssen Pharmaceutica N.V. dated as of March 31, 1999, as amended by the First Amendment, dated as of July 31, 2003.</a>	Exhibit 10.25 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.9	<a href="#">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.</a>	Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 25, 2012

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>	<u>Incorporated by reference herein</u>	
		<u>Form</u>	<u>Date</u>
10.9.1	<a href="#">Amendment No. 2, dated as of February 14, 2013, to Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012, among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto, Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the arrangers and agents party thereto.</a>	Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	February 19, 2013
10.9.2	<a href="#">Amendment No. 3 and Waiver to Amended and Restated Credit Agreement, dated as of May 22, 2013, among Alkermes, Inc., Alkermes plc, Alkermes Pharma Ireland Limited, Alkermes US Holdings, Inc., Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the lenders party thereto.</a>	Exhibit 10.52 of the Alkermes plc Annual Report on Form 10-K (File No. 011-35299)	May 23, 2013
10.9.3	<a href="#">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.</a>	Exhibit 10.2 of the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	November 2, 2016
10.10 #*	<a href="#">License and Collaboration Agreement, dated November 27, 2017, by and between Alkermes Pharma Ireland Limited and Biogen Swiss Manufacturing GmbH.</a>		
10.11 †	<a href="#">Employment agreement, dated as of December 12, 2007, by and between Richard F. Pops and Alkermes, Inc.</a>	Exhibit 10.1 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 11, 2008
10.11.1 †	<a href="#">Amendment to Employment Agreement, dated as of October 7, 2008, by and between Alkermes, Inc. and Richard F. Pops.</a>	Exhibit 10.5 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	October 7, 2008
10.11.2 †	<a href="#">Amendment No. 2 to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops, dated September 10, 2009.</a>	Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	September 11, 2009
10.12 †	<a href="#">Form of Employment Agreement, dated as of December 12, 2007, entered into by and between Alkermes, Inc. and each of Kathryn L. Biberstein, Elliot W. Ehrich, M.D., James M. Frates and Michael J. Landine.</a>	Exhibit 10.3 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 11, 2008
10.12.1 †	<a href="#">Form of Amendment to Employment Agreement entered into by and between Alkermes, Inc. and each of Kathryn L. Biberstein, Elliot W. Ehrich, M.D. and James M. Frates, Michael J. Landine.</a>	Exhibit 10.7 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	October 7, 2008
10.13 †	<a href="#">Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and each of Kathryn L. Biberstein and James M. Frates.</a>	Exhibit 10.15 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 30, 2008

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Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.14 †	<a href="#">Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and each of Elliot W. Ehrich, M.D. and Michael J. Landine.</a>	Exhibit 10.15(a) to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 30, 2008
10.15 †	<a href="#">Shane Cooke Offer Letter, dated as of September 15, 2011.</a>	Exhibit 10.5 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.15.1 †	<a href="#">Employment Agreement by and between Alkermes Pharma Ireland Limited and Shane Cooke, dated as of September 16, 2011.</a>	Exhibit 10.6 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.16 †	<a href="#">Offer Letter between Alkermes, Inc. and Mark P. Stejbach, effective as of February 15, 2012.</a>	Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	March 5, 2012
10.16.1 †	<a href="#">Employment Agreement by and between Alkermes, Inc. and Mark P. Stejbach, dated as of February 29, 2012.</a>	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	March 5, 2012
10.16.2 †	<a href="#">Amendment to Employment Agreement, dated as of July 21, 2015, by and between Mark P. Stejbach and Alkermes, Inc.</a>	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 30, 2015
10.17 †	<a href="#">Form of Employment Agreement entered into by and between Alkermes, Inc. and each of Iain M. Brown, David J. Gaffin and Craig C. Hopkinson, M.D.</a>	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	November 2, 2016
10.17.1#†	<a href="#">Offer Letter between Alkermes, Inc. and Craig C. Hopkinson M.D., effective as of April 24, 2017.</a>		
10.18 †	<a href="#">Form of Indemnification Agreement by and between Alkermes, Inc. and each of its directors and executive officers.</a>	Exhibit 10.1 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	March 25, 2010
10.19 †	<a href="#">Form of Deed of Indemnification for Alkermes plc Officers.</a>	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.20 †	<a href="#">Form of Deed of Indemnification for Alkermes plc Directors/Secretary.</a>	Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.21 †	<a href="#">Form of Deed of Indemnification for Alkermes, Inc. and Subsidiaries Directors/Secretary.</a>	Exhibit 10.3 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>	<u>Incorporated by reference herein</u>	
		<u>Form</u>	<u>Date</u>
10.22 †	<a href="#">Alkermes, Inc. Amended and Restated 1999 Stock Option Plan.</a>	Appendix A to the Alkermes, Inc. Definitive Proxy Statement on Form DEF 14/A (File No. 001-14131)	July 27, 2007
10.22.1 †	<a href="#">Form of Incentive Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended.</a>	Exhibit 10.35 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	June 14, 2006
10.22.2 †	<a href="#">Form of Non-Qualified Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended.</a>	Exhibit 10.36 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	June 14, 2006
10.23 †	<a href="#">Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.</a>	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
10.23.1 †	<a href="#">Alkermes plc 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee Director).</a>	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
10.23.2 †	<a href="#">Alkermes plc 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only - Irish).</a>	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
10.23.3 †	<a href="#">Alkermes plc 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only – U.S.).</a>	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
10.23.4 †	<a href="#">Alkermes plc 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Time Vesting Non-Qualified Option – Irish).</a>	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



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<u>Exhibit No.</u>	<u>Description of Exhibit</u>	<u>Incorporated by reference herein</u>	
		<u>Form</u>	<u>Date</u>
10.23.5 †	<a href="#">Alkermes plc 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Time Vesting Non-Qualified Option – U.S.)</a>	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
10.23.6 †	<a href="#">Alkermes plc 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option – U.S.)</a>	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
10.23.7 †	<a href="#">Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only)</a>	Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	May 22, 2009
10.24 †	<a href="#">Alkermes plc 2011 Stock Option and Incentive Plan, as amended.</a>	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299)	May 24, 2017
10.24.1 †	<a href="#">Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option – U.S.), as amended.</a>	Exhibit 10.26.1 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.24.2 †	<a href="#">Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Time Vesting Non-Qualified Option – U.S.), as amended.</a>	Exhibit 10.26.2 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.24.3 †	<a href="#">Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Performance Vesting Non-Qualified Option – U.S.)</a>	Exhibit 10.26.3 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.24.4 †	<a href="#">Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only – U.S.), as amended.</a>	Exhibit 10.75 of the Alkermes plc Transition Report on Form 10-KT (File No. 011-35299)	February 27, 2014
10.24.5 †	<a href="#">Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only – U.S.), as amended.</a>	Exhibit 10.26.5 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.24.6 †	<a href="#">Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only - Irish), as amended.</a>	Exhibit 10.77 of the Alkermes plc Transition Report on Form 10-KT (File No. 011-35299)	February 27, 2014
10.24.7 †	<a href="#">Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only - Irish)</a>	Exhibit 10.26.7 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
10.24.8 †	<a href="#">Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee Director).</a>	Exhibit 10.3 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016
10.24.9 †	<a href="#">Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Time Vesting Non-Qualified Option – Irish).</a>	Exhibit 10.26.9 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.24.10 †	<a href="#">Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Performance Vesting Non-Qualified Option – Irish).</a>	Exhibit 10.26.10 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
21.1 #	<a href="#">List of subsidiaries</a>		
23.1 #	<a href="#">Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm</a>		
24.1 #	<a href="#">Power of Attorney (included on the signature pages hereto)</a>		
31.1 #	<a href="#">Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934</a>		
31.2 #	<a href="#">Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934</a>		
32.1 ‡	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>		
101.INS +#	XBRL Instance Document		
101.SCH +#	XBRL Taxonomy Extension Schema Document		
101.CAL +#	XBRL Taxonomy Extension Calculation Linkbase Document		
101.DEF +#	XBRL Taxonomy Extension Definition Linkbase Document		
101.LAB +#	XBRL Taxonomy Extension Label Linkbase Document		
101.PRE +#	XBRL Taxonomy Extension Presentation Linkbase Document		
†	Indicates a management contract or any compensatory plan, contract or arrangement.		
+	XBRL (Extensible Business Reporting Language).		
#	Filed herewith.		
‡	Furnished herewith.		
*	Confidential treatment has been granted or requested for certain portions of this exhibit. Such portions have been filed separately with the SEC pursuant to a confidential treatment request.		

**Item 16. Form 10-K Summary**

Not applicable.



**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, 2017 and 2016, and the related consolidated statements of operations and comprehensive loss, of changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2017, 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, 2017, 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, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017 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, 2017, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

***Change in Accounting Principle***

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for share based payments 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

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

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

/s/PricewaterhouseCoopers LLP

Boston, Massachusetts  
February 16, 2018

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

**ALKERMES PLC AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**December 31, 2017 and 2016**

	<u>December 31, 2017</u>	<u>December 31, 2016</u>
	(In thousands, except share and per share amounts)	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 191,296	\$ 186,378
Investments—short-term	242,208	310,856
Receivables, net	233,590	191,102
Inventory	93,275	62,998
Prepaid expenses and other current assets	48,475	39,344
Total current assets	<u>808,844</u>	<u>790,678</u>
PROPERTY, PLANT AND EQUIPMENT, NET	284,736	264,785
INTANGIBLE ASSETS—NET	256,168	318,227
INVESTMENTS—LONG-TERM	157,212	121,931
GOODWILL	92,873	92,873
CONTINGENT CONSIDERATION	84,800	63,200
DEFERRED TAX ASSETS	98,560	47,768
OTHER ASSETS	14,034	26,961
<b>TOTAL ASSETS</b>	<b><u>\$ 1,797,227</u></b>	<b><u>\$ 1,726,423</u></b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 286,166	\$ 207,055
Long-term debt—short-term	3,000	3,000
Deferred revenue—short-term	1,956	1,938
Total current liabilities	<u>291,122</u>	<u>211,993</u>
LONG-TERM DEBT	278,436	280,666
OTHER LONG-TERM LIABILITIES	19,204	17,161
DEFERRED REVENUE—LONG-TERM	5,657	7,122
Total liabilities	<u>594,419</u>	<u>516,942</u>
<b>COMMITMENTS AND CONTINGENCIES (Note 16)</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Preferred shares, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at December 31, 2017 and 2016, respectively	—	—
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 156,057,632 and 154,191,281 shares issued; 154,009,456 and 152,430,514 shares outstanding at December 31, 2017 and 2016, respectively	1,557	1,539
Treasury shares, at cost (2,048,176 and 1,760,767 shares at December 31, 2017 and 2016, respectively)	(89,347)	(72,639)
Additional paid-in capital	2,338,755	2,231,797
Accumulated other comprehensive loss	(3,792)	(3,274)
Accumulated deficit	(1,044,365)	(947,942)
Total shareholders' equity	<u>1,202,808</u>	<u>1,209,481</u>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b><u>\$ 1,797,227</u></b>	<b><u>\$ 1,726,423</u></b>

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

**ALKERMES PLC AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**Years Ended December 31, 2017, 2016 and 2015**

	<u>Year Ended December 31,</u>		
	<u>2017</u>	<u>2016</u>	<u>2015</u>
	<b>(In thousands, except per share amounts)</b>		
<b>REVENUES:</b>			
Manufacturing and royalty revenues	\$ 505,308	\$ 487,247	\$ 475,288
Product sales, net	362,834	256,146	149,028
License revenue	28,000	—	—
Research and development revenue	7,232	2,301	4,019
Total revenues	<u>903,374</u>	<u>745,694</u>	<u>628,335</u>
<b>EXPENSES:</b>			
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	154,748	132,122	138,989
Research and development	412,889	387,148	344,404
Selling, general and administrative	421,578	374,130	311,558
Amortization of acquired intangible assets	62,059	60,959	57,685
Total expenses	<u>1,051,274</u>	<u>954,359</u>	<u>852,636</u>
<b>OPERATING LOSS</b>	<u>(147,900)</u>	<u>(208,665)</u>	<u>(224,301)</u>
<b>OTHER INCOME (EXPENSE), NET:</b>			
Interest income	4,649	3,752	3,330
Interest expense	(12,008)	(14,889)	(13,247)
Change in the fair value of contingent consideration	21,600	7,900	(2,300)
Gain on the Gainesville Transaction	—	—	9,636
Gain on sale of property, plant and equipment	—	—	2,862
Other (expense) income, net	(9,615)	(2,485)	15
Total other income (expense), net	<u>4,626</u>	<u>(5,722)</u>	<u>296</u>
<b>LOSS BEFORE INCOME TAXES</b>	<u>(143,274)</u>	<u>(214,387)</u>	<u>(224,005)</u>
<b>INCOME TAX PROVISION (BENEFIT)</b>	<u>14,671</u>	<u>(5,943)</u>	<u>3,158</u>
<b>NET LOSS</b>	<u>\$ (157,945)</u>	<u>\$ (208,444)</u>	<u>\$ (227,163)</u>
<b>LOSS PER ORDINARY SHARE:</b>			
Basic and diluted	<u>\$ (1.03)</u>	<u>\$ (1.38)</u>	<u>\$ (1.52)</u>
<b>WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:</b>			
Basic and diluted	<u>153,415</u>	<u>151,484</u>	<u>149,206</u>
<b>COMPREHENSIVE LOSS:</b>			
Net loss	\$ (157,945)	\$ (208,444)	\$ (227,163)
Holding (loss) gain, net of a tax (benefit) provision of \$(295), \$237 and \$(292), respectively	(518)	522	(661)
<b>COMPREHENSIVE LOSS</b>	<u>\$ (158,463)</u>	<u>\$ (207,922)</u>	<u>\$ (227,824)</u>

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



**ALKERMES PLC AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**Years Ended December 31, 2017, 2016 and 2015**

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount				Shares	Amount	
(In thousands, except share data)								
BALANCE —								
December 31, 2014	148,545,150	\$ 1,482	\$ 1,942,878	\$ (3,136)	\$ (512,335)	(1,006,631)	\$ (32,052)	\$ 1,396,837
Issuance of ordinary shares under employee stock plans	3,538,308	35	44,934	—	—	—	—	44,969
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share based awards	45,483	1	704	—	—	(421,321)	(26,609)	(25,904)
Share-based compensation expense	—	—	97,619	—	—	—	—	97,619
Excess tax benefit from share-based compensation	—	—	28,576	—	—	—	—	28,576
Unrealized loss on marketable securities, net of tax benefit of \$(292)	—	—	—	(659)	—	—	—	(659)
Net loss	—	—	—	—	(227,163)	—	—	(227,163)
BALANCE —								
December 31, 2015	152,128,941	\$ 1,518	\$ 2,114,711	\$ (3,795)	\$ (739,498)	(1,427,952)	\$ (58,661)	\$ 1,314,275
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 share based awards	16,267	2	273	—	—	(287,409)	(16,708)	(16,433)
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	<u>156,057,632</u>	<u>\$ 1,557</u>	<u>\$ 2,338,755</u>	<u>\$ (3,792)</u>	<u>\$ (1,044,365)</u>	<u>(2,048,176)</u>	<u>\$ (89,347)</u>	<u>\$ 1,202,808</u>

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

**ALKERMES PLC AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**Years Ended December 31, 2017, 2016 and 2015**

	<b>Year Ended December 31,</b>		
	<b>2017</b>	<b>2016</b>	<b>2015</b>
	<b>(In thousands)</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (157,945)	\$ (208,444)	\$ (227,163)
Adjustments to reconcile net loss to cash flows from operating activities:			
Depreciation and amortization	98,523	94,256	85,596
Share-based compensation expense	83,917	94,396	97,341
Impairment of investment in Reser Therapeutics, Inc.	10,471	—	—
Deferred income taxes	7,234	(9,689)	(37,580)
Change in the fair value of contingent consideration	(21,600)	(7,900)	2,300
Excess tax benefit from share-based compensation	—	(4,229)	(28,576)
Gain on the Gainesville Transaction	—	—	(9,636)
Loss on debt refinancing	—	2,075	—
Gain on sale of property, plant and equipment	—	—	(3,272)
Other non-cash charges	3,471	2,936	(1,351)
Changes in assets and liabilities:			
Receivables	(42,489)	(35,616)	(16,455)
Inventory	(30,191)	(26,381)	3,687
Prepaid expenses and other assets	(9,506)	(15,014)	15,931
Accounts payable and accrued expenses	72,658	45,870	76,155
Deferred revenue	(1,447)	(649)	(629)
Other long-term liabilities	6,094	4,587	3,292
Cash flows provided by (used in) operating activities	<u>19,190</u>	<u>(63,802)</u>	<u>(40,360)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Additions of property, plant and equipment	(51,300)	(43,657)	(52,877)
Proceeds from the sale of equipment	162	194	535
Purchases of investments	(431,712)	(375,099)	(508,683)
Sales and maturities of investments	464,494	560,805	467,573
Investment in Reser Therapeutics, Inc.	—	(15,000)	—
Net proceeds from the Gainesville Transaction	—	—	49,966
Cash flows (used in) provided by investing activities	<u>(18,356)</u>	<u>127,243</u>	<u>(43,486)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	23,517	20,308	44,969
Employee taxes paid related to net share settlement of equity awards	(16,433)	(13,467)	(25,904)
Principal payments of long-term debt	(3,000)	(3,429)	(6,750)
Excess tax benefit from share-based compensation	—	4,229	28,576
Payment made for debt refinancing	—	(65,813)	—
Cash flows provided by (used in) financing activities	<u>4,084</u>	<u>(58,172)</u>	<u>40,891</u>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>4,918</b>	<b>5,269</b>	<b>(42,955)</b>
<b>CASH AND CASH EQUIVALENTS—Beginning of period</b>	<b>186,378</b>	<b>181,109</b>	<b>224,064</b>
<b>CASH AND CASH EQUIVALENTS—End of period</b>	<b><u>\$ 191,296</u></b>	<b><u>\$ 186,378</u></b>	<b><u>\$ 181,109</u></b>
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>			
Cash paid for interest	\$ 11,143	\$ 12,458	\$ 12,323
Cash paid for taxes	\$ 2,992	\$ 5,531	\$ 705
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 11,151	\$ 5,766	\$ 6,054
Fair value of warrants received as part of the Gainesville Transaction	\$ —	\$ —	\$ 2,123
Fair value of contingent consideration received as part of the Gainesville Transaction	\$ —	\$ —	\$ 57,600

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

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

**1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION**

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

**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.

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

*Use of Estimates*

The preparation of the Company’s consolidated financial statements in accordance with accounting principles generally accepted in the United States (“U.S.”) (“GAAP”) requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates and judgments and methodologies, including those related to revenue recognition and related allowances, its collaborative relationships, clinical trial expenses, the valuation of inventory, impairment and amortization of intangibles and long-lived assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of investments, contingent consideration and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

*Cash and Cash Equivalents*

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

*Receivables, net*

The Company’s allowance for doubtful accounts was \$0.2 million and \$0.1 million at December 31, 2017 and 2016, respectively.

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

***Investments***

The Company has investments in various types of securities, consisting primarily of U.S. government and agency obligations, corporate debt securities and debt securities issued by foreign agencies and backed by foreign governments. The Company generally holds its interest bearing investments with major financial institutions and in accordance with documented investment policies. The Company limits the amount of credit exposure to any one financial institution or corporate issuer. At December 31, 2017, substantially all these investments were classified as available for sale and were recorded at fair value.

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

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

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

***Fair Value of Financial Instruments***

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

- *Level 1*—these valuations are based on a market approach using quoted prices in active markets for identical assets. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 1 inputs at December 31, 2017 included U.S. treasury securities and a fixed term deposit account;
- *Level 2*—these valuations are based on a market approach using quoted prices obtained from brokers or dealers for similar securities or for securities for which the Company has limited visibility into their trading volumes. Valuations of these financial instruments do not require a significant degree of judgment. Assets and liabilities utilizing Level 2 inputs at December 31, 2017 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, 2017, assets utilizing Level 3 inputs included contingent consideration and warrants to purchase the common stock of Recro.

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

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

***Inventory***

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

***Property, Plant and Equipment***

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

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

***Business Acquisitions and Divestitures***

The Company's consolidated financial statements include the operations of an acquired business after the completion of the acquisition. The Company accounts for acquired businesses using the acquisition method of accounting. The acquisition method of accounting for acquired businesses requires, among other things, that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date, and that the fair value of acquired in-process research and development be recorded on the balance sheet. Also, transaction costs are expensed as incurred. Any excess of the purchase price over the assigned values of the net assets acquired is recorded as goodwill. Contingent consideration, if any, is included within the acquisition cost and is recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is re-measured to fair value at each reporting date until the contingency is resolved. Changes in the fair value of the contingent consideration are recognized in earnings.

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

***Contingent Consideration***

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

The period over which the Company discounts its contingent consideration is based on the current development stage of the product candidate, the specific development plan for that product candidate, adjusted for the probability of completing the development steps, and when contingent payments would be triggered. In estimating the probability of

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

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.

***Revenue Recognition***

**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<sup>®</sup>/XEPLION<sup>®</sup> and INVEGA TRINZA<sup>®</sup>/TREVICTA<sup>®</sup> as well as RISPERDAL CONSTA<sup>®</sup>, Acorda Therapeutics, Inc. ("Acorda") for AMPYRA<sup>®</sup>/FAMPYRA<sup>®</sup> and AstraZeneca plc ("AstraZeneca") for BYDUREON<sup>®</sup>. Substantially all of the products developed under the Company's collaborative arrangements are currently being marketed as approved products. The Company receives payments for manufacturing services and/or royalties on net product sales.



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

Multiple Element Arrangements

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

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

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

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

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

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

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

under the agreement. Biogen paid a portion of the BIIB098 development costs the Company incurred in 2017 and, beginning on January 1, 2018, Biogen will be responsible for all BIIB098 development costs the Company incurs, subject to annual budget limitations. The Company has retained the right to manufacture clinical supplies and commercial supplies of BIIB098 and all other products covered by patents licensed to Biogen under the agreement, subject to Biogen's right to manufacture or have manufactured commercial supplies as a back-up manufacturer and subject to good faith agreement by the parties on the terms of such manufacturing arrangements.

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

The consideration allocable to the delivered unit or units of accounting is limited to the amount that is not contingent upon the delivery of additional items or meeting other specified performance conditions. Therefore, the Company will exclude from the allocable consideration the milestone payments and royalties, regardless of the probability that such milestone and royalty payments will be made, until the events that give rise to such payments actually occur.

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

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

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

*Manufacturing revenues*—The Company recognizes manufacturing revenues from the sale of products it manufactures for resale by its licensees. Manufacturing revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured. The sales price for certain of the Company's manufacturing revenues is based on the end-market sales price earned by its partners. As the end-market sale occurs after the Company has shipped its product and the risk of loss has passed to its partner, the Company estimates the sales price for such products based on information supplied to it by the Company's partners, its historical transaction experience and other third-party data. Differences between actual manufacturing revenues and estimated manufacturing

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

revenues are reconciled and adjusted for in the period in which they become known, which is generally within the quarter. The difference between the Company's actual and estimated manufacturing revenues has not been material.

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

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

*Research and development 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.

Product Sales, Net

The Company's product sales, net consist of sales of VIVITROL<sup>®</sup>, and since its approval by the U.S. Food and Drug Administration ("FDA") in October 2015, ARISTADA<sup>®</sup>, in the U.S. primarily to wholesalers, specialty distributors and pharmacies. Product sales are recognized when persuasive evidence of an arrangement exists, title to the product and associated risk of loss has passed to the customer, which is considered to occur when the product has been received by the customer, the sales price is fixed or determinable and collectability is reasonably assured.

The Company records its product sales net of the following significant categories of sales discounts and allowances at the time of shipment:

- *Medicaid Rebates*—the Company records accruals for rebates to states under the Medicaid Drug Rebate Program as a reduction of sales when the product is shipped into the distribution channel. The Company rebates individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is based on the Company's average manufacturer prices. The Company estimates expected unit sales and rebates per unit under the Medicaid program and adjust its rebate based on actual unit sales and rebates per unit. To date, actual Medicaid rebates have not differed materially from the Company's estimates;
- *Chargebacks*—chargebacks are discounts that occur when contracted indirect customers purchase directly from wholesalers and specialty distributors. Contracted customers generally purchase the product at its contracted price. The wholesaler or specialty distributor, in turn, then generally charges back to the Company the difference between the wholesale acquisition cost and the contracted price paid to the wholesaler or specialty distributor by the customer. The allowance for chargebacks is based on actual and expected utilization of these programs. Chargebacks could exceed historical experience and the Company's estimates of future participation in these programs. To date, actual chargebacks have not differed materially from the Company's estimates;
- *Product Discounts*—cash consideration, including sales incentives, given by the Company under agreements with a number of wholesaler, distributor, pharmacy, and treatment provider customers that provide them with a discount on the purchase price of products. To date, actual product discounts have not differed materially from the Company's estimates;
- *Co-pay Assistance*—the Company has a program whereby a patient can receive monetary assistance each month toward their product co-payment, co-insurance or deductible, provided the patient meets certain eligibility criteria. Reserves for such co-pay assistance are recorded upon the product sale. To date, actual co-pay assistance has not differed materially from the Company's estimates; and

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

- *Product Returns*—the Company records an estimate for product returns at the time its customer takes title to the Company's product. The Company estimates this liability based on its historical return levels and specifically identified anticipated returns due to known business conditions and product expiry dates. Return amounts are recorded as a deduction to arrive at product sales, net. Once product is returned, it is destroyed. At December 31, 2017, the product return reserve was estimated to be approximately 1.5% of each of the Company's VIVITROL and ARISTADA gross product sales.

***Foreign Currency***

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within "Other income (expense), net" in the accompanying consolidated statements of operations and comprehensive loss. During the years ended December 31, 2017, 2016 and 2015, the Company recorded a gain on foreign currency translation of \$3.7 million, \$0.1 million and \$1.4 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, 2017, 2016 and 2015:

<u>Customer</u>	<u>Year Ended December 31,</u>					
	<u>2017</u>		<u>2016</u>		<u>2015</u>	
	<u>Receivables</u>	<u>Revenue</u>	<u>Receivables</u>	<u>Revenue</u>	<u>Receivables</u>	<u>Revenue</u>
Janssen	31 %	33 %	33 %	36 %	44 %	40 %
Acorda	14 %	13 %	17 %	15 %	*	17 %

\* In 2015, receivables related to Acorda did not exceed 10% of the Company's total receivables as of December 31, 2015.

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

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

***Geographic Information***

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

(In thousands)	Year Ended December 31,		
	2017	2016	2015
Revenue by region:			
U.S.	\$ 700,090	\$ 557,312	\$ 448,639
Ireland	9,706	4,407	3,902
Rest of world	193,578	183,975	175,794
Assets by region:			
Current assets:			
U.S.	\$ 402,481	\$ 382,168	\$ 360,154
Ireland	403,167	407,761	394,281
Rest of world	3,196	749	527
Long-term assets:			
U.S.:			
Other	\$ 360,641	\$ 236,175	\$ 294,158
Ireland:			
Intangible assets	\$ 256,168	\$ 318,227	\$ 379,186
Goodwill	92,873	92,873	92,873
Other	278,701	288,470	334,565

***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, 2017, 2016 and 2015, advertising costs totaled \$34.4 million, \$24.0 million and \$10.6 million, respectively.

***Share-Based Compensation***

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

***Stock Options***

Stock option grants to employees expire ten years from the grant date and generally vest one-fourth per year over four years from the anniversary of the date of grant, provided the employee remains continuously employed with the Company, except as otherwise provided in the plan. Stock option grants to directors are for ten-year terms and generally vest over a one-year period provided the director continues to serve on the Company’s board of directors through the vesting date, except as otherwise provided in the plan. The estimated fair value of options is recognized over the

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

requisite service period, which is generally the vesting period. Share-based compensation expense is based on awards ultimately expected to vest. Forfeitures are estimated based on historical experience at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates.

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

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

	<b>Year Ended December 31,</b>		
	<b>2017</b>	<b>2016</b>	<b>2015</b>
Expected option term	5 - 8 years	5 - 7 years	5 - 7 years
Expected stock volatility	43 % - 47 %	39 % - 53 %	38 % - 46 %
Risk-free interest rate	1.69 % - 2.38 %	0.95 % - 2.14 %	1.29 % - 2.02 %
Expected annual dividend yield	—	—	—

*Time-Vested Restricted Stock Units*

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

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

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

***Comprehensive Loss***

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

***Loss Per Share***

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

***Segment Information***

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

***Employee Benefit Plans***

***401(k) Plan***

The Company maintains a 401(k) retirement savings plan (the "401(k) Plan"), which covers substantially all of its U.S.-based employees. Eligible employees may contribute up to 100% of their eligible compensation, subject to certain Internal Revenue Service ("IRS") limitations. The Company matches 100% of employee contributions up to the first 5% of employee pay, up to IRS limits. Employee and Company contributions are fully vested when made. During the years ended December 31, 2017, 2016 and 2015, the Company contributed \$9.8 million, \$8.1 million and \$6.6 million, respectively, to match employee deferrals under the 401(k) Plan.

***Defined Contribution Plan***

The Company maintains a defined contribution plan for its Ireland-based employees (the "Defined Contribution Plan"). The Defined Contribution Plan provides for eligible employees to contribute up to the maximum of 40%, depending upon their age, of their total taxable earnings subject to an earnings cap of €115,000. The Company provides a match of up to 18% of taxable earnings depending upon an individual's contribution level. During the years ended December 31, 2017, 2016 and 2015, the Company contributed \$3.7 million, \$3.2 million and \$3.0 million, respectively, in contributions to the Defined Contribution Plan.

***New Accounting Pronouncements***

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

In May 2014, the FASB issued guidance that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be



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entitled in exchange for those goods or services. The guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to fulfill a contract. Numerous updates have been issued subsequent to the initial guidance that provide clarification on a number of specific issues and require additional disclosures.

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

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

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

In March 2016, the FASB issued guidance as part of its simplification initiative to eliminate the requirement to retroactively adopt the equity method of accounting when an investment qualifies for the use of the equity method as a result of an increase in the level of ownership interest or degree of influence. This guidance became effective for the Company on January 1, 2017, and the adoption of this guidance did not have an impact on the Company's consolidated financial statements.

In March 2016, the FASB issued guidance as part of its simplification initiative that involves several aspects of the accounting for share-based payment transactions. The amendments in this update established that: (i) all excess tax benefits and tax deficiencies be recognized as income tax expense or benefit in the income statement; (ii) excess tax benefits be classified as an operating activity in the statement of cash flows; (iii) the entity make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest, which is current GAAP, or account for forfeitures as they occur; (iv) the threshold to qualify for equity classification permits withholding up to the maximum statutory tax rates in the applicable jurisdictions; and (v) cash paid by an employer when directly withholding shares for tax withholding purposes be classified as a financing activity in the statement of cash flows. This guidance

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

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

In August 2016, the FASB issued guidance to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This guidance becomes effective for the Company in its year ending December 31, 2018, with early adoption permitted. The Company elected to early adopt this guidance as of January 1, 2017. The adoption of this guidance had no impact on the Company's statement of cash flows.

In October 2016, the FASB issued guidance to simplify and improve accounting on transfers of assets between affiliated entities. The updated guidance eliminates the prohibition for all intra-entity asset transfers, except for inventory. This guidance becomes effective for the Company in its year ending December 31, 2018, and upon adoption of the new standard, a cumulative-effect adjustment of approximately \$0.9 million will be recorded within retained earnings, related to the reversal of an unamortized deferred tax charge on a prior sale of intellectual property between Alkermes, Inc. and Alkermes Pharma Ireland Limited.

In January 2017, the FASB issued guidance to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This guidance becomes effective for the Company in its year ending December 31, 2018, with early adoption permitted for transactions that occurred before the issuance date or effective date of the guidance if the transactions were not reported in financial statements that have been issued or made available for issuance. The Company elected to early adopt this guidance, as of January 1, 2017. The adoption of this guidance had no impact on the Company's consolidated financial statements.

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

In May 2017, the FASB issued guidance that amends the scope of modification accounting for share-based payment arrangements to address both diversity in practice and the cost and complexity of accounting for the change to the terms or conditions of a share-based payment award. The amendment provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The guidance becomes effective for the Company in its year ending December 31, 2018 and early adoption is permitted. The standard may impact the Company in future periods if modifications are made to certain of its share-based awards.

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

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

**3. INVESTMENTS**

Investments consist of the following:

<b>December 31, 2017</b>	Amortized Cost	Gross Unrealized Losses			Estimated Fair Value
		Gains	Less than One Year	Greater than One Year	
<b>Short-term investments:</b>					
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	<u>242,703</u>	<u>5</u>	<u>(232)</u>	<u>(268)</u>	<u>242,208</u>
<b>Long-term investments:</b>					
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
	<u>154,325</u>	<u>—</u>	<u>(688)</u>	<u>(105)</u>	<u>153,532</u>
Held-to-maturity securities:					
Fixed term deposit account	1,667	222	—	—	1,889
Certificates of deposit	1,791	—	—	—	1,791
	<u>3,458</u>	<u>222</u>	<u>—</u>	<u>—</u>	<u>3,680</u>
Total long-term investments	<u>157,783</u>	<u>222</u>	<u>(688)</u>	<u>(105)</u>	<u>157,212</u>
Total investments	<u>\$ 400,486</u>	<u>\$ 227</u>	<u>\$ (920)</u>	<u>\$ (373)</u>	<u>\$ 399,420</u>

<b>December 31, 2016</b>					
<b>Short-term investments:</b>					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 177,203	\$ 96	\$ (51)	\$ —	\$ 177,248
Corporate debt securities	128,119	47	(53)	—	128,113
International government agency debt securities	5,511	—	(16)	—	5,495
Total short-term investments	<u>310,833</u>	<u>143</u>	<u>(120)</u>	<u>—</u>	<u>310,856</u>
<b>Long-term investments:</b>					
Available-for-sale securities:					
U.S. government and agency debt securities	81,839	—	(391)	—	81,448
Corporate debt securities	31,223	—	(89)	—	31,134
International government agency debt securities	5,992	—	(18)	—	5,974
	<u>119,054</u>	<u>—</u>	<u>(498)</u>	<u>—</u>	<u>118,556</u>
Held-to-maturity securities:					
Fixed term deposit account	1,667	—	(7)	—	1,660
Certificates of deposit	1,715	—	—	—	1,715
	<u>3,382</u>	<u>—</u>	<u>(7)</u>	<u>—</u>	<u>3,375</u>
Total long-term investments	<u>122,436</u>	<u>—</u>	<u>(505)</u>	<u>—</u>	<u>121,931</u>
Total investments	<u>\$ 433,269</u>	<u>\$ 143</u>	<u>\$ (625)</u>	<u>\$ —</u>	<u>\$ 432,787</u>

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

(In thousands)	Year Ended December 31,		
	2017	2016	2015
Proceeds from the sales and maturities of marketable securities	\$ 464,494	\$ 560,805	\$ 467,573
Realized gains	\$ 9	\$ 206	\$ 111
Realized losses	\$ 3	\$ 28	\$ 3

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

The Company's available-for-sale and held-to-maturity securities at December 31, 2017 had contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	\$ 234,771	\$ 234,273	\$ 1,791	\$ 1,791
After 1 year through 5 years	162,257	161,467	1,667	1,889
Total	<u>\$ 397,028</u>	<u>\$ 395,740</u>	<u>\$ 3,458</u>	<u>\$ 3,680</u>

At December 31, 2017, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted of U.S. government and agency debt securities, corporate debt securities and international government 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 Reset Therapeutics, Inc. ("Reset"), a related party. The Company made an upfront, non-refundable payment of \$10.0 million in partial consideration of the grant to the Company of the rights and licenses included in such agreement, which was included in R&D expense in the three months ended March 31, 2016, and simultaneously made a \$15.0 million investment in exchange for shares of Reset's Series B Preferred Stock. The Company was accounting for its investment in Reset under the equity method based on its percentage of ownership, its seat on the board of directors and its belief that it can exert significant influence over the operating and financial policies of Reset.

In September 2017, the Company recorded an other-than-temporary impairment charge of \$10.5 million within "Other income (expense), net" in the accompanying consolidated statements of operations and comprehensive loss, which represented the Company's remaining investment in Reset, as the Company believes that Reset is unable to generate future earnings that justify the carrying amount of the investment. During the years ended December 31, 2017 and 2016, the Company recorded a reduction in its investment in Reset of \$2.8 million and \$1.7 million, respectively, which represented the Company's proportional share of Reset's net loss for the periods. The Company's \$13.3 million investment at December 31, 2016 was included within "Other assets" in the accompanying consolidated balance sheets.

In May 2014, the Company entered into an agreement whereby it is committed to provide up to €7.4 million to a partnership, Fountain Healthcare Partners II, L.P. of Ireland ("Fountain"), which was created to carry on the business of investing exclusively in companies and businesses engaged in the healthcare, pharmaceutical and life sciences sectors. As of December 31, 2017, the Company's total contribution in Fountain was equal to €3.7 million, and its commitment represents approximately 7% of the partnership's total funding. The Company is accounting for its investment in Fountain under the equity method. During the years ended December 31, 2017, 2016 and 2015, the Company recorded a reduction in its investment in Fountain of \$0.1 million, \$0.4 million and \$0.2 million, respectively, which represented the Company's proportional share of Fountain's net loss for the period.

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

**4. 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, 2017	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents	\$ 1,889	\$ 1,889	\$ —	\$ —
U.S. government and agency debt securities	198,918	124,958	73,960	—
Corporate debt securities	140,087	—	140,087	—
International government agency debt securities	56,735	—	56,735	—
Contingent consideration	84,800	—	—	84,800
Common stock warrants	1,395	—	—	1,395
Total	<u>\$ 483,824</u>	<u>\$ 126,847</u>	<u>\$ 270,782</u>	<u>\$ 86,195</u>
	December 31, 2016	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents	\$ 1,660	\$ 1,660	\$ —	\$ —
U.S. government and agency debt securities	258,696	156,370	102,326	—
Corporate debt securities	159,247	—	159,247	—
International government agency debt securities	11,469	—	11,469	—
Contingent consideration	63,200	—	—	63,200
Common stock warrants	1,392	—	—	1,392
Total	<u>\$ 495,664</u>	<u>\$ 158,030</u>	<u>\$ 273,042</u>	<u>\$ 64,592</u>

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

There were no transfers of any securities from Level 1 to Level 2 or from Level 2 to Level 1 during the year ended December 31, 2017. The following table is a rollforward of the fair value of the Company's investments whose fair value was determined using Level 3 inputs at December 31, 2017:

(In thousands)	Fair Value
Balance, January 1, 2017	\$ 64,592
Increase in the fair value of contingent consideration	21,600
Increase in the fair value of warrants	3
Balance, December 31, 2017	<u>\$ 86,195</u>

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

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, receivables, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The fair value of the remaining financial instruments not currently recognized at fair value on the Company's consolidated balance sheets at December 31, 2017 consisted of a \$300.0 million term loan, bearing interest at LIBOR plus 2.75% with a LIBOR floor of 0.75% and maturity of September 25, 2021 ("Term Loan B-1"). The estimated fair value of Term Loan B-1, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and which may not be representative of actual values that could have been, or will be, realized in the future, was as follows at December 31, 2017:

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

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

**5. INVENTORY**

Inventory consists of the following:

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

(1) At December 31, 2017 and 2016, the Company had \$8.7 million and \$7.1 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

**6. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consist of the following:

(In thousands)	December 31, 2017	December 31, 2016
Land	\$ 6,293	\$ 5,913
Building and improvements	155,198	152,871
Furniture, fixtures and equipment	289,455	251,437
Leasehold improvements	19,578	19,241
Construction in progress	54,270	41,254
Subtotal	524,794	470,716
Less: accumulated depreciation	(240,058)	(205,931)
Total property, plant and equipment, net	<u>\$ 284,736</u>	<u>\$ 264,785</u>

Depreciation expense was \$36.5 million, \$33.3 million and \$27.9 million for the years ended December 31, 2017, 2016 and 2015, respectively. Also, during the years ended December 31, 2017, 2016 and 2015, the Company wrote off furniture, fixtures and equipment that had a carrying value of \$0.1 million, \$0.9 million and \$0.1 million, respectively, at the time of disposition.

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

**7. GOODWILL AND INTANGIBLE ASSETS**

Goodwill and intangible assets consist of the following:

(In thousands)	Weighted Amortizable Life (Years)	Year Ended December 31, 2017			Year Ended December 31, 2016		
		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	\$ (269,392)	\$ 196,198	\$ 465,590	\$ (218,318)	\$ 247,272
NanoCrystal technology	13	74,600	(31,283)	43,317	74,600	(24,384)	50,216
OCR technologies	12	42,560	(25,907)	16,653	42,560	(21,821)	20,739
Total		<u>\$ 582,750</u>	<u>\$ (326,582)</u>	<u>\$ 256,168</u>	<u>\$ 582,750</u>	<u>\$ (264,523)</u>	<u>\$ 318,227</u>

The Company's finite-lived intangible assets consist of collaborative agreements and the NanoCrystal and OCR technologies acquired as part of the EDT acquisition. The Company recorded \$62.1 million, \$61.0 million and \$57.7 million of amortization expense related to its finite-lived intangible assets during the years ended December 31, 2017,

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

2016 and 2015, respectively. Based on the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheets at December 31, 2017 is expected to be approximately \$65.0 million, \$55.0 million, \$50.0 million, \$40.0 million and \$35.0 million in the years ending December 31, 2018 through 2022, respectively. Although the Company believes such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future revenues, there is the potential for the Company's actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets will change in proportion to the change in revenues.

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

**8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consist of the following:

(In thousands)	December 31, 2017	December 31, 2016
Accounts payable	\$ 55,526	\$ 46,275
Accrued compensation	54,568	45,622
Accrued sales discounts, allowances and reserves	111,137	60,973
Accrued other	64,935	54,185
Total accounts payable and accrued expenses	<u>\$ 286,166</u>	<u>\$ 207,055</u>

**9. LONG-TERM DEBT**

Long-term debt consists of the following:

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

***Term Loans***

Term Loan B-1 was issued with a principal balance of \$300.0 million, interest payable of LIBOR plus 2.75% with a LIBOR floor of 0.75%, and an original issue discount of \$3.0 million. Term Loan B-1 amortizes in equal quarterly amounts of 0.25% of the original principal amount of the loan, with the balance payable at maturity. In October 2016, the Company amended Term Loan B-1, which, among other things, extended the due date from September 25, 2019 to September 25, 2021 (the "Refinancing").

The Refinancing involved multiple lenders who were considered members of a loan syndicate. In determining whether the Refinancing was to be accounted for as a debt extinguishment or a debt modification, the Company considered whether creditors remained the same or changed and whether the changes in debt terms were substantial. A change in the debt terms was considered to be substantial if the present value of the remaining cash flows under the new terms of Term Loan B-1 are at least 10% different from the present value of the remaining cash flows under the original terms of Term Loan B-1 (commonly referred to as the "10% Test"). The Company performed a separate 10% Test for each individual creditor participating in the loan syndication. The loans of any creditors no longer participating in the loan syndication were accounted for as a debt extinguishment. The Refinancing resulted in a \$2.1 million charge in the three months ended December 31, 2016, which was included in "Interest expense" in the accompanying consolidated statement of operations and comprehensive loss.

A second term loan was issued with a principal balance of \$75.0 million, interest payable of LIBOR plus 2.75% with no LIBOR floor, and an original issue discount of \$0.4 million ("Term Loan B-2"). Term Loan B-2 amortized in equal quarterly amounts of 1.25% of the original principal amount of the loan, with the balance payable at maturity. In September 2016, Term Loan B-2 matured and the Company repaid the outstanding principal balance of \$60.9 million in its entirety.



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

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

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

<b>Year Ending December 31:</b>	
2018	\$ 3,000
2019	3,000
2020	3,000
2021	275,250
<b>Total</b>	<b>\$ 284,250</b>

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

Term Loan B-1 has an incremental facility capacity in an amount of \$140.0 million, plus additional amounts as long as the Company meets certain conditions, including a specified leverage ratio. Term Loan B-1 includes a number of restrictive covenants that, among other things and subject to certain exceptions and baskets, impose operating and financial restrictions on the Company and certain of its subsidiaries. Term Loan B-1 also contains customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at December 31, 2017.

At December 31, 2017, the Company’s balance of unamortized deferred financing costs and unamortized original issue discount costs were \$1.0 million and \$1.8 million, respectively. These costs are being amortized to interest expense over the estimated repayment period of Term Loan B-1 using the effective interest method. During the years ended December 31, 2017, 2016 and 2015, the Company had amortization expense of \$0.8 million, \$0.9 million and \$0.9 million, respectively, related to deferred financing costs and original issue discount.

#### **10. LOSS PER SHARE**

Basic loss per ordinary share is calculated based upon net loss available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the years ended December 31, 2017, 2016 and 2015, as the Company was in a net loss position, the diluted loss per share did not assume conversion or exercise of stock options 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:

<b>(In thousands)</b>	<b>Year Ended December 31.</b>		
	<b>2017</b>	<b>2016</b>	<b>2015</b>
Stock options	9,540	10,166	9,179
Restricted stock units	2,119	1,320	1,351
<b>Total</b>	<b>11,659</b>	<b>11,486</b>	<b>10,530</b>

#### **11. 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, 2017, approximately \$101.0 million was available to repurchase ordinary shares pursuant to the repurchase program. All shares repurchased are recorded as treasury stock. The repurchase program has no set expiration date and may be suspended or discontinued at any time. During the years ended December 31, 2017 and 2016, the Company did not acquire any ordinary shares under the repurchase program.

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

**12. SHARE-BASED COMPENSATION**

*Share-based Compensation Expense*

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

(In thousands)	Year Ended December 31,		
	2017	2016	2015
Cost of goods manufactured and sold	\$ 7,596	\$ 8,633	\$ 8,880
Research and development	22,635	24,023	24,201
Selling, general and administrative	53,686	61,740	64,260
Total share-based compensation expense	<u>\$ 83,917</u>	<u>\$ 94,396</u>	<u>\$ 97,341</u>

During the years ended December 31, 2017, 2016 and 2015, \$0.4 million, \$1.1 million and \$1.1 million, respectively, of share-based compensation expense was capitalized and recorded as "Inventory" in the accompanying consolidated balance sheets.

*Share-Based Compensation Plans*

The Company has two compensation plans pursuant to which awards are currently being made: (i) the 2011 Stock Option and Incentive Plan (the "2011 Plan"); and (ii) the 2008 Stock Option and Incentive Plan (the "2008 Plan"). The Company has two share-based compensation plans pursuant to which outstanding awards have been made, but from which no further awards can or will be made: (i) the 1999 Stock Option Plan (the "1999 Plan"); and (ii) the 2006 Stock Option Plan for Non-Employee Directors (the "2006 Plan"). The 2011 Plan and the 2008 Plan provide for the issuance of non-qualified and incentive stock options, restricted stock, restricted stock units, cash-based awards and performance shares to employees, officers and directors of, and consultants to, the Company in such amounts and with such terms and conditions as may be determined by the compensation committee of the Company's board of directors, subject to provisions of the 2011 Plan and the 2008 Plan.

At December 31, 2017, there were 9.5 million ordinary shares authorized for issuance under the Company's stock plans. The 2011 Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 1.8-to-1 ratio and the 2008 Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 2-to-1 ratio.

*Stock Options*

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

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

The weighted average grant date fair value of stock options granted during the years ended December 31, 2017, 2016 and 2015 was \$25.81, \$17.11 and \$28.88, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2017, 2016 and 2015 was \$40.4 million, \$35.0 million and \$127.7 million, respectively.

At December 31, 2017, there were 5.0 million stock options expected to vest with a weighted average exercise price of \$50.09 per share, a weighted average contractual remaining life of 8.3 years and an aggregate intrinsic value of \$39.0 million. At December 31, 2017, the aggregate intrinsic value of stock options exercisable was \$259.1 million with a weighted average remaining contractual term of 4.7 years. The number of stock options expected to vest was determined by applying the pre-vesting forfeiture rate to the total outstanding options. The intrinsic value of a stock option is the amount by which the market value of the underlying stock exceeds the exercise price of the stock option.

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

At December 31, 2017, there was \$50.6 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of 1.9 years. Cash received from option exercises under the Company's award plans during the years ended December 31, 2017, 2016 and 2015 was \$23.5 million, \$20.3 million and \$45.0 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, 2017	2,074,416	\$ 42.60
Granted	703,630	\$ 54.85
Vested	(730,085)	\$ 43.14
Forfeited	(111,153)	\$ 44.73
Unvested, December 31, 2017	<u>1,936,808</u>	\$ 46.72

The weighted average grant date fair value of time-vested RSUs granted during the years ended December 31, 2017, 2016 and 2015 were \$54.85, \$32.27 and \$71.16, respectively. The total fair value of time-vested RSUs that vested during the years ended December 31, 2017, 2016 and 2015, was \$31.5 million, \$26.0 million and \$21.3 million, respectively.

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

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

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

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

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

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

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

**13. 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, 2017, 2016 and 2015 is as follows:

(In thousands)	Year Ended December 31,		
	2017	2016	2015
<b>MANUFACTURING AND ROYALTY REVENUE:</b>			
Significant collaborative arrangements	\$ 462,568	\$ 431,302	\$ 401,236
All other collaborative arrangements	42,740	55,945	74,052
Total manufacturing and royalty revenue	\$ 505,308	\$ 487,247	\$ 475,288
<b>LICENSE REVENUE:</b>			
Significant collaborative arrangements	\$ 28,000	\$ —	\$ —
Total research and development revenue	\$ 28,000	\$ —	\$ —
<b>RESEARCH AND DEVELOPMENT REVENUE:</b>			
Significant collaborative arrangements	\$ 2,314	\$ 403	\$ 582
All other collaborative arrangements	4,918	1,898	3,437
Total research and development revenue	\$ 7,232	\$ 2,301	\$ 4,019

The Company’s significant collaborative arrangements are described below:

***Janssen***

INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA

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

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

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

Under its agreements with Janssen, the Company recognized royalty revenues from the end-market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA of \$214.9 million, \$184.2 million and \$149.7 million during the years ended December 31, 2017, 2016 and 2015, respectively.

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

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

Under its agreements with Janssen, the Company recognized manufacturing revenues related to RISPERDAL CONSTA of \$64.8 million, \$64.9 million and \$76.5 million during the years ended December 31, 2017, 2016 and 2015, respectively. Under its agreements with Janssen, the Company recognized royalty revenues related to RISPERDAL CONSTA of \$20.1 million, \$22.3 million and \$24.2 million during the years ended December 31, 2017, 2016 and 2015, respectively.

***Acorda***

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

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

Acorda has the right to terminate the amended and restated license agreement upon 90 days' written notice. The Company has the right to terminate the amended and restated license agreement for countries in which Acorda fails to

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

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 on the later of (i) September 26, 2018 or (ii) the expiration of the last to expire of our patents or the existence of a threshold level of competition in the marketplace.

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

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

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

During the years ended December 31, 2017, 2016 and 2015, the Company recognized \$117.0 million, \$114.2 million and \$104.7 million, respectively, of revenues from its arrangements with Acorda.

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

***AstraZeneca***

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

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

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

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

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

During the years ended December 31, 2017, 2016 and 2015, the Company recognized \$45.7 million, \$45.6 million and \$46.1 million, respectively, of revenues from its arrangements with respect to BYDUREON.

***Biogen***

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

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



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

also eligible to receive additional payments upon achievement of milestones with respect to the first two products, other than BIIB098, covered by patents licensed to Biogen under the agreement.

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

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

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

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

#### 14. INCOME TAXES

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

(In thousands)	Year Ended December 31,		
	2017	2016	2015
Current income tax provision:			
U.S. federal	\$ 6,964	\$ 3,163	\$ 29,959
U.S. state	350	480	1,615
Ireland	—	—	77
Rest of world	123	103	94
Deferred income tax provision (benefit):			
U.S. federal	8,188	(9,278)	(18,336)
U.S. state	(933)	(269)	(604)
Ireland	(21)	(142)	(9,647)
Total tax provision (benefit)	\$ 14,671	\$ (5,943)	\$ 3,158

The income tax provision in 2017 and 2015 and the income tax benefit in 2016 was primarily due to U.S. federal and state taxes. The unfavorable change in income taxes in 2017, as compared to 2016, was primarily due to the enactment of the Tax Cuts and Jobs Act (the "Act" or "Tax Reform") and an increase in income earned in the U.S.,

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

partially offset by the recognition of excess tax benefits related to share-based compensation. The favorable change in income taxes in 2016, as compared to 2015, was primarily due to a reduction in income earned in the U.S. A \$4.2 million and \$28.6 million benefit was recorded to additional paid-in capital in the years ended December 31, 2016 and 2015, respectively, with a corresponding reduction to current taxes payable. This was primarily due to the utilization of current year tax benefits and NOL carryforwards derived from the exercise of employee stock options and vesting of restricted stock units.

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

No provision for income tax has been provided on undistributed earnings of the Company's foreign subsidiaries because such earnings may be repatriated to Ireland without incurring any tax liability. Cumulative unremitted earnings of overseas subsidiaries totaled approximately \$160.3 million at December 31, 2017.

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

(In thousands)	Year Ended December 31,		
	2017	2016	2015
Ireland	\$ (172,363)	\$ (212,198)	\$ (289,105)
U.S.	2,414	(18,935)	38,398
Rest of world	26,675	16,746	26,702
Loss before provision (benefit) for income taxes	<u>\$ (143,274)</u>	<u>\$ (214,387)</u>	<u>\$ (224,005)</u>

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

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

In March 2016, the FASB issued guidance as part of its simplification initiative that involves several aspects of the accounting for share-based payment transactions including the requirement that all future excess tax benefits and tax deficiencies be recognized as income tax expense or benefit in the income statement. On January 1, 2017, the Company adopted this standard on a modified retrospective basis, which resulted in a \$57.8 million increase to its deferred tax assets, a \$3.7 million decrease in liabilities and a \$61.5 million favorable cumulative-effect adjustment to accumulated deficit due to the change in the accounting treatment of excess tax benefits.

**ALKERMES PLC AND SUBSIDIARIES**  
**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 <sup>(1)</sup>	Balance at End of Period
Deferred tax asset valuation for the year ended December 31, 2015	\$ (71,796)	\$ (34,950)	\$ (106,746)
Deferred tax asset valuation for the year ended December 31, 2016	\$ (106,746)	\$ (35,113)	\$ (141,859)
Deferred tax asset valuation for the year ended December 31, 2017	\$ (141,859)	\$ (30,938)	\$ (172,797)

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

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

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

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

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

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

**ALKERMES PLC 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:

(In thousands, except percentage amounts)	Year Ended December 31,		
	2017	2016	2015
Statutory tax rate	12.5 %	12.5 %	12.5 %
Income tax provision at statutory rate	\$ (17,909)	\$ (26,798)	\$ (28,001)
Change in valuation allowance	26,771	35,290	37,312
Federal tax law change <sup>(1)</sup>	21,453	—	—
Impairment on equity method investment	1,662	—	—
Uncertain tax positions	830	910	1,213
Foreign rate differential <sup>(2)</sup>	(682)	2,723	13,951
Share-based compensation	(1,205)	2,072	738
U.S. state income taxes, net of U.S. federal benefit	(558)	(2)	557
Intercompany amounts <sup>(3)</sup>	(5,041)	(5,209)	(3,649)
Irish rate differential <sup>(4)</sup>	(2,675)	(5,231)	(7,318)
R&D credit	(9,326)	(10,572)	(12,193)
Other permanent items <sup>(5)</sup>	1,351	874	548
Income tax provision (benefit)	<u>\$ 14,671</u>	<u>\$ (5,943)</u>	<u>\$ 3,158</u>
Effective tax rate	(10.2)%	2.8 %	(1.4)%

- (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, 2014	\$ 2,565
Additions based on tax positions related to prior periods	—
Additions based on tax positions related to the current period	1,213
Balance, December 31, 2015	\$ 3,778
Reductions based on tax positions related to prior periods	(7)
Additions based on tax positions related to the current period	917
Balance, December 31, 2016	\$ 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	<u>\$ 5,518</u>

The unrecognized tax benefits at December 31, 2017, if recognized, would affect the Company's effective tax rate. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. The Company has elected to include interest and penalties related to uncertain tax positions as a component of its provision for taxes. For the years ended December 31, 2017, 2016 and 2015, the Company's accrued interest and penalties related to uncertain tax positions were not material.

The Company's major taxing jurisdictions include Ireland and the U.S. (federal and state). These jurisdictions have varying statutes of limitations. In the U.S., the 2014 through 2017 fiscal years remain subject to examination by the respective tax authorities. In Ireland, the years 2013 to 2017 remain subject to examination by the Irish tax authorities. Additionally, because of the Company's Irish and U.S. loss carryforwards and credit carryforwards, certain tax returns from fiscal years 1999 onward may also be examined. These years generally remain open for three to four years after the loss carryforwards and credit carryforwards have been utilized.

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

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

#### 15. DIVESTITURE

On April 10, 2015, the Company completed the Gainesville Transaction with Recro pursuant to a Purchase and Sale Agreement (the "Purchase Agreement") entered into on March 7, 2015 among the Company and the Purchasers.

In accordance with the terms of the Purchase Agreement, at the closing of the Disposition, the Purchasers made an initial cash payment to the Company of \$50.0 million, a \$4.0 million payment related to the net working capital, and issued the Company a seven-year warrant to purchase an aggregate of 350,000 shares of Recro common stock at a per share exercise price equal to \$19.46, two times the closing price of Recro's common stock on the day prior to closing. The Company is also eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and any other product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of the Company's intellectual property to which Recro was provided a right of use, through license or transfer, pursuant to the Gainesville Transaction (together, the "Meloxicam Products") and up to \$125.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products.

The gain on the Gainesville Transaction was determined as follows:

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

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

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

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

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

- The Company is entitled to receive \$45.0 million upon regulatory approval of an NDA for the first Meloxicam Product. The fair value of the regulatory milestone was estimated based on applying the likelihood of achieving the regulatory milestone and applying a discount rate from the expected time the milestone occurs to the balance sheet date. The Company expects the regulatory milestone event to occur in the second quarter of 2018 and used a discount rate of 3.0%;

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

- 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 given approval and IP protection. The Company then discounted these expected payments using a discount rate of 15.0%, 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 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, 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 ranged from 3.5% to 5.4%.

At December 31, 2017 and 2016, the Company determined that the value of the Gainesville Transaction’s contingent consideration was \$84.8 million and \$63.2 million, respectively. The Company recorded the increase of \$21.6 million and \$7.9 million and a decrease of \$2.3 million in the value of the contingent consideration during the years ended December 31, 2017, 2016 and 2015, respectively, within “Change in the fair value of contingent consideration” in the accompanying consolidated statements of operations and comprehensive loss.

The warrants that the Company received in connection with the Disposition for the purchase of 350,000 shares of Recro’s common stock were determined to have a fair value of \$2.1 million on the closing date of the transaction. At December 31, 2017, the Company determined that the value of these warrants had decreased to \$1.4 million and recorded the warrants within “Other long-term assets” in the accompanying consolidated balance sheets. The company used a Black-Scholes model with the following assumptions to determine the fair value of these warrants at December 31, 2017:

Closing stock price at December 31, 2017	\$ 9.25
Warrant strike price	\$ 19.46
Expected term (years)	4.27
Risk-free rate	2.09 %
Volatility	77.0 %

The increase in the fair value of the warrants of less than \$0.1 million and the decrease in the fair value of the warrants of \$0.4 million and \$0.3 million during the years ended December 31, 2017, 2016 and 2015, respectively, was recorded within “Other income (expense), net” in the accompanying consolidated statements of operations and comprehensive loss.

**16. COMMITMENTS AND CONTINGENCIES**

*Lease Commitments*

The Company leases certain of its offices, research laboratories and manufacturing facilities under operating leases that expire through the year 2029. Certain of the leases contain provisions for extensions of up to ten years. These lease commitments are primarily related to the Company’s corporate headquarters in Ireland and its corporate office and R&D facility in Massachusetts. As of December 31, 2017, 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,	
2018	\$ 9,174
2019	9,092
2020	6,404
2021	2,448
2022	1,195
Thereafter	3,615
	<u>\$ 31,928</u>

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

Rent expense related to operating leases charged to operations was \$9.4 million, \$8.1 million and \$7.2 million for the years ended December 31, 2017, 2016 and 2015, respectively. The amount in 2015 was net of sublease income of \$0.7 million. In addition to its lease commitments, the Company had open purchase orders totaling \$473.9 million at December 31, 2017.

***Litigation***

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. On a quarterly basis, the Company reviews the status of each significant matter and assesses its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, the Company would accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on the Company's best estimates based on available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, the Company may reassess the potential liability related to these matters and may revise these estimates, which could result in material adverse adjustments to the Company's operating results. At December 31, 2017, there are no potential losses from claims, asserted or unasserted, or legal proceedings the Company feels are probable of occurring.

**INVEGA SUSTENNA ANDA Litigation**

In January 2018, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva, who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of United States Patent No. 9,439,906. Requested judicial remedies included recovery of litigation costs and injunctive relief. The Company is not a party to these proceedings.

For information about risks relating to the INVEGA SUSTENNA Paragraph IV litigation, see "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."

**AMPYRA ANDA Litigation**

Ten separate Paragraph IV Certification Notices have been received by the Company and/or its partner Acorda from: Accord Healthcare, Inc. ("Accord"); Actavis Laboratories FL, Inc. ("Actavis"); Alkem Laboratories Ltd. ("Alkem"); Apotex Corporation and Apotex, Inc. (collectively, "Apotex"); Aurobindo Pharma Ltd. ("Aurobindo"); Mylan Pharmaceuticals, Inc. ("Mylan"); Par Pharmaceutical, Inc. ("Par"); Roxane Laboratories, Inc. ("Roxane"); Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. (collectively, "Sun"); and Teva Pharmaceuticals USA, Inc. ("Teva," and collectively with Accord, Actavis, Alkem, Apotex, Aurobindo, Mylan, Par, Roxane and Sun, the "ANDA Filers") advising that each of the ANDA Filers had submitted an abbreviated NDA ("ANDA") to the FDA seeking marketing approval for generic versions of AMPYRA (dalfampridine) Extended-Release Tablets, 10 mg. The ANDA Filers challenged the validity of the Orange Book-listed patents for AMPYRA, and they also asserted that their generic versions do not infringe certain claims of these patents. In response, the Company and/or Acorda filed lawsuits against the ANDA Filers in the U.S. District Court for the District of Delaware (the "Delaware Court") asserting infringement of U.S. Patent No. 5,540,938 (the "'938 Patent"), which the Company owns, and U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which are owned by Acorda. Requested judicial remedies included recovery of litigation costs and injunctive relief. Mylan challenged the jurisdiction of the Delaware Court with respect to the Delaware action. In January 2015, the Delaware Court denied Mylan's motion to dismiss. Subsequently, in January 2015, the Delaware Court granted Mylan's request for an interlocutory appeal of its jurisdictional decision to the Federal Circuit. In March 2016, the Federal Circuit denied Mylan's appeal. Mylan requested the Federal Circuit to reconsider its decision. However, on June 20, 2016, the Federal Circuit denied Mylan's request. Mylan filed an appeal with the U.S. Supreme Court, which was denied.



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

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

The Company and/or Acorda entered into a settlement agreement with each of Accord, Actavis, Alkem, Apotex, Aurobindo, Par and Sun (collectively, the "Settling ANDA Filers") to resolve the patent litigation that the Company and/or Acorda brought against the Settling ANDA Filers in the Delaware Court. As a result of the settlement agreements, the Settling ANDA Filers will be permitted to market generic versions of AMPYRA in the U.S. at a specified date in the future. The parties submitted their respective settlement agreements to the U.S. Federal Trade Commission and the U.S. Department of Justice, as required by federal law. The settlements with the Settling ANDA Filers did not impact the patent litigation that the Company and Acorda brought against the remaining ANDA Filers (the "Non-Settling ANDA Filers"), as described in this Annual Report.

On March 31, 2017, after a bench trial, the Delaware Court issued an opinion (the "Delaware Court Decision"), upholding the validity of the '938 Patent, which pertains to the formulation of AMPYRA and is set to expire in July 2018, and finding that Apotex, Mylan, Roxane and Teva stipulated that their proposed generic forms of AMPYRA infringed the '938 Patent. The Delaware Court also invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. In May 2017, Acorda filed its appeal of the Delaware Court Decision with the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") with respect to the findings on U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. In June 2017, the Non-Settling ANDA Filers filed their cross-appeal of the Delaware Court Decision with the Federal Circuit with respect to the validity of the '938 Patent. The Company and Acorda filed their opening brief on August 7, 2017. The Non-Settling ANDA Filers responded on October 2, 2017. The Company and Acorda filed a response and reply brief on November 13, 2017, and the Non-Settling ANDA Filers filed their reply brief on November 27, 2017. A date for oral argument before the Federal Circuit has not yet been set.

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

**Government Matters**

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

**Securities Litigation**

On November 22, 2017, a purported stockholder of the Company filed a putative class action against the Company and certain of its officers in the United States District Court for the Southern District of New York captioned *Gagnon v. Alkermes plc, et al.*, No. 1:17-cv-09178. The complaint was filed on behalf of a putative class of purchasers of Alkermes securities during the period of February 24, 2015 to November 3, 2017, and alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, based on allegedly false or misleading statements and omissions regarding the Company's marketing practices related to VIVITROL. The lawsuit seeks, among other things, unspecified damages for alleged inflation in the price of securities, and reasonable costs and expenses, including attorneys' fees. For information about risks relating to this action, see "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."

A complete version of this Exhibit has been filed separately with the Securities and Exchange Commission pursuant to an application requesting confidential treatment pursuant to Rule 24b-2 promulgated under the Securities Act of 1934, as amended. Certain confidential portions of this Exhibit were omitted and replaced with double asterisks (\*\*).

*Execution Version*

**LICENSE AND COLLABORATION AGREEMENT**

**BETWEEN**

**ALKERMES PHARMA IRELAND LIMITED**

**AND**

**BIOGEN SWISS MANUFACTURING GMBH**

**NOVEMBER 27, 2017**

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## LICENSE AND COLLABORATION AGREEMENT

This **License And Collaboration Agreement** (the "*Agreement*") is entered into effective as of November 27, 2017 (the "*Effective Date*") by and between **Alkermes Pharma Ireland Limited**, a private limited company incorporated in Ireland (registered number 448848) whose registered address is Connaught House, 1 Burlington Road, Dublin 4, Ireland ("*Alkermes*"), and **Biogen Swiss Manufacturing GmbH**, a Swiss limited liability company with its principal office at Landis & Gyr Strasse 3, CHR-6300 Zug, Switzerland ("*Biogen*").

### Recitals:

**Whereas**, Alkermes is developing the Alkermes 8700 Product for the treatment of MS;

**Whereas**, Biogen has experience and expertise in the development and commercialization of pharmaceutical products;

**Whereas**, Alkermes will continue the development of the Alkermes 8700 Product in the U.S. for the treatment of MS through the Transfer Completion Date pursuant to the terms of this Agreement;

**Whereas**, Alkermes will manufacture and supply to Biogen Clinical Supplies of the Alkermes 8700 Product and potentially other Products pursuant to the terms of a Clinical Supply Agreement;

**Whereas**, on all of the terms and subject to the conditions set forth in this Agreement Biogen desires to appoint Alkermes as the toll manufacturer for Commercial Supplies of the Alkermes 8700 Product in the Territory at a site outside of the United States, and Alkermes is willing to accept such appointment, subject to the terms of a supply agreement to be negotiated by the Parties; and

**Whereas**, Alkermes wishes to grant to Biogen, and Biogen wishes to obtain, an exclusive license to Exploit the Products in the Field in the Territory, all on the terms and subject to the conditions set forth in this Agreement.

**Now, Therefore**, in consideration of the premises and the mutual covenants and agreements set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

### Article 1

#### Definitions

**1.1. Defined Terms.** When used in this Agreement, each of the following terms shall have the meanings set forth in this Article 1:

**1.1.1.** "*Affiliate*" with respect to any Party, means any entity that, directly or indirectly, controls, is controlled by, or is under common control with such Party, but only for so long as such control continues. For these purposes, "*control*" will refer to: (i) the



possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract or otherwise or (ii) the ownership, directly or indirectly, of at least fifty percent (50%) of the equity securities of the entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, at least fifty percent (50%) of the equity securities of the entity entitled to vote in the election of the corresponding managing authority or entitled to direct the management and policies of such entity).

**1.1.2.** “*Alkermes 8700 Product*” means the oral Product in Development by Alkermes as of the Effective Date and containing as its active ingredient the compound having the structure set forth in Exhibit A.

**1.1.3.** “*Alkermes 8700 Product 505(b)(2) NDA*” means the NDA for the Alkermes 8700 Product in the Initial Indication to be submitted by Alkermes to the FDA in the U.S. pursuant to (a) the 505(b)(2) regulatory pathway, as set forth in the Initial Development Plan or (b) the 505(b)(1) regulatory pathway, solely in the event that Biogen grants to Alkermes the right of reference in accordance with Section 3.3.2.

**1.1.4.** “*Alkermes Collaboration Know-How*” means Collaboration Know-How invented solely by Alkermes’ or its Affiliates’ employees, agents or independent contractors in the performance of activities under the Initial Development Plan during the Term.

**1.1.5.** “*Alkermes Collaboration Patents*” means all Collaboration Patents that Cover Alkermes Collaboration Know-How.

**1.1.6.** “*Allocable Overhead*” means [\*\*].

**1.1.7.** “*Applicable Law*” means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any applicable Governmental Authority, including any rules, regulations, guidelines or other requirements of the Regulatory Authorities, that may be in effect from time to time in the Territory.

**1.1.8.** “*Bankruptcy Code*” means Title 11, U.S. Code, or analogous provisions of Applicable Law outside the U.S.

**1.1.9.** “*Biogen Collaboration Know-How*” means Collaboration Know-How invented solely by Biogen’s or its Affiliates’ or Sublicensees’ employees, agents or independent contractors in the performance of activities under the Initial Development Plan during the Term.

**1.1.10.** “*Biogen Collaboration Patents*” means all Collaboration Patents that Cover Biogen Collaboration Know-How.

**1.1.11.** “*Business Day*” means a day on which banking institutions in Cambridge, Massachusetts, Zug, Switzerland and Dublin, Ireland are open for business.

**1.1.12.** “*Calendar Quarter*” means each three (3)-month period of January through March, April through June, July through September and October through December.

**1.1.13.** “*Calendar Year*” means each annual twelve (12)-month period starting on January 1 and ending on December 31.

**1.1.14.** “*Change of Control*” means, with respect to a Party, (i) an acquisition, reorganization, merger or consolidation of such Party with a Third Party in which the holders of the voting securities of such Party outstanding immediately prior thereto cease to beneficially own at least fifty percent (50%) of the combined voting power of the surviving entity, directly or indirectly, immediately after such acquisition, reorganization, merger or consolidation, (ii) a transaction or series of related transactions in which a Third Party, together with its Affiliates (if applicable), becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (iii) the sale or other transfer to a Third Party of all or substantially all of such Party’s assets.

**1.1.15.** “*Clinical Supplies*” means supplies of a Product and Placebo to be used for the conduct of pre-clinical studies, Post-Marketing Commitments or Clinical Trials of a Product in the Field in the Territory pursuant to this Agreement.

**1.1.16.** “*Clinical Supply Agreement*” means a supply agreement between the Parties for the Manufacture by Alkermes of Clinical Supplies.

**1.1.17.** “*Clinical Trials*” means human studies designed to measure the safety or efficacy of a Product.

**1.1.18.** “*Code*” means the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the American Medical Association (AMA) Guidelines on Gifts to Physicians from Industry.

**1.1.19.** “*Collaboration Know-How*” means any Know-How invented during the Term by a Party’s or its Affiliates’, licensees’ or Sublicensees’ employees, agents or independent contractors, either alone or jointly with the other Party’s or its Affiliates’, licensees’ or Sublicensees’ employees, agents or independent contractors, in the performance of activities under the Initial Development Plan during the Term.

**1.1.20.** “*Collaboration Patents*” means any Patent Rights invented by a Party’s or its Affiliates’, licensees’ or Sublicensees’ employees, agents or independent contractors, either alone or jointly with the other Party’s or its Affiliates’, licensees’ or Sublicensees’ employees, agents or independent contractors, in the performance of activities under the Initial Development Plan during the Term that Cover any Collaboration Know-How.

**1.1.21.** “*Collaboration Technology*” means the Collaboration Know-How and the Collaboration Patents.

**1.1.22.** “*Combination Product*” means any single product in finished form containing as active ingredients both (i) a Product and (ii) one or more other pharmaceutically active compounds or substances that are not Products, whether co-formulated or co-packaged

(i.e., within a single box or sales unit); (such pharmaceutically active compounds or substances, the “*Other Components*”).

**1.1.23.** “*Commercial Supplies*” or “*Commercial Supply*” means supplies of a Product for commercial sale or as promotional samples, or for use in Post-Marketing Clinical Trials.

**1.1.24.** “*Commercialization*” means the performance of any and all activities directed to promoting, marketing, importing, exporting, distributing, selling or offering to sell a Product following or in expectation of receipt of Regulatory Approval (but excluding Development and Manufacture). When used as a verb, “*Commercialize*” means to engage in Commercialization.

**1.1.25.** “*Commercially Reasonable Efforts*” [\*\*].

**1.1.26.** “*Complete GI Tolerability Data Package*” means, with respect to Part B of the GI Tolerability Clinical Trial and the Long-Term Safety Clinical Trial, in each case, full demographic and patient-level data for all patients enrolled in each such trial (including, for the Long-Term Safety Clinical Trial, a breakdown of those patients that were previously enrolled in the GI Tolerability Clinical Trial and those patients not previously enrolled in such trial) and a complete set of all data and results available for each such trial, including all data and results that would fall into the categories set forth on Schedule 1.1.26 for each of Part B of the GI Tolerability Clinical Trial and the Long-Term Safety Clinical Trial.

**1.1.27.** “*Confidentiality Agreements*” means (i) the Mutual Confidentiality Agreement dated September 9, 2015 by and between Alkermes and Biogen, Inc., as reinstated, amended and extended on September 15, 2017 and (ii) the Confidentiality Agreement dated April 8, 2013 between Alkermes, Inc. and Biogen, Inc. (formerly known as Biogen Idec Inc.).

**1.1.28.** “*Controlled*” means, with respect to Patent Rights or Know-How, that the applicable Party, in whole or in part, owns or has a license to such Patent Rights or Know-How (but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) and has the ability to grant a license or a sublicense, as applicable, or to otherwise disclose proprietary or trade secret information, to such other Party, without misappropriating the proprietary or trade secret information of a Third Party or violating the terms of any agreement or other arrangement with any Third Party existing and in effect at the time such Party would be required hereunder to grant the other Party such license or sublicense; *provided, however*, that if a Party is acquired pursuant to a Change of Control, the acquired Party will not be deemed to Control any Know-How, Patent Rights or other intellectual property rights owned or controlled prior to such Change of Control by any entities that were not Affiliates of the acquired Party prior to such Change of Control and become Affiliates of the acquired Party in connection with such Change of Control.

**1.1.29.** “*Cover*” means, as to a particular subject matter at issue and a claim of a relevant Patent Right, that, in the absence of a license granted under, or ownership of, such Patent Right, the making, using, selling, offering for sale or importation of such subject

matter would infringe such Patent Right or, as to a pending claim included in such Patent Right, the making, using, selling, offering for sale or importation of such subject matter would infringe such pending claim if such claim were to issue in an issued patent without modification.

**1.1.30.** “*Development*” means the performance of any and all activities relating to preparation, submission, obtaining, supporting or maintaining Regulatory Approval of a Product in the Field in the Territory and to maintaining, supporting or expanding such Regulatory Approval, including pre-clinical studies, pharmacokinetic studies, toxicology studies, formulation, test method development, assay development and stability testing, manufacturing process development, manufacturing technical support, biomarker development, validation and scale-up (including bulk compound production), Manufacturing of Clinical Supplies and activities relating to developing the ability to Manufacture and to continue to Manufacture the Product, quality assurance and quality control for formulations of a Product, design and conduct of Clinical Trials or studies (including all Post-Marketing Commitments), report writing, statistical analysis and regulatory affairs including regulatory legal services. When used as a verb, “*Develop*” means to engage in Development.

**1.1.31.** “*Development Costs*” means all costs incurred (*i.e.*, paid or accrued) by either Party or each such Party’s Affiliates or licensees or Sublicensees (as applicable), in each case, in accordance with GAAP applied on a consistent basis, to the extent attributable to Development of the Alkermes 8700 Product in the Initial Indication for the purpose of obtaining, supporting or maintaining Regulatory Approval of the Alkermes 8700 Product in the U.S. (including the performance of all Post-Marketing Commitments) or fulfilling such Party’s responsibilities under the Initial Development Plan in accordance therewith and with this Agreement. Such costs shall include:

(i) costs of research or Development, including costs of studies on the toxicological, pharmacokinetic, metabolic or clinical aspects of the Alkermes 8700 Product in the Initial Indication conducted internally or by individual investigators or consultants, necessary or desirable for the purpose of obtaining, supporting or maintaining Regulatory Approval of the Alkermes 8700 Product in the Initial Indication in the U.S. and for conducting Post-Marketing Commitments to support or maintain such Regulatory Approval, including the costs of personnel engaged in the foregoing activities at the applicable Development FTE Rate;

(ii) Fully Burdened Manufacturing Costs of Clinical Supplies;

(iii) costs of manufacturing process development, validations, scale-up, quality assurance and quality control for the Alkermes 8700 Product pursued by the Parties under the Initial Development Plan, to the extent not included in the Fully Burdened Manufacturing Costs of Clinical Supplies;

(iv) costs of preparing and reviewing data or information for the purpose of submitting the Alkermes 8700 Product 505(b)(2) NDA to the FDA;

(v) costs of communications and meetings with the FDA, and exchange of information and assistance related thereto, in each case, until the earlier of (a)

Regulatory Approval of the Alkermes 8700 Product 505(b)(2) NDA and completion of all associated Post-Marketing Commitments or (b) the date of an Alkermes Approval Failure; and

(vi) costs incurred in connection with receiving, investigating, recording, reviewing, communicating and exchanging adverse events and other reportable information, in each case, as provided in any safety data exchange agreement entered into between the Parties to the extent relating to the Development of the Alkermes 8700 Product in the Initial Indication in the U.S.

For clarity, any Development Cost incurred by a Party or its Affiliates or licensees or Sublicensees (as applicable) under this Agreement or any Supply Agreement shall be charged only once.

**1.1.32.** “*Development FTE Rate*” means initially an amount equal to [\*\*] U.S. Dollars (US\$[\*\*]) per FTE per year; on January 1, 2019, and annually thereafter, such amount shall be adjusted to reflect any increase, since the prior adjustment (or the initial rate, as applicable), based on the most recent monthly index available as of the adjustment date set forth in the Bureau of Labor Statistics Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI-W), Size Class A, all items less energy, which, for clarity, was 266.558 in June 2017.

**1.1.33.** “*Distributor*” means, with respect to a country, any Third Party that purchases its requirements for Products in such country from Biogen or its Affiliates or Sublicensees and is appointed as a distributor to distribute, market and resell such Product in such country, even if such Third Party is granted ancillary rights to develop, package or obtain Regulatory Approval of such Product in order to distribute, market or sell such Product in such country.

**1.1.34.** “*DMF*” means dimethyl fumarate.

**1.1.35.** “*EMA*” means the European Medicines Agency or any successor agency.

**1.1.36.** “*Exploit*” means to perform Medical Activities, Develop, Manufacture and Commercialize, including to make, have made, use, sell, offer for sale, import and export.

**1.1.37.** “*FDA*” means the U.S. Food and Drug Administration or any successor agency.

**1.1.38.** “*Field*” means the treatment, prevention or diagnosis of any human disease, disorder or condition.

**1.1.39.** “*First Commercial Sale*” means, with respect to a Product in a country in the Territory, the first sale for use or consumption by the general public of such Product by Biogen or an Affiliate or Sublicensee to a Third Party in such country after such Product has been granted Regulatory Approval by the appropriate Regulatory Authority(ies) in such country. Any transfer of a Product as part of an expanded access program, compassionate

sales or use program, an indigent program, as *bona fide* samples, as donations, for the performance of Clinical Trials or for similar *bona fide* business purposes in accordance with Applicable Law shall not constitute a "First Commercial Sale" hereunder.

**1.1.40.** "**First FDA Approval**" means the FDA's approval of an NDA for the Alkermes 8700 Product in the Initial Indication in the U.S.

**1.1.41.** "**FTE**" means the equivalent of one (1) person who is employed by a Party or its Affiliates, or (solely with respect to technical personnel) hired as an independent contractor by a Party or its Affiliates in lieu of such Party's own employees, who is qualified to perform the tasks assigned to such person. For FTEs performing Development activities pursuant to the Initial Development Plan, one (1) FTE shall perform a total of [\*\*] hours of work per Calendar Year. Any FTE who devotes less or more than and [\*\*] hours of work per Calendar Year to such work shall be treated as an FTE on a pro-rata basis calculated by dividing the actual number of hours spent on such work during such Calendar Year by and [\*\*]. Such FTEs shall be charged at an hourly rate hereunder by the Parties.

**1.1.42.** "**Fully Burdened Manufacturing Cost**" means the costs incurred (i.e., paid or accrued) by a Party, its Affiliates or agents in the Manufacture (including shipping or storage costs) of a Product or Placebo, as applicable, which shall be the sum of direct labor, direct material and Allocable Overhead incurred in the Manufacture of such Product or Placebo as determined in accordance with GAAP as consistently applied by such Party or its Affiliates. Notwithstanding the foregoing, Fully Burdened Manufacturing Costs exclude (i) all payments (including upfront fees, milestones and royalties) to any Third Party to obtain rights (whether by acquisition, license or otherwise) to any intellectual property that is necessary or useful to Manufacture Clinical Supplies or Commercial Supplies in any country and (ii) any and all costs and expenses incurred in connection with the acquisition of any such rights.

**1.1.43.** "**Fumaderm**" means Biogen's oral fumaric acid ester pharmaceutical product.

**1.1.44.** "**GAAP**" means U.S. Generally Accepted Accounting Principles.

**1.1.45.** "**GI**" means gastrointestinal.

**1.1.46.** "**GI Event**" means any one or more of nausea, vomiting, diarrhea, abdominal pain, upper abdominal pain or lower abdominal pain, in any case, experienced by a patient in a Clinical Trial.

**1.1.47.** "**GI Inferiority**" will be deemed to exist if (i) the [\*\*] of patients not previously enrolled in the GI Tolerability Clinical Trial or otherwise exposed to a fumarate that discontinue participation in the Long-Term Safety Clinical Trial due to a GI Event is greater than [\*\*] or (ii) the percentage of patients who discontinue participation in the ALKS 8700 arm of Part B of the GI Tolerability Clinical Trial due to a GI Event is greater than the percentage of patients who discontinue participation in the Tecfidera® arm of Part B of the GI Tolerability Clinical Trial due to a GI Event, in all cases as set forth in the Complete GI Tolerability Data Package, *provided that*, if the rate of discontinuations due to a GI Event in Part A of the GI Tolerability Clinical Trial is lower in the Tecfidera® arm of such trial and the Parties jointly

agree in writing not to conduct Part B of the GI Tolerability Clinical Trial, then GI Inferiority will be deemed to exist. If the Parties jointly agree in writing not to conduct Part B of the GI Tolerability Clinical Trial for reasons other than because the rate of discontinuations due to a GI Event in Part A of the GI Tolerability Clinical Trial is lower in the Tecfidera® arm of such trial, then, unless the Parties jointly agree otherwise in writing, GI Inferiority will not be deemed to exist.

**1.1.48.** “*GI Tolerability Clinical Trial*” means the Clinical Trial sponsored by Alkermes, Inc., an Affiliate of Alkermes, with ClinicalTrials.gov identifier NCT03093324.

**1.1.49.** “*Governmental Approvals*” means all applications, notices, petitions, filings, ruling requests, and other documents and obtaining all consents, waivers, licenses, orders, registrations, approvals, permits, rulings, authorizations and clearances necessary or advisable to be obtained from any Governmental Authority in order to consummate the transactions contemplated by this Agreement.

**1.1.50.** “*Governmental Authority*” means any court, tribunal, agency, department, legislative body, commission or other instrumentality of any supra-national, national, state, county, city or other political subdivision in the world.

**1.1.51.** “*HSR Act*” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and the rules and regulations thereunder, each as amended.

**1.1.52.** “*IND*” means an Investigational New Drug Application, as defined in the Federal Food, Drug, and Cosmetic Act, as amended or similar application or submission that is required to be filed with any Regulatory Authority before beginning Clinical Trials of a pharmaceutical product.

**1.1.53.** “*Initial GI Tolerability Data Package*” means (a) with respect to Part A of the GI Tolerability Clinical Trial, full demographic and patient-level data for all patients enrolled therein and those elements set forth on Schedule 1.1.26 and (b) with respect to the Long-Term Safety Clinical Trial, full demographic and patient-level data for all patients enrolled in such trial (including a breakdown of those patients that were previously enrolled in the GI Tolerability Clinical Trial and those patients not previously enrolled in such trial) and a complete set of all data and results available for such trial, including all data and results that would fall into the categories set forth on Schedule 1.1.26, *provided that* the information set forth in clause (b) will only be provided as of the date that the information set forth in the foregoing clause (a) of this definition is available.

**1.1.54.** “*Initial Indication*” means the treatment of MS.

**1.1.55.** “*Know-How*” means all non-public, proprietary data and results, technical information, know-how, inventions, discoveries, trade secrets, processes, procedures, techniques, new developments, compositions, products, compounds, material, methods, formulas, formulation, improvements, protocol, result of experimentation or testing, technology, ideas or other proprietary information and documentation thereof (including related papers, invention disclosures, blueprints, drawings, flowcharts, diagrams, diaries, notebooks, specifications,



methods of Manufacture, methods of service, data processing techniques, compilations of information, customer and supplier lists, pricing and cost information, and business and marketing plans and proposals), design or other know-how, whether or not patentable or copyrightable. Know-How shall not include any Patent Rights with respect thereto.

**1.1.56.** “*Knowledge*” means, with respect to Alkermes, the actual knowledge of [\*\*] based on such individuals’ good faith understanding of the facts and information in their possession or control following reasonable inquiry and investigation of Alkermes personnel and [\*\*], in each case, with relevant functional responsibilities with respect to such facts and information.

**1.1.57.** “*Licensed Know-How*” means (i) any Know-How Controlled by Alkermes or its Affiliates on the Effective Date or during the Term that (a) is or was used in the Development or Manufacture of Products, (b) is or was embodied in Products or (c) is necessary to Exploit the Products in the Field in the Territory, (ii) all Alkermes Collaboration Know-How and (iii) Alkermes’ interest in the Joint Collaboration Know-How.

**1.1.58.** “*Licensed Patents*” means (i) the Patent Rights set forth on Exhibit B, (ii) any Patent Rights Controlled by Alkermes or its Affiliates issuing from or claiming priority directly or indirectly to Patent Rights listed on Exhibit B, (iii) the Alkermes Collaboration Patents, (iv) Alkermes’ interest in the Joint Collaboration Patents and (v) any Patent Rights Controlled by Alkermes or its Affiliates on the Effective Date or during the Term that Cover Licensed Know-How or that are necessary to Exploit any compound or product Covered by any Patent Rights set forth in the foregoing clauses (i) through (iv), in each case, in the Field in the Territory. The Licensed Patents as of the Effective Date are listed on Exhibit B, *provided* that any Patent Right that is not listed on Exhibit B, but is otherwise described in this Section 1.1.58, shall still be considered a Licensed Patent hereunder.

**1.1.59.** “*Long-Term Safety Clinical Trial*” means the Clinical Trial sponsored by Alkermes, Inc., an Affiliate of Alkermes, with ClinicalTrials.gov identifier NCT02634307.

**1.1.60.** “*Manufacturing*” means the performance of any or all activities directed to producing, manufacturing, validating, scaling up, processing, filling, finishing, quality control, quality assurance, testing and release, shipping and warehousing of a Product or Placebo. When used as a verb, “*Manufacture*” means to engage in Manufacturing.

**1.1.61.** “*Medical Activities*” means any and all activities directed to the formulation and performance of (i) Post-Marketing Clinical Trials; (ii) market and key opinion leader plans for the development of the Products, including plans to support continuing medical education; (iii) publication plans for the Products; (iv) plans to ensure appropriate medical information responses with respect to the Products; (v) safety monitoring plans for the Products; (vi) plans and expected activities for field based medical affairs personnel for the Products; and (vii) other comparable medical affairs activities.

**1.1.62.** “*MMF*” means monomethyl fumarate.

**1.1.63.** “*MS*” means multiple sclerosis.

**1.1.64.** “*NDA*” means a New Drug Application filed with the FDA as described in 21 C.F.R. § 314 or any equivalent or corresponding application for Regulatory Approval (including pricing and reimbursement approval required by Applicable Law prior to sale of a pharmaceutical product) in any country or regulatory jurisdiction other than the U.S.

**1.1.65.** “*Net Sales*” means, with respect to any Product, the amount billed in arm’s-length transactions by a Party, an Affiliate of such Party, or any permitted Sublicensee [\*\*].

**1.1.66.** “*OIG Guidance*” means the Office of Inspector General of the Department of Health and Human Services Compliance Program Guidance for Pharmaceutical Manufacturers.

**1.1.67.** “*Party*” means Biogen or Alkermes and, when used in the plural, will mean both Biogen and Alkermes.

**1.1.68.** “*Patent Rights*” means any and all of the following: (i) patent applications (including provisional patent applications) and patents (including the inventor’s certificates); (ii) any substitution, extension (including patent term extensions, patent term adjustments, supplementary protection certificates and pediatric exclusivity periods), registration, confirmation, reissue, continuation, divisional, continuation-in-part, reexamination, renewal, patent of addition or the like thereof or thereto; and (iii) all foreign counterparts of any of the foregoing, including PCT applications.

**1.1.69.** “*Person*” means any individual, firm, corporation, partnership, trust, business trust, joint venture, limited liability company, Governmental Authority, association or other entity.

**1.1.70.** “*Placebo*” means an inactive substitute for a Product.

**1.1.71.** “*Post-Marketing Clinical Trial*” means a clinical trial of a Product in human patients (including investigator-initiated trials) that is conducted for a purpose other than to obtain, support or maintain Regulatory Approval.

**1.1.72.** “*Post-Marketing Commitments*” means any and all items, tasks, activities, studies, trials or other commitments the completion of which is recommended or required by the FDA in connection with the initial grant of Regulatory Approval for the Alkermes 8700 Product in the Initial Indication in the U.S. or to support or maintain such Regulatory Approval.

**1.1.73.** “*Product*” means any product that is Covered by a Valid Claim of a Licensed Patent; *provided, however,* that, if any Product ceases to meet the preceding definition in a country due to the expiration of the last Valid Claim of a Licensed Patent Covering such product in such country, then such product shall continue to constitute a “Product” under this Agreement.

**1.1.74.** “*Regulatory Approval*” means all approvals necessary for the Commercialization of a pharmaceutical product for one or more indications in a country or

regulatory jurisdiction, which may include satisfaction of applicable regulatory and notification requirements and, where required by Applicable Law, separate pricing and reimbursement approvals prior to sale of a pharmaceutical product.

**1.1.75.** “*Regulatory Authority*” means any applicable supranational, national, regional, state or local regulatory agency, department, bureau, commission, council, or other government entity involved in regulating Development and granting Regulatory Approval for a pharmaceutical product in a regulatory jurisdiction within the Territory, including the FDA and the EMA.

**1.1.76.** “*Serious Failure to Supply*” shall mean that in a given Calendar Year, for reasons other than a Force Majeure Delay or a default of Biogen, Alkermes fails on at least [\*\*] occasions to supply Biogen with those quantities of Product forecasted and ordered in accordance with the terms of the applicable Supply Agreement, and the cumulative shortfall for such Calendar Year attributable to such failure(s) is at least [\*\*] of the aggregate amount so forecasted and ordered from Alkermes for delivery in such Calendar Year.

**1.1.77.** “*Sublicense Agreement*” means a written, definitive agreement for a sublicense between Biogen and a Sublicensee.

**1.1.78.** “*Sublicensee*” means any Third Party, other than a Distributor, to whom rights are granted under any of the rights licensed to Biogen by Alkermes under Section 6.1 with respect to any Product, including through any license, sublicense, co-development, co-discovery, co-promotion, distribution, joint venture, Development and Commercialization collaboration or similar transaction between Biogen (or an Affiliate of Biogen) and such Third Party.

**1.1.79.** “*Supply Agreement*” means the Clinical Supply Agreement or any supply agreement entered into between the Parties for the toll manufacture by Alkermes of Commercial Supplies.

**1.1.80.** “*Tecfidera<sup>®</sup>*” means Biogen’s oral DMF pharmaceutical product.

**1.1.81.** “*Tecfidera<sup>®</sup> Competing Product*” means any pharmaceutical product of any Third Party which contains the same active pharmaceutical ingredient as Tecfidera<sup>®</sup>, and is approved in reliance, in whole or in part, on a prior Regulatory Approval of Tecfidera<sup>®</sup>, *provided that* Tecfidera<sup>®</sup> Competing Product shall not include such pharmaceutical product of a Third Party where Biogen licenses or sublicenses rights to such Third Party to commercialize such pharmaceutical product (whether directly or by license, covenant not to sue, settlement agreement, release or any other arrangement or means).

**1.1.82.** “*Tecfidera<sup>®</sup> Competition*” means, with respect to a given Calendar Year in the U.S., that during such Calendar Year, the aggregate net revenue earned by Biogen and its Affiliates and their respective sublicensees and licensees from sales of Tecfidera<sup>®</sup> and the Alkermes 8700 Product, in each case in the U.S. in such Calendar Year, is *less than* [\*\*] of the aggregate net revenue earned by Biogen and its Affiliates and their respective sublicensees and licensees from sales of Tecfidera<sup>®</sup> and the Alkermes 8700 Product, in each case, in the U.S. in

the last full Calendar Year prior to the Calendar Year in which a Tecfidera ® Competing Product is first sold in the U.S.

**1.1.83.** “*Territory*” means all countries of the world.

**1.1.84.** “*Third Party*” means any Person other than the Parties or their respective Affiliates.

**1.1.85.** “*U.S.*” means the United States of America.

**1.1.86.** “*U.S. Dollars*” or “*US\$*” means United States Dollars.

**1.1.87.** “*Valid Claim*” means a claim of an issued and unexpired Patent Right or pending claim of a patent application, which claim or pending claim has not been revoked or held unenforceable, unallowable, unpatentable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, which claim or pending claim is not appealable or has not been appealed within the time allowed for appeal, and which claim or pending claim has not been cancelled, withdrawn from consideration, abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination, *inter partes* review, post-grant review or disclaimer, opposition procedure, nullity suit, or otherwise; *provided, however*, that if the holding of such court or Governmental Authority is later reversed by a court or Governmental Authority with overriding authority, the claim shall be reinstated as a Valid Claim with respect to Net Sales made after the date of such reversal; and *provided, further*, that a claim of a patent application pending for more than [\*\*] years ([\*\*]) years from the earliest date from which such patent application claims priority shall not be considered to be a Valid Claim for purposes of this Agreement unless and until a patent with respect to such application issues with such claim, in which case such claim will be reinstated and be deemed to be a Valid Claim, but only as of the date of issuance of such patent.

**1.2. Additional Definitions.** The following terms have the meanings set forth in the corresponding Sections of this Agreement:

<b>Terms</b>	<b>Section</b>
Agreement	Preamble
Alkermes	Preamble
Alkermes Approval Failure	3.3.1
Alkermes Indemnified Party	11.2
Alkermes Manufacturing Know-How	3.2.3(iv)
ANDA	7.5.2(ii)
Auditing Party	9.7.2
Biogen	Preamble
Biogen Indemnified Party	11.3
Claim	11.2
Complaining Party	12.1.2
Confidential Information	8.1
CPR Rules	12.1.3
Dispute	12.1.1

<b>Terms</b>	<b>Section</b>
Dispute Notice	12.1.2
DT	3.1.1
Effective Date	Preamble
Force Majeure Delay	14.8
GI Tolerability Data Package Notice	3.2.5(i)
Hatch-Waxman Act	7.5.1
Indemnitee	11.4
Infringement	7.5.1
Infringement Claim	7.6.1
Initial Development Plan	3.1.2
IP	13.6.1
Joint Collaboration Know-How	7.1.2(i)
Joint Collaboration Patents	7.1.2(i)
Joint Collaboration Technology	7.1.2(i)
JSC	2.1.1
Losses	11.2
Minimum Annual Payment(s)	9.5.1(ii)
Minimum Annual Payment Term	9.5.1(ii)
Minimum Payment Commencement Date	9.5.1(ii)
Option Payment	9.2
Other Component	1.1.22
Patent Action	6.3
Patent Committee	7.3
Product Trademarks	7.6.1
Prosecution	7.4.1(i)
Protection	7.4.1(ii)
Quality Agreement	3.3.1
Recording Party	9.7.1
Related Party	1.1.65
Response	12.1.2
Royalty Term	9.5.3
Senior Management	12.1.2
ST	5.2
Sued Party	7.6.1
Surviving Sublicensee	13.5.4
Team Leader	3.1.1
Term	13.1
Transfer Completion Date	3.3.1
Transition Plan	3.2.3(iii)
Up-Front Payment	9.1
VAT	9.11.4

**1.3. Interpretation.** Except where the context expressly requires otherwise in this Agreement, (a) the use of any gender herein shall be deemed to encompass references to either or

both genders, and the use of the singular shall be deemed to include the plural (and vice versa); (b) the words “include,” “includes,” and “including” shall be deemed to be followed by the phrase “without limitation” and shall not be interpreted to limit the provision to which it relates; (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”; (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (e) any reference herein to any Person shall be construed to include the Person’s successors and assigns to the extent not prohibited by this Agreement; (f) the words “herein,” “hereof,” and “hereunder,” and words of similar import, shall be construed to refer to this Agreement in its entirety, as the context requires, and not to any particular provision hereof; (g) all references herein to Sections, Articles, Exhibits, or Schedules shall be construed to refer to Sections, Articles, Exhibits, or Schedules of this Agreement, and references to this Agreement include all Schedules and Exhibits hereto; (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent,” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging); (j) references to any specific law, rule or regulation, or article, Section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof; (k) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or”; (l) references to a particular statute or regulation include all rules and regulations thereunder and any predecessor or successor statute, rules or regulations, in each case, as amended or otherwise modified from time to time; and (m) whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified.

## **Article 2**

### **MANAGEMENT OF THE COLLABORATION**

#### **2.1. Joint Steering Committee.**

**2.1.1. Establishment of the JSC.** Within thirty (30) days after the Effective Date, the Parties shall establish the joint steering committee (the “*JSC*”), which will have overall responsibility for the collaboration between the Parties with respect to the Development of the Alkermes 8700 Product in the Initial Indication in the U.S. as contemplated by this Agreement. The JSC will comprise two (2) representatives of each Party, who will be appointed (and may be replaced at any time) by each Party upon notice to the other Party in accordance with this Agreement. Such representatives will include individuals of each Party with decision-making authority with respect to the matters within the authority of the JSC. To conduct the activities described in Section 2.1.2 below, the JSC will meet at least once each Calendar Quarter until disbandment of the JSC pursuant to Section 2.2, or more frequently if agreed by the JSC.

**2.1.2. JSC Responsibilities.** The JSC will perform the following functions:

(i) for the Alkermes 8700 Product in the Initial Indication in the U.S., review and, in its discretion, approve amendments to the Initial Development Plan, including the applicable annual budget or the regulatory strategy, in each case, as set forth therein;

(ii) review reports received from the ST (the supply team established pursuant to Section 5.2) and provide direction to the ST regarding the performance of its responsibilities under the Clinical Supply Agreement;

(iii) serve as the first forum for the settlement of disputes or disagreements between the Parties arising in the DT (the development team established pursuant to Section 3.1.1) or the ST; and

(iv) perform such other functions as appropriate to further the purposes of this Agreement as determined by mutual agreement of the Parties.

**2.1.3. JSC Chairperson; Procedures.** For a one (1)-year period commencing on the Effective Date, a Biogen representative to the JSC will serve as the chairperson of the JSC. For each subsequent one (1)-year period, JSC representatives of the Parties will alternate as the chairperson of the JSC. The chairperson will establish the timing and agenda for all JSC meetings and will send notice of such meetings, including the agenda therefor, to all JSC members; *provided, however*, that either Party may request that specific items be included in the agenda and may request that additional meetings be scheduled as needed. The location of each regularly scheduled JSC meeting will be agreed upon by the Parties. Meetings may also be held telephonically or by videoconference. A quorum of at least one (1) JSC representative appointed by each Party shall be present at or shall otherwise participate in each JSC meeting. If mutually agreed by the Parties on a case-by-case basis, the JSC may invite other non-members to participate in the discussions and meetings of the JSC, *provided* that the presence of such participants shall not be considered in determining whether there is a quorum at the JSC. The chairperson shall appoint one (1) person (who need not be a member of the JSC) to attend each meeting and record the minutes of such meeting in writing. Such minutes shall be circulated to the Parties promptly following each meeting for review, comment and approval. If no comments are received from a Party within thirty (30) days after receipt of the minutes by such Party, then such minutes shall be deemed to be approved by such Party.

**2.1.4. JSC Decision Making.** As a general principle, the JSC will operate by consensus, with the JSC representatives of each Party collectively having one (1) vote, respectively. In the event that the JSC members do not reach consensus with respect to a matter that is within the JSC's decision-making authority within twenty (20) days after they have met and attempted to reach such consensus, such matter may be escalated to resolution by Senior Management by the written request of either Party. If Senior Management is unable to resolve such matter within ten (10) days of such written request, then:

(i) Alkermes shall have the final decision-making authority if such matter relates to (a) the contents of the Alkermes 8700 Product 505(b)(2) NDA or the conduct of any Clinical Trial of the Alkermes 8700 Product in the Initial Indication conducted by or on behalf of Alkermes pursuant to the Initial Development Plan, including the decision to remove Development activities (other than the GI Tolerability Clinical Trial) not required by the FDA for approval of the Alkermes 8700 Product 505(b)(2) NDA; (b) subject to Section 3.2.4(iv), the design and conduct of Part B of the GI Tolerability Clinical Trial (but, not whether to discontinue such trial); (c) the Manufacture of Clinical Supplies of the Alkermes 8700 Product, subject to the terms of the Clinical Supply Agreement; and (d) prior to the Transfer Completion Date, Regulatory Authority interactions, regulatory strategy (*provided that* Alkermes may not deviate from pursuit of obtaining Regulatory Approval of the Alkermes 8700 Product in the Initial Indication via the 505(b)(2) regulatory pathway unless the right of reference is granted to Alkermes in accordance with Section 3.3.2), communications, and activities related to the Alkermes 8700 Product in the Initial Indication and regulatory filings for, and Regulatory Approval of, the Alkermes 8700 Product in the Initial Indication in the U.S.;

(ii) with respect to any amendments to the Initial Development Plan to add one (1) or more Development activities, Alkermes shall have final decision-making authority with respect to the design and execution of such Development activities and Biogen shall have final decision-making authority with respect to any increase in the Initial Development Plan budget associated with such Development activities; and

(iii) Biogen shall have the final decision-making authority with respect to any other matter not set forth in Section 2.1.4(i) and Section 2.1.4(ii).

Notwithstanding anything to the contrary, to the extent any matters are required by Applicable Law or due to safety concerns with respect to a Product to be resolved within a shorter period of time than the periods set forth in this Section 2.1.4, the periods set forth in this Section 2.1.4 will be shortened as appropriate to permit the resolution of such matters within the required period.

**2.2. Alkermes' Participation in the JSC.** The Parties agree that participation in the JSC is a right rather than an obligation of Alkermes, and Alkermes may elect at any time or from time to time not to participate in the JSC or any other committee, subcommittee, team or subteam contemplated hereunder. Accordingly, the Parties also agree that Alkermes' decision not to participate in the JSC or any other committee, subcommittee, team or subteam contemplated hereunder will not constitute a breach of Alkermes' material obligations hereunder. During any period that Alkermes has elected not to participate in the JSC or any other committee, subcommittee, team or subteam contemplated hereunder, each Party shall have the obligation to provide and the right to continue to receive the information it would otherwise be required to provide and entitled to receive under this Agreement and to participate directly with the other Party in discussions, reviews and approvals currently allocated to the JSC or such other committee, subcommittee, team or subteam pursuant to this Agreement.

**2.3. Disbandment of the JSC.** The JSC will automatically disband on the earlier of (a) the mutual written agreement of the Parties and (b) the Transfer Completion Date. Thereafter,



Biogen shall have the sole decision-making authority over all matters that were within the authority of the JSC prior to such disbandment.

### Article 3

#### DEVELOPMENT

##### 3.1. Development Team.

**3.1.1. Establishment of Development Team.** Within thirty (30) days after the Effective Date, the Parties shall establish the development team (the “*DT*”) to coordinate and implement all activities for the Development of the Alkermes 8700 Product in the Initial Indication in the United States, within the annual budgets included in the Initial Development Plan. One (1) representative from each Party shall be designated as that Party’s “*Team Leader*” to act as the primary DT contact for that Party. Unless otherwise agreed by the Parties, the DT shall comprise an equal number of representatives of each Party as is reasonably necessary to accomplish the goals of the DT hereunder. Such representatives will include individuals with expertise and responsibilities in the areas of clinical development, process sciences, quality control, quality assurance, regulatory affairs and product development. Either Party may replace any or all of its DT representatives, including its Team Leader, at any time upon notice to the other Party in accordance with this Agreement.

**3.1.2. Development Team Responsibilities.** The DT will perform the following functions:

(i) for the Alkermes 8700 Product in the Initial Indication in the U.S., formulating amendments to the Initial Development Plan, including, in each case, the applicable annual budget or the regulatory strategy, in each case, set forth therein;

(ii) coordinating implementation of all Development activities for the Alkermes 8700 Product in the Initial Indication in the U.S. pursuant to the Initial Development Plan;

(iii) generating forecasts of supply requirements for the Alkermes 8700 Product and Placebo pursuant to the Initial Development Plan and delivering such forecasts to the ST;

(iv) exchanging information and facilitating cooperation and coordination between the Parties as they exercise their respective rights and meet their respective obligations under the Initial Development Plan;

(v) providing status updates to the JSC regarding Development activities for the Alkermes 8700 Product in the Initial Indication in the U.S. pursuant to the Initial Development Plan, including progress towards achieving key milestone events and Development Cost expenditures; and

(vi) performing such other functions as appropriate to further the purposes of this Agreement as determined by mutual agreement of the Parties.

In addition, the DT may designate subteams as appropriate to facilitate coordination and cooperation in key areas. The development plan for the Alkermes 8700 Product in the Initial Indication in the U.S. and the accompanying budget are attached hereto as Exhibit C (as amended from time to time in accordance with this Agreement, the “**Initial Development Plan**”). This Initial Development Plan shall be deemed to have been reviewed and approved by the JSC. The Initial Development Plan attached hereto as Exhibit C covers Development activities for the Alkermes 8700 Product in the Initial Indication in the U.S. through the filing of the Alkermes 8700 Product 505(b)(2) NDA (including the regulatory strategy for obtaining, supporting or maintaining Regulatory Approval of the Alkermes 8700 Product in the Initial Indication in the U.S.). The Initial Development Plan may be amended upon the written agreement of each Party to include additional Development activities for the Alkermes 8700 Product in the Initial Indication in the U.S. but, notwithstanding anything to the contrary set forth under this Agreement, will not include any Post-Marketing Commitments or Post-Marketing Clinical Trials for the Alkermes 8700 Product. The DT may formulate amendments to the Initial Development Plan at any time and submit such amendments to the JSC for review and approval in accordance with Section 2.1.2(i).

**3.1.3. Development Team Procedures.** For a one (1)-year period beginning on the Effective Date, the Team Leader of Alkermes shall serve as the chairperson of the DT. Thereafter, the Team Leader of Biogen shall serve as the chairperson of the DT. The chairperson shall establish the timing and agenda for all DT meetings and shall send notice of such meetings, including the agenda therefor, to all DT members; *provided, however*, that either Party may request that specific items be included in the agenda and may request that additional meetings be scheduled as needed. The DT will meet at least once each month or as agreed by the DT, until the disbandment of the DT pursuant to Section 3.1.5. The first DT meeting shall be held at Alkermes’ offices. Thereafter, the location of regularly scheduled DT meetings shall alternate between the offices of the Parties, unless otherwise agreed. Meetings may be held telephonically or by videoconference. A quorum of at least two (2) DT members appointed by each Party shall be present at or shall otherwise participate in each DT meeting. If mutually agreed by the Parties on a case-by-case basis, the DT may invite other non-members to participate in the discussions and meetings of the DT, *provided* that the presence of such participants shall not be considered in determining whether there is a quorum at the DT. The chairperson shall appoint one (1) person (who need not be a member of the DT) to attend each meeting and record the minutes of such meeting in writing. Such minutes shall be circulated to the Parties promptly following the meeting for review, comment and approval. If no comments are received from a Party within ten (10) Business Days after receipt of the minutes by such Party, such minutes shall be deemed to be approved by such Party.

**3.1.4. Development Team Decision Making.** As a general principle, the DT will operate by consensus, with the DT representatives of each Party collectively having one (1) vote, respectively. In the event that the DT members do not reach consensus with respect to a matter that is within the purview of the DT within twenty (20) days after they have met and attempted to reach such consensus, such matter shall be presented to the JSC for resolution.

**3.1.5. Disbandment of the DT.** The DT will automatically disband on the earlier of (i) the mutual written agreement of the Parties and (ii) the Transfer Completion

Date. Thereafter, Biogen shall have the sole decision-making authority over all matters that were within the authority of the DT prior to such disbandment.

### **3.2. Development Responsibilities and Rights.**

**3.2.1. Development Responsibilities of Alkermes.** During the Term, Alkermes shall use commercially reasonable efforts to perform all activities allocated to Alkermes in the Initial Development Plan. During the Term, until the earlier of the Transfer Completion Date or an Alkermes Approval Failure, Alkermes shall be responsible for any and all interactions with the FDA in relation to the Initial Development Plan, activities conducted thereunder and the Alkermes 8700 Product 505(b)(2) NDA (other than in connection with any Post-Marketing Commitments, for which Biogen shall be responsible), including any required modifications to such Alkermes 8700 Product 505(b)(2) NDA. In addition, and without limiting the generality of the foregoing, during the Term, until the earlier of the Transfer Completion Date or an Alkermes Approval Failure, Alkermes shall use reasonable efforts to pursue and obtain Regulatory Approval of the Alkermes 8700 Product in the Initial Indication in the U.S. If Alkermes desires to perform any tasks, obligations or support that Alkermes is required to perform or provide hereunder through any of its Affiliates, contractors or agents, then Alkermes may engage such Affiliates, contractors or agents to perform such tasks, obligations or support, but Alkermes shall remain responsible for performance of its obligations hereunder.

#### **3.2.2. Development Rights of Biogen.**

(i) Following the Transfer Completion Date, Biogen shall have the unilateral right, itself or through its Affiliates, Sublicensees, subcontractors or Distributors, to conduct Development of the Alkermes 8700 Product in the Initial Indication in the U.S., and to perform Medical Activities, in each case, in its sole discretion (unless otherwise agreed by the Parties).

(ii) During the Term, Biogen shall have the unilateral right, itself or through its Affiliates, Sublicensees, subcontractors or Distributors, to conduct Development of, and perform Medical Activities with respect to, Products throughout the Territory, other than the Alkermes 8700 Product in the Initial Indication in the U.S. (which is covered in Section 3.2.2(i)), in each case, in its sole discretion.

(iii) Subject to Section 3.3.4, following receipt of Regulatory Approval for the Alkermes 8700 Product 505(b)(2) NDA, Biogen shall use Commercially Reasonable Efforts to conduct any Post-Marketing Commitments for the Alkermes 8700 Product in the Initial Indication in the U.S. required in connection with such Regulatory Approval.

#### **3.2.3. Transfer of Data and Technology.**

(i) **As of the Effective Date.** Promptly following the Effective Date, but in any event no later than sixty (60) days thereafter, Alkermes shall transfer to Biogen, at Biogen's sole cost and expense [\*\*] and thereafter at Alkermes' cost, a true and complete copy of (a) all data and results generated from any Development activities conducted by or on behalf of Alkermes with respect to any Product prior to the Effective Date (as evidenced by all completed pre-clinical study reports and completed clinical study reports for Clinical Trials of

the Alkermes 8700 Product in the Initial Indication) and (b) all Trial Master Files (including any Trial Master File plans, tables of contents or indices and any evidence or certification of related quality checks) or equivalents thereof, for all completed or ongoing Clinical Trials of any Product conducted by or on behalf of Alkermes. If Biogen requests other tangible embodiments of the Licensed Know-How or additional data or results or any other documentation relating to such data or results in respect of Development activities conducted by or on behalf of Alkermes prior to the Effective Date, where the applicable pre-clinical study report or clinical study report for such activities has not yet been completed, then Alkermes shall attempt in good faith to provide such requested embodiments, data or results or other documentation related thereto to Biogen.

(ii) **During the Term.** Thereafter, on a quarterly basis until Alkermes' completion of all of its obligations under the Initial Development Plan in accordance with Section 3.2.1, or more frequently as (a) new data and results with respect to the Products or (b) new or updated Trial Master Files, in each case ((a) and (b)), come into Alkermes' possession or Control, and in any event sufficiently prior to the date of the First FDA Approval such that the transfer of the Alkermes 8700 Product 505(b)(2) NDA pursuant to Section 3.3.1 can occur immediately following the First FDA Approval, Alkermes shall transfer to Biogen, at Biogen's sole cost and expense, a true and complete copy of any such new data and results (including all elements set forth on Schedule 1.1.26) generated from any Development activities conducted by or on behalf of Alkermes with respect to any Product for all ongoing Clinical Trials conducted by or on behalf of Alkermes (including the Long-Term Safety Clinical Trial and the GI Tolerability Clinical Trial), as evidenced by all completed pre-clinical study reports and completed clinical study reports for other Clinical Trials of the Alkermes 8700 Product in the Initial Indication, or new or updated Trial Master Files or new tangible embodiments of the Licensed Know-How. Without limiting the foregoing, Alkermes shall, prior to the Transfer Completion Date, transfer or have transferred to Biogen true and complete copies of (1) all data and results generated from any Development activities conducted by or on behalf of Alkermes with respect to the Products for all completed Clinical Trials conducted by or on behalf of Alkermes (including all pre-clinical studies and Clinical Trials of the Alkermes 8700 Product in the Initial Indication) and (2) all Trial Master Files (including any Trial Master File plans, tables of contents or indices and any evidence or certification of related quality checks) or equivalents thereof, for all completed Clinical Trials of the Alkermes 8700 Product conducted by or on behalf of Alkermes. Any transfer under this Section 3.2.3 shall be in such format as mutually agreed by the Parties, *provided that* upon Biogen's request, Alkermes agrees to transfer such materials in electronic form. If Biogen requests other tangible embodiments of the Licensed Know-How or additional data or results or any other documentation relating to such data or results in respect of Development activities conducted by or on behalf of Alkermes under the Initial Development Plan, where the applicable pre-clinical study report or clinical study report for such activities has not yet been completed, then Alkermes shall attempt in good faith to provide such requested embodiments, data or results or other documentation related thereto to Biogen.

(iii) **Transition Plan.** Following the completion of Alkermes' obligations under the Initial Development Plan in accordance with Section 3.2.1, the Parties shall cooperate with each other to ensure a smooth transition to Biogen or Biogen's designee of ongoing Development activities related to the Alkermes 8700 Product in the Initial Indication,

including taking the actions specified in a transition plan that may be entered into between the Parties after the Effective Date by written agreement of the Parties, as such plan may be updated from time to time upon written agreement of the Parties (the “**Transition Plan**”). If there is any inconsistency between the Transition Plan and this Agreement, the terms of this Agreement shall prevail.

(iv) **Manufacturing Technology Transfer.** Upon Biogen’s written request, Alkermes will promptly make available to Biogen all Licensed Know-How (including all historical process or analytical information (*i.e.*, all experimentally or literature-derived data used to Manufacture any Product)) to enable the Manufacture of all Products by or on behalf of Biogen (the “*Alkermes Manufacturing Know-How*”), by providing copies or samples of relevant documentation, materials and other embodiments of such Licensed Know-How, including data within reports, notebooks and electronic files. Alkermes will perform services reasonably requested by Biogen to facilitate the technology transfer described in this Section 3.2.3(iv) in a professional and workmanlike manner in accordance with Biogen’s reasonable instructions, and Biogen will reimburse Alkermes at the Development FTE Rate for all internal costs incurred in connection with the performance of such services performed and for all external expenses directly related thereto. Any materials provided by Alkermes in connection with the transfer of the Alkermes Manufacturing Know-How will remain the sole property of Alkermes.

#### **3.2.4. Initial GI Tolerability Data Package Transfer.**

(i) **Initial GI Tolerability Data Package.** Within a reasonable time period following the completion of the last visit for the last patient of Part A of the GI Tolerability Clinical Trial (including the two (2) week safety follow-up period for such last patient), Alkermes will provide written notice to Biogen (such notice, a “*GI Tolerability Data Package Notice*”) that includes:

(A) The Initial GI Tolerability Data Package; and

(B) Wire transfer instructions for payment of the Option Payment pursuant to Section 9.2 of this Agreement.

(ii) **Incomplete Initial GI Tolerability Data Package.** Following receipt of the Initial GI Tolerability Data Package Notice as set forth under Section 3.2.4(i), Biogen will have fifteen (15) days to notify Alkermes if the GI Tolerability Data Package included therein is missing any information related to Part A of the GI Tolerability Clinical Trial set forth in clause (a) of the definition of Initial GI Tolerability Data Package, which notice will describe the information that is missing from such Initial GI Tolerability Data Package. Alkermes will provide Biogen with such missing information identified in such notice, to the extent such information is Controlled by Alkermes, as soon as reasonably practicable.

(iii) **Extension of the Initial GI Tolerability Data Package Period.** If Alkermes provides any information to Biogen following the receipt of the GI Tolerability Data Package Notice pursuant to Section 3.2.4(i) and such information is, in Biogen’s reasonable discretion, material information that was not previously provided to Biogen, then upon written notice from Biogen to Alkermes, the [\*\*-]day period within which Biogen would be obligated to

make the Option Payment in accordance with Section 9.2 will be extended such that there is at least [\*\*] days between Biogen's receipt of such information and the date on which Biogen would be obligated to make such Option Payment under Section 9.2.

(iv) **Discussion Regarding Part B.** Following receipt of the GI Tolerability Data Package Notice as set forth under Section 3.2.4(i), (a) the Parties will discuss in good faith whether to conduct Part B of the GI Tolerability Clinical Trial and (b) unless the Parties have agreed not to conduct such Part B of the GI Tolerability Clinical Trial, Alkermes will use commercially reasonable efforts to develop and provide to Biogen no later than thirty (30) days after the delivery of the GI Tolerability Data Package (1) a plan for Part B of such trial that is reasonably designed and powered to sufficiently differentiate between the Alkermes 8700 Product and Tecfidera® with respect to GI Events and (2) a proposed budget for the conduct of activities under such plan for Part B of the GI Tolerability Clinical Trial. Thereafter, at Biogen's request, the Parties will discuss in good faith such plan and associated budget and if Biogen wishes to make any changes to the plan (including to increase the scope or power of such trial) in a manner that increases the associated budget therefor, then the Parties would discuss such proposed changes in good faith and attempt to reach agreement on such expanded scope or power and associated increase in budget. If the Parties mutually agree in writing with respect to the plan for the conduct of Part B of the GI Tolerability Clinical Trial and the associated budget for the Development activities to be conducted under such plan, then (A) the DT will amend the Initial Development Plan to include the conduct of Part B of the GI Tolerability Clinical Trial in accordance with the agreed-to plan and the agreed-to budget associated with such Development activities in accordance with Section 3.1.2 and (B) Alkermes will conduct Part B of the GI Tolerability Clinical Trial materially in accordance with such agreed-to plan, unless otherwise jointly agreed in writing by the Parties.

### **3.2.5. Complete GI Tolerability Data Package Transfer.**

(i) **Complete GI Tolerability Data Package.** Within a reasonable time period following the completion of the last visit for the last patient of Part B of the GI Tolerability Clinical Trial (including any applicable safety follow-up period for such last patient), Alkermes will provide to Biogen the Complete GI Tolerability Data Package.

(ii) **Incomplete Complete GI Tolerability Data Package .** Following receipt of the Complete GI Tolerability Data Package, Biogen will have fifteen (15) days to notify Alkermes if the Complete GI Tolerability Data Package is missing any information, which notice will describe the information that is missing from such Complete GI Tolerability Data Package. Alkermes will provide Biogen with such missing information identified in such notice, to the extent such information is Controlled by Alkermes, as soon as reasonably practicable.

### **3.3. Regulatory Filings.**

**3.3.1. Alkermes 8700 Product in the Initial Indication in the U.S.** Until the Transfer Completion Date, Alkermes shall be responsible for making all regulatory filings with the FDA in respect of the Alkermes 8700 Product in the Initial Indication, including the Alkermes 8700 Product 505(b)(2) NDA. Alkermes shall use commercially reasonable efforts to submit all such regulatory filings in accordance with the Initial Development Plan. All such

filings and Regulatory Approval (if granted) for the Alkermes 8700 Product 505(b)(2) NDA shall initially be held by and in the name of Alkermes until assignment thereof to Biogen pursuant to this Section 3.3.1. Alkermes will (A) send a letter to the FDA to transfer and assign to Biogen Alkermes' entire right, title and interest in and to all regulatory filings related to the Alkermes 8700 Product in the Initial Indication, including the Alkermes 8700 Product 505(b)(2) NDA and (B) transfer to Biogen a complete copy of the approved Alkermes 8700 Product 505(b)(2) NDA and all regulatory filings, regulatory documentation and other supplements and records related to such NDA that are required to be kept under 21 C.F.R. § 314.81, in each case, within one (1) Business Day following:

(i) receipt of Regulatory Approval of the Alkermes 8700 Product 505(b)(2) NDA; or

(ii) Biogen's request, if (a) Alkermes receives a complete response letter from the FDA in connection with the Alkermes 8700 Product 505(b)(2) NDA failing to grant Regulatory Approval for the Alkermes 8700 Product in the Initial Indication in the U.S. that suggests additional Development activities or other requirements, (b) after using reasonable efforts to discuss with the FDA, Alkermes is not able to narrow or eliminate such suggested additional Development activities or such other requirements and (c) even if Alkermes were to perform such additional Development activities or comply with such other requirements (including through the grant from Biogen of the right of reference in accordance with Section 3.3.2), there could be no reasonable expectation that the 8700 Product 505(b)(2) NDA could receive Regulatory Approval by December 31, 2021 (the occurrence of the events set forth in the foregoing clauses ((a) through (c)), an "**Alkermes Approval Failure**";

The date on which Alkermes completes its obligations set forth in clauses (A) and (B) of this Section 3.3.1 shall be deemed the "**Transfer Completion Date**."

**3.3.2. Right of Reference.** If, subsequent to filing the Alkermes 8700 Product 505(b)(2) NDA, (i) Alkermes receives feedback from the FDA, whether through a complete response letter or otherwise, that the FDA requires access to certain additional data to determine whether to grant approval for the Alkermes 8700 Product in the Initial Indication in the U.S. and (ii) the Parties, working in good faith, agree that such information is included in the U.S. Regulatory Approvals for Tecfidera® or related submissions filed with the FDA and should be included in the Alkermes 8700 Product 505(b)(2) NDA, then, until the earliest of the date of (a) approval of the Alkermes 8700 Product 505(b)(2) NDA, (b) an Alkermes Approval Failure or (c) any notice of termination of this Agreement, Biogen will, within two (2) Business Days of the occurrence of the events set forth in the foregoing clauses (i) and (ii), grant to Alkermes a fully paid-up and royalty-free right of reference to such U.S. Regulatory Approvals for Tecfidera® and related submissions filed with the FDA, for the sole purpose of obtaining Regulatory Approval of the Alkermes 8700 Product 505(b)(2) NDA.

Upon such grant of a right of reference, Biogen will take such actions as may be reasonably requested by Alkermes to give effect to the intent and benefit of such right of reference as set forth in this Section 3.3.2.

**3.3.3. Other Products.** Biogen shall have the unilateral right, in its sole discretion and at its own cost and expense, to submit any regulatory filings, including INDs and NDAs for, and seek Regulatory Approval of, any Products in the Field in the Territory, other

than the Alkermes 8700 Product in the Initial Indication in the U.S., prior to the date of the Alkermes Approval Failure.

**3.3.4. Alkermes Approval Failure.** Notwithstanding anything else in this Agreement, in the event of an Alkermes Approval Failure, Biogen shall have no obligation to Exploit (including, for clarity, to seek Regulatory Approval for) the Alkermes 8700 Product. In addition, in the event of such an Alkermes Approval Failure, upon written agreement of the Parties, Alkermes may conduct additional Development of the Alkermes 8700 Product in the Initial Indication in the U.S. at its own cost and expense, including Clinical Trials (and, for clarity, the costs of such Development activities will not be treated as Development Costs for purposes of this Agreement unless otherwise agreed by the Parties).

### **3.4. Regulatory Meetings and Communications.**

**3.4.1. Responsibilities for the Alkermes 8700 Product in the Initial Indication in the U.S.** Until the Transfer Completion Date, Alkermes shall be primarily responsible for conducting meetings and discussions with the FDA related to the Alkermes 8700 Product in the Initial Indication, subject to Section 3.4.3.

**3.4.2. Responsibilities for Other Products.** Biogen shall have the unilateral right, itself or through its Affiliates, Sublicensees, subcontractors or Distributors, to conduct meetings and discussions with Regulatory Authorities in the Territory related to Products in the Field, other than, prior to the Transfer Completion Date, discussions with the FDA related to the Alkermes 8700 Product in the Initial Indication, in its sole discretion.

#### **3.4.3. Regulatory Authority Communications by Alkermes.**

(i) Alkermes shall give Biogen reasonable advance notice of meetings and discussions, including meetings or discussions that take place via teleconference or videoconference, with the FDA related to the Alkermes 8700 Product in the Initial Indication, and Biogen shall have the right to send one (1) representative of its regulatory department with expertise in matters related to interactions with Regulatory Authorities to participate in person at all such meetings and discussions.

(ii) If Alkermes has written communications with the FDA (other than administrative correspondence) relating to the Alkermes 8700 Product in the Initial Indication, then Alkermes shall notify Biogen and, (a) as soon as practicable, but in no case later than forty-eight (48) hours following receipt of any such written communication from the FDA, provide a copy to Biogen of such communication(s) and (b) no later than twenty-four (24) hours in advance of sending any written communication to the FDA in response to such FDA communication, provide an advance copy to Biogen of any such written communication. Alkermes shall provide to Biogen substantive drafts of the NDA for the Alkermes 8700 Product in the Initial Indication prior to its submission, (a) following completion of material modules of such NDA or (b) at the request of Biogen. Alkermes shall consider in good faith any comments received from Biogen's representative related to the draft NDA for the Alkermes 8700 Product in the Initial Indication, communications with the FDA as set forth in this Section 3.4.3(ii) and any Post-Marketing Commitments, in each case, as described in this Section 3.4. In the event that, at



any time prior to the Transfer Completion Date, Biogen receives any written communication from the FDA relating to the Alkermes 8700 Product in the Initial Indication, Biogen shall notify Alkermes and provide a copy to Alkermes of any such written communication promptly following such communication's receipt. Prior to the Transfer Completion Date, Biogen shall not respond to any such communication but shall permit Alkermes to respond on Biogen's behalf; *provided, however*, that Biogen shall have the right to respond to communications from the FDA to the extent reasonably required to comply with Applicable Laws.

(iii) In the event that, at any time during the Term, Alkermes receives any written communication from any Regulatory Authority relating to any Product, other than any such communication from the FDA relating to the Alkermes 8700 Product in the Initial Indication prior to the Transfer Completion Date, Alkermes shall notify Biogen and provide a copy to Biogen of any such written communication promptly following receipt of such communication. Alkermes shall not respond to any such communication and instead shall permit Biogen to respond on Alkermes' behalf; *provided, however*, that during any period in which Alkermes is responsible for Manufacturing any Product, Alkermes shall have the right to respond to communications from the FDA or other Regulatory Authority to the extent solely related to the Manufacture of a Product by or on behalf of Alkermes or its Affiliate or reasonably required to comply with Applicable Laws.

**3.5. Debarment Limitations.** In the course of Development of the Products in the Territory by or on behalf of a Party, each Party shall not knowingly use any employee or consultant who is or has been debarred by the FDA or any other Regulatory Authority, or, to the best of such Party's knowledge, who is or has been the subject of debarment proceedings by the FDA or any such Regulatory Authority. Such Party shall promptly notify the other Party of, and provide the other Party with a copy of, any correspondence or other reports that such Party receives from any Third Party with respect to any use of a debarred employee or consultant in connection with such Party's performance of its obligations under this Agreement.

**3.6. Compliance.** Each Party shall conduct its Development activities under this Agreement in compliance with all Applicable Laws and the terms and conditions set forth in this Agreement.

**3.7. Safety Reporting.** Within sixty (60) days after the Effective Date, the Parties shall enter into a mutually acceptable safety data exchange agreement, setting forth guidelines and procedures for the receipt, investigation, recordation, review, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, technical complaints and any other information concerning the safety of the Products, as well as safety governance and decision-making roles. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, reporting obligations to the FDA or any other Regulatory Authority. Furthermore, such guidelines and procedures shall be consistent with relevant International Council on Harmonization (ICH) guidelines, except where said guidelines may conflict with reporting requirements of local Regulatory Authorities, in which case local reporting requirements shall prevail. The Parties' costs incurred in connection with receiving, investigating, recording, reviewing, communicating and exchanging adverse events and other reportable information as provided in such safety data exchange agreement shall be included as an element of Development Costs (to the extent relating to the Development of a Product).

### 3.8. Development Costs.

**3.8.1. Development Costs Incurred by Alkermes.** Biogen shall be responsible for fifty percent (50%) of all Development Costs in excess of the first Fifty-Six Million U.S. Dollars (US\$56,000,000) incurred by Alkermes in the conduct of the activities under the Initial Development Plan during Calendar Year 2017. Starting with Calendar Year 2018 and thereafter until the completion of the activities allocated to Alkermes under the Initial Development Plan, Biogen shall be responsible for all Development Costs incurred by Alkermes in the conduct of its activities in the Initial Development Plan, to the extent such Development Costs do not exceed [\*\*] percent ([\*\*]%) of the aggregate costs and expenses set forth in the annual budget for the Initial Development Plan for each such Calendar Year. Subject to the last sentence of Section 3.9, (a) to the extent Alkermes incurs any Development Costs that exceed [\*\*] percent ([\*\*]%) of the aggregate costs and expenses set forth in the annual budget for the Initial Development Plan for such Calendar Year, each Party shall be responsible for [\*\*] percent ([\*\*]%) of such excess amounts, up to an amount equal to [\*\*] percent ([\*\*]%) of the aggregate costs and expenses set forth in the annual budget for the Initial Development Plan for such Calendar Year and (b) to the extent Alkermes incurs any Development Costs that exceed [\*\*] percent ([\*\*]%) of the aggregate costs and expenses set forth in the annual budget for the Initial Development Plan for such Calendar Year, Alkermes shall be responsible for such excess amounts; *provided that*, if the Alkermes 8700 Product 505(b)(2) NDA receives Regulatory Approval from the FDA prior to December 31, 2021, then Biogen will reimburse Alkermes for [\*\*] percent ([\*\*]%) of all such Development Costs in excess of [\*\*] percent ([\*\*]%) of the aggregate costs and expenses set forth in the annual budget for the Initial Development Plan for such Calendar Year to the extent that such Development Costs are incurred in the performance of activities that generate data and results that are submitted as part of such approved Alkermes 8700 Product 505(b)(2) NDA.

**3.8.2. Development Costs Incurred by Biogen.** Biogen shall be solely responsible for all Development Costs incurred by Biogen.

**3.8.3. Development Costs Payments.** Biogen will, within forty-five (45) days after the end of Calendar Year 2017, pay Alkermes the Development Costs due under Section 3.8.1 for such Calendar Year. Starting with Calendar Year 2018 and thereafter, for each Calendar Quarter for which Development Costs are payable by Biogen to Alkermes pursuant to Section 3.8.1, Biogen will, within forty-five (45) days after the receipt of an invoice from Alkermes for such Development Costs, pay Alkermes the amount due for such Calendar Quarter.

**3.9. Initial Development Plan Budget.** Responsibility for amendments to the Initial Development Plan budget shall rest with the DT, subject to review and approval by the JSC. Updates to such budget will be prepared on an annual basis as set forth in Section 3.1.2. In addition, if Alkermes identifies a potential overage of greater than [\*\*] percent ([\*\*]%) of the aggregate costs and expenses expected to be incurred in performing Development activities pursuant to the Initial Development Plan for a given Calendar Year, then Alkermes shall notify Biogen of such potential overage (through the DT). Following such notice, the DT shall discuss in good faith at its next meeting whether to make any amendment to the Initial Development Plan budget to account for such potential overage, which amendment, if applicable, shall be presented to the JSC for its review and approval. Notwithstanding anything to the contrary set

forth in this Agreement, Biogen shall not be responsible for bearing its share of any Development Costs that exceed [\*\*] percent ([\*\*]%) of the amounts set forth in the annual budget under the Initial Development Plan in accordance with Section 3.8.1 to the extent that such excess Development Costs are incurred as a result of (i) Alkermes' failure to perform its Development obligations in accordance with the Initial Development Plan or this Agreement, or (ii) a delay in Development of the Alkermes 8700 Product due to the gross negligence or willful misconduct of Alkermes.

#### Article 4

### COMMERCIALIZATION

**4.1. Commercialization Rights.** During the Term, Biogen shall have the unilateral right, itself or through its Affiliates, Sublicensees, subcontractors or Distributors, to Commercialize the Products in the Field in the Territory in its sole discretion.

**4.2. Commercialization Efforts.** Subject to Section 3.3.4, following (i) receipt of Regulatory Approval for the Alkermes 8700 Product in the Initial Indication in the U.S., (ii) the Transfer Completion Date and (iii) the completion of any Post-Marketing Commitments that the FDA requires be completed prior to the commencement of Commercialization activities, Biogen shall use Commercially Reasonable Efforts to Commercialize the Alkermes 8700 Product in the Initial Indication in the U.S.

**4.3. Commercialization Costs.** Biogen shall be responsible for all costs of conducting Commercialization of Products.

**4.4. Compliance.** Biogen shall Commercialize the Products in the Field in the Territory in compliance with all Applicable Laws, the Code, the OIG Guidance and the terms and conditions set forth in this Agreement.

#### Article 5

### MANUFACTURE AND SUPPLY

#### 5.1. Supply and Quality Agreements.

**5.1.1. Clinical Supplies.** Within ninety (90) days after the Effective Date, the Parties will negotiate in good faith and execute a Clinical Supply Agreement pursuant to which Alkermes will Manufacture or have Manufactured, and Biogen and its Affiliates and Sublicensees will purchase exclusively from Alkermes, Clinical Supplies (*provided that* Biogen may qualify to Manufacture, or engage and qualify a Third Party to Manufacture, Clinical Supplies as a back-up manufacturer in the event of a Force Majeure Delay or a Serious Failure to Supply). The Clinical Supply Agreement will reflect the terms and conditions included in Exhibit D and such other commercially reasonable and customary terms and conditions, satisfactory in form and substance to the Parties and their legal advisors, as are necessary or appropriate for transactions of this type and that will allow Biogen to be supplied with Product in a manner appropriate to meet its obligations and exercise its rights under this Agreement, subject to both Parties' compliance with the terms and conditions of such Clinical Supply Agreement.

Notwithstanding anything to the contrary set forth in this Agreement or the Clinical Supply Agreement, the Fully Burdened Manufacturing Costs of Clinical Supplies will be included in the Development Costs under this Agreement and will not be charged to Biogen under the Clinical Supply Agreement. Within one hundred and twenty (120) days after the Effective Date, the Parties will negotiate in good faith and execute a technical and quality agreement, which will be appended to the Clinical Supply Agreement and which will specify certain quality assurance and quality control requirements relating to the Manufacture of such Clinical Supplies. Notwithstanding anything to the contrary set forth in this Section 5.1.1, if (i) Alkermes foregoes its exclusive right to Manufacture or have Manufactured Clinical Supplies or (ii) there is a Serious Failure to Supply, then, in any case ((i) – (ii)), (a) Biogen and its Affiliates and Sublicensees shall have no further obligation to purchase Clinical Supplies from Alkermes, (b) Biogen shall have the exclusive right to Manufacture or to have Manufactured Clinical Supplies and (c) Alkermes shall promptly conduct a transfer of Manufacturing technology to Biogen or its designee to enable Biogen or such designee to Manufacture Clinical Supplies. In addition, in the event of a Force Majeure Delay (and for the duration thereof), until such time as Alkermes is able to resume sufficient Manufacturing to meet Biogen's demand for Clinical Supplies, Biogen may Manufacture itself or have Manufactured by its back-up manufacturer, all Clinical Supplies for which Alkermes is unable to meet Biogen's demand.

**5.1.2. Commercial Supplies.** Pursuant to this Agreement, Biogen has the right to Manufacture or have Manufactured Commercial Supplies. Biogen has considered in good faith, and hereby appoints, Alkermes as the toll manufacturer for such Commercial Supplies for Commercialization in the Territory at a site outside of the United States, and Biogen and its Affiliates and Sublicensees will purchase Commercial Supplies exclusively from Alkermes (*provided that* Biogen may qualify to Manufacture, or engage and qualify a Third Party to Manufacture, Commercial Supplies as a back-up manufacturer so long as such Third Party Manufacturer does not Manufacture more than [\*\*] percent ([\*\*]%) of Commercial Supplies in the aggregate in any Calendar Year, except in the event of a Force Majeure Delay or a Serious Failure to Supply). This appointment is subject to the Parties negotiating in good faith and entering into a commercial supply agreement pursuant to which Biogen would engage Alkermes on a toll manufacturing basis to Manufacture Commercial Supplies and Biogen would purchase such Commercial Supplies in accordance with the terms and conditions included in Exhibit E and such other commercially reasonable and customary terms and conditions, satisfactory in form and substance to the Parties and their legal advisors, as are necessary or appropriate for transactions of this type and that will allow Biogen to be supplied with Product in a manner appropriate to meet its obligations and exercise its rights under this Agreement, subject to both Parties' compliance with the terms and conditions of such commercial supply agreement. In connection with such commercial supply agreement, the Parties will also negotiate in good faith and execute a technical and quality agreement, which will be appended to the commercial supply agreement and which will specify certain quality assurance and quality control requirements relating to the Manufacture of such Commercial Supplies. If, following the use of good faith efforts, the Parties are unable to reach agreement on the terms of a commercial supply agreement within a period of six (6) months from the commencement of negotiations, then Biogen shall have the right (in its sole discretion) to Manufacture or have Manufactured Commercial Supplies. Notwithstanding anything to the contrary set forth in this Section 5.1.2, if (i) Alkermes foregoes its exclusive right to Manufacture or have Manufactured Commercial Supplies, (ii) Alkermes undergoes a Change of Control in which the acquirer is a competitor of

Biogen set forth on Schedule 5.1 or a Third Party toll manufacturer that Manufactures a competing fumarate product or (iii) there is a Serious Failure to Supply, then, in any case ((i) – (iii)), (a) Biogen and its Affiliates and Sublicensees shall have no further obligation to exclusively purchase Commercial Supplies from Alkermes, (b) Biogen shall have the exclusive right to Manufacture or to have Manufactured Commercial Supplies and (c) Alkermes shall promptly conduct a transfer of Manufacturing technology to Biogen or its designee to enable Biogen or such designee to Manufacture Commercial Supplies. In addition, in the event of a Force Majeure Delay (and for the duration thereof), until such time as Alkermes is able to resume sufficient Manufacturing to meet Biogen’s demand for Commercial Supplies, Biogen may Manufacture itself or have Manufactured by its back-up manufacturer, all Commercial Supplies for which Alkermes is unable to meet Biogen’s demand.

**5.2. Supply Team.** The Parties will establish a supply team (the “*ST*”) pursuant to the provisions of the Clinical Supply Agreement. The *ST* will report to the JSC.

## Article 6

### LICENSE GRANTS

#### 6.1. Patent and Know-How License Grant.

**6.1.1. Grant to Biogen.** Subject to the terms and conditions of this Agreement, Alkermes hereby grants to Biogen an exclusive (even as to Alkermes and its Affiliates, except as expressly set forth in Section 6.1.4), royalty-bearing, worldwide license, with the right to sublicense through multiple tiers pursuant to Section 6.1.2, under the Licensed Patents and the Licensed Know-How to Exploit the Products in the Field in the Territory.

**6.1.2. Sublicenses.** Biogen will have the right to grant sublicenses through multiple tiers to Affiliates and Third Parties of the rights granted to Biogen under this Agreement in accordance with the terms and conditions of this Section 6.1.2. The grant of any such sublicense will not relieve Biogen of its obligations under this Agreement (including its financial obligations). In addition, such sublicense will be consistent in all respects with all applicable terms and conditions of this Agreement. With respect to any sublicense with a Sublicensee other than an Affiliate, Biogen shall provide Alkermes with a copy of such sublicense, and any modification or termination thereof, promptly after execution of such sublicense, modification or termination (and in any event within thirty (30) days after such sublicense has been fully executed or modified or termination of such sublicense has occurred); *provided* that any such copy may be redacted to remove any confidential, proprietary or competitive information of Biogen or its Sublicensee, and any other information not necessary for Alkermes to assess Biogen’s compliance with the terms of this Section 6.1.2.

**6.1.3. No Implied Licenses; Negative Covenant.** Except as expressly granted herein, neither Party grants to the other Party any right or license under any intellectual property rights Controlled by such first Party.

**6.1.4. Alkermes Reservation of Rights.** The license granted in Section 6.1.1 is subject to a reserved non-exclusive, non-transferable, and, except as necessary or

useful for Alkermes to Manufacture Clinical Supplies and Commercial Supplies in accordance with this Agreement and the applicable Supply Agreements, non-sublicenseable right of Alkermes under the Licensed Patents and Licensed Know-How solely to exercise its rights and perform its obligations under this Agreement and any Supply Agreement.

**6.2. Patent Update.** At least once annually, Alkermes will provide to Biogen an update to the list of Licensed Patents set forth on Exhibit B, and Exhibit B shall automatically be modified to include such updates. Notwithstanding the foregoing, and for the avoidance of doubt, any Patent Right that satisfies the definition of a “Licensed Patent” under Section 1.1.58 shall automatically constitute a Licensed Patent under this Agreement, notwithstanding any failure or delay in including such Patent Right on the list of Licensed Patents set forth on Exhibit B.

**6.3. Termination of License to Contested Patent Rights.** If Biogen or any of its Affiliates or Sublicensees initiates or provides financial support (other than equity funding) or information to a Third Party for purposes of initiating any action or proceeding in any forum of competent jurisdiction in the Territory (including a court, a patent office or an arbitral tribunal, and whether in the form of petitions for declaratory relief, claims, counterclaims, defenses, interferences, petitions for reexamination, *inter partes* review, post-grant review, or otherwise, but excluding any action that may be necessary or reasonably required in response to a subpoena or court or administrative law request or order) that any Patent Right (or any claim thereof) within the Licensed Patents is unpatentable, invalid, unenforceable, or not infringed (any such action or proceeding, a “*Patent Action*”) and a final, non-appealable order is made in any such forum that such Patent Right or claim thereof is patentable, valid, enforceable or infringed, as applicable, then Alkermes, as the licensor of the Licensed Patents under this Agreement, may at its discretion, (a) invoice Biogen for all expenses incurred by Alkermes in such Patent Action, including reasonable attorneys’ fees, experts’ fees and other costs of investigation or defense, court costs and other litigation expenses, and Biogen shall pay all undisputed amounts set forth in such invoice within sixty (60) days after receipt of such invoice, (b) terminate its license to Biogen pursuant to this Article 6 to such Patent Right, whereupon such Patent Right will no longer be deemed to be within the Licensed Patents or (c) take both actions outlined in clauses (a) and (b) of this sentence. Notwithstanding the foregoing, (1) if any Affiliate of Biogen that becomes an Affiliate of Biogen through a Change of Control of Biogen is engaged in a Patent Action at the time of such Change of Control, the provisions of this Section 6.3 shall not be deemed to apply as a result of such Patent Action by such Affiliate of Biogen, (2) Biogen shall have the right to defend itself against any action or proceeding in any forum of competent jurisdiction in the Territory brought by Alkermes or any of its Affiliates or Sublicensees alleging infringement of any Patent Right and (3) in the case of a Patent Action by a Sublicensee, Alkermes shall not have the right to take the actions described in the preceding sentence unless Biogen fails to either terminate the applicable sublicense or cause the Sublicensee to cease pursuing such Patent Action within sixty (60) days of the date that Biogen becomes aware of such Patent Action.

**6.4. Non-Suit.** During the Term until the Transfer Completion Date, Biogen, on behalf of itself and of any Affiliates, Sublicensees, successors and assigns, agrees on a worldwide basis not to file or maintain any lawsuit, cause of action or other legal action against Alkermes or its Affiliates under any Patent Rights Controlled by Biogen that Cover the Alkermes 8700 Product solely for purposes of Exploiting the Alkermes 8700 Product in accordance with

this Agreement. Biogen shall cause all of its Affiliates, Sublicensees, successors and assigns to be bound by the obligations of this Section 6.4.

**6.5. Non-Interference.** During the Term until the Transfer Completion Date, Biogen and its Affiliates, Sublicensees, successors and assigns shall not, and shall not cause or provide support to any Third Party to, initiate or otherwise undertake any of the following actions against the Alkermes 8700 Product: interfering with efforts to obtain and maintain Regulatory Approval of the Alkermes 8700 Product in the U.S., or advocating for non-approval or limited Regulatory Approval of the Alkermes 8700 Product in the U.S., including the filing of a lawsuit against the FDA or the filing or submission of any Citizen Petitions, correspondence or other written submissions with the FDA. Biogen shall cause all of its Affiliates, Sublicensees, successors and assigns to be bound by these obligations.

**6.6. Exclusivity.** During the Term, neither Party nor any of such Party's Affiliates, or Sublicensees (who are granted research and Development rights under this Agreement), shall (i) directly or indirectly research, develop or commercialize any pro-drug or salt of MMF or DMF or (ii) acquire any right, title or interest from a Third Party in any pro-drug or salt of MMF or DMF, except, in each case (i) or (ii), with respect to the conduct of such activities by Biogen or its Affiliates with respect to Tecfidera® and Fumaderm® (in each case, using the same active pharmaceutical ingredient(s) included in Tecfidera® or Fumaderm®, as applicable, as of the Effective Date, in any form, formulation, combination, administration, dosage or delivery mechanism (but not including any pro-drug or salt of DMF or MMF (other than DMF))) or any Product. Notwithstanding anything to the contrary in this Agreement, upon a finding of GI Inferiority of the Alkermes 8700 Product, (a) if Biogen has Commercialized the Alkermes 8700 Product, then the exclusivity obligations of Alkermes and its Affiliates set forth in this Section 6.6 shall remain in effect, and the exclusivity obligations of Biogen and its Affiliates and Sublicensees (who are granted research and Development rights under this Agreement) set forth in this Section 6.6 shall automatically terminate or (b) if Biogen has not Commercialized the Alkermes 8700 Product in the U.S. within six (6) months after the receipt of Regulatory Approval for the Alkermes 8700 Product in the Initial Indication in the U.S. and the completion of any Post-Marketing Commitments that the FDA requires be completed prior to the commencement of Commercialization activities, then the exclusivity obligations of Alkermes and Biogen and their respective Affiliates, and with respect to Biogen, Sublicensees (who are granted research and Development rights under this Agreement), set forth in this Section 6.6 shall automatically terminate. In the event that a Party or its Affiliate, or Sublicensee (who is granted research and development rights under this Agreement), obtains, whether through acquisition, merger or other similar transaction, control of any entity that is engaging in any activities that would cause such Party to breach this Section 6.6, then such Party shall not be deemed in breach of this Section 6.6 if (1) such Party or its Affiliate or, with respect to Biogen, Sublicensee, or the applicable entity divests such rights (through sale, exclusive license or other transfer) within six (6) months from the date such rights are obtained and (2) all activities by such Party or its Affiliate or Sublicensee with respect to the applicable competitive compound or product during such six (6)-month period are conducted independently of the activities conducted by such Party or its Affiliates or Sublicensees pursuant to this Agreement with customary firewall separations, and no intellectual property of such Party or its Affiliates or the other Party or its Affiliates relating to any Product is used in the conduct of such activities. Notwithstanding anything to the contrary in this Section 6.6, if a Party or its Affiliate or

Sublicensee undergoes a Change of Control (in the case of a Sublicensee, applying that term as if such Sublicensee were a Party) in which the acquirer or its Affiliate (in each case, that was not an Affiliate of such Party prior to such Change of Control) is engaging in any activities that would cause such Party to breach this Section 6.6, such Party shall not be deemed to be in breach of this Section 6.6 as a result of such Change of Control, *provided* that, during the period in which such Party is subject to exclusivity obligations under this Section 6.6, all activities by such Party or its Affiliate or Sublicensee with respect to the applicable competitive compound or product are conducted independently of the activities conducted pursuant to this Agreement with customary firewall separations, and no intellectual property of such Party or its Affiliates or the other Party or its Affiliates relating to any Product is used in the conduct of such activities.

## Article 7

### INTELLECTUAL PROPERTY RIGHTS

#### 7.1. Ownership of Intellectual Property.

**7.1.1. Product Trademarks.** Biogen may, in its sole discretion, select any trademarks, trade dress, designs, logos or slogans to be used in connection with the Exploitation of the Products in the Field in the Territory (collectively, the “*Product Trademarks*”) and will own all such Product Trademarks. Neither Alkermes nor its Affiliates shall use or seek to register, anywhere in the world, any trademarks that are confusingly similar to any Product Trademark.

#### 7.1.2. Collaboration Technology.

(i) **Ownership.** Alkermes shall own all rights, title and interests in and to any and all Alkermes Collaboration Know-How and Alkermes Collaboration Patents. Biogen shall own all rights, title and interests in and to any and all Biogen Collaboration Know-How and Biogen Collaboration Patents. The Parties shall jointly own any and all Collaboration Know-How invented jointly by a Party’s or its Affiliates’ employees, agents or independent contractors, on the one hand, and the other Party’s or its Affiliates’ employees, agents or independent contractors, on the other hand, in the performance of activities under the Initial Development Plan during the Term (“*Joint Collaboration Know-How*”), and any and all Collaboration Patents Covering such Collaboration Know-How (“*Joint Collaboration Patents*”) and, collectively with the Joint Collaboration Know-How, the “*Joint Collaboration Technology*”). Subject to Section 6.6 and the licenses granted under this Agreement, each Party shall be free to exploit, either itself or through the grant of licenses to Third Parties (which Third Party licenses may be further sublicensable), its rights in and to the Joint Collaboration Technology, throughout the world without restriction, without the need to obtain further consent from the other Party, and without any duty to account or payment of any compensation to the other Party; *provided, however*, that if either Party disclaims in writing its ownership interest in any Joint Collaboration Technology, then such Joint Collaboration Technology shall become solely owned by the other Party and such disclaiming Party will and hereby does assign to the other Party its rights, title and interests in and to such disclaimed Collaboration Technology. Inventorship of any Collaboration Technology shall be determined in accordance with United States patent laws.



(ii) **Assignment of Inventions.** To the extent either Party or any of its Affiliates obtains any rights, title or interests in or to any Collaboration Technology of the other Party, such first Party, on behalf of itself and its Affiliates, hereby assigns to the other Party all such rights, title and interests to the extent necessary to effectuate the allocation of ownership set forth in Section 7.1.2(i). Each employee, agent or independent contractor (including all subcontractors) of a Party or its respective Affiliates performing work under this Agreement shall, prior to commencing such work, be bound by invention assignment obligations, including: (a) promptly reporting any invention, discovery, process or other intellectual property right; (b) presently assigning to the applicable Party or Affiliate all of his or her right, title and interest in and to any invention, discovery, process or other intellectual property; (c) cooperating in the preparation, filing, prosecution, maintenance and enforcement of any patent or patent application; and (d) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement. It is understood and agreed that such invention assignment agreement need not reference or be specific to this Agreement.

**7.2. Disclosure of Inventions.** During the Term, each Party will promptly (but no later than sixty (60) days following such Party's receipt of an invention disclosure) provide to the other Party any invention disclosure submitted to such Party that discloses any Collaboration Technology.

**7.3. Patent Committee.** Each Party will appoint one (1) representative with patent and intellectual property expertise no later than forty-five (45) days after the Effective Date. Such representatives (the "**Patent Committee**") will meet (in person, by telephone or videoconference) upon request by either Party during the Term to coordinate, discuss, and review strategies with respect to Prosecuting and enforcing the Licensed Patents and the Joint Collaboration Patents.

**7.4. Patent Filings.**

**7.4.1. Prosecution.**

(i) **By Alkermes.** Alkermes will have the first right, at its own cost and expense and using patent counsel of its choosing, to prepare, file, prosecute and maintain the Licensed Patents and the Joint Collaboration Patents, including any appeal proceeding made at the applicable patent office following such patent office's failure to issue any such patent (collectively, "**Prosecution**" and when used as a verb, "**Prosecute**" means to engage in Prosecution). Alkermes will provide Biogen with copies of all material documents and correspondence relating to the Prosecution of the Licensed Patents and the Joint Collaboration Patents (a) promptly after receipt, with respect to communications from applicable patent authorities and (b) a reasonable time in advance of filing, for documents to be filed by Alkermes, in each case (a) and (b), to allow Biogen time to review such materials and comment thereon. Alkermes will reasonably consider Biogen's reasonable comments on the documents filed, but Alkermes will not be obligated to implement such comments. Biogen will provide Alkermes all reasonable assistance in the Prosecution of such Licensed Patents and Joint Collaboration Patents, including by making its employees, agents and consultants reasonably available to Alkermes (or

Alkermes' authorized attorneys, agents or representatives), to the extent reasonably necessary to enable Alkermes to undertake Prosecution as contemplated by this Agreement.

(ii) **By Biogen.** If Alkermes elects to halt Prosecution of any patents or patent applications within the Licensed Patents or the Joint Collaboration Patents in any country in the Territory, then Alkermes will notify Biogen in a timely manner to permit the preservation of any rights in such country with respect to such Licensed Patents or Joint Collaboration Patents. Following written notification from Biogen to Alkermes that Biogen wishes to assume Prosecution of such Licensed Patents or Joint Collaboration Patents in such country, Alkermes will permit Biogen to so assume Prosecution of such Licensed Patents or Joint Collaboration Patents (as applicable), at its own cost and expense and using patent counsel of its choosing. In addition, and notwithstanding anything to the contrary set forth in this Agreement, Biogen will have the first right, at its sole cost and expense and using patent counsel of its choosing, to direct and control any patent interferences, reexaminations, *inter partes* reviews, reissuances, revocations, oppositions and appeals from any such proceedings of the Licensed Patents and the Joint Collaboration Patents (collectively, "**Protection**"). Alkermes will provide Biogen reasonable assistance in the Prosecution and Protection of such Licensed Patents or Joint Collaboration Patents, including by making its employees, agents and consultants reasonably available to Biogen (or Biogen's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable Biogen to undertake Prosecution and Protection as contemplated by this Agreement. If Biogen elects to halt Protection of any patents or patent applications within the Licensed Patents or the Joint Collaboration Patents in any country in the Territory, then Biogen will notify Alkermes in a timely manner to permit the preservation of any rights in such country with respect to such Licensed Patents or Joint Collaboration Patents. Following written notification from Alkermes to Biogen that Alkermes wishes to assume Protection of such Licensed Patents or Joint Collaboration Patents in such country, Biogen will permit Alkermes to so assume Protection of such Licensed Patents or Joint Collaboration Patents (as applicable) at its own cost and expense and using patent counsel of its choosing. Biogen will provide reasonable assistance in the Protection of such Licensed Patents or Joint Collaboration Patents, including by making its employees, agents and consultants reasonably available to Alkermes (or Alkermes' authorized attorneys, agents or representatives), to the extent reasonably necessary to enable Alkermes to undertake Protection as contemplated by this Agreement. Notwithstanding the foregoing, Biogen shall forfeit its right to control Protection of any Licensed Patents and Joint Collaboration Patents that are or become subject to a Patent Action under Section 6.3.

(iii) **Other Patent Rights.** Except as expressly provided in this Section 7.4.1, each Party shall have the sole right, in its sole discretion, to conduct Prosecution of any Patent Rights owned by such Party.

**7.4.2. Common Interest.** All information exchanged between the Parties or between the Parties' outside patent counsel regarding Prosecution of the Licensed Patents, and the Joint Collaboration Patents shall be deemed Confidential Information of the prosecuting Party subject to Article 8. In addition, the Parties acknowledge and agree that, with regard to Prosecution of the Licensed Patents and the Joint Collaboration Patents, the interests of the Parties as licensor and licensee are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of,

any legal privilege concerning the Licensed Patents or the Joint Collaboration Patents, including privilege under the common interest doctrine and similar or related doctrines.

**7.4.3. Patent Term Extensions.** The Parties will use reasonable efforts and cooperate with one another to obtain all available supplementary protection certificates, patent term restorations and other patent extensions with respect to the Products, and to make any filings with respect thereto. Alkermes will cooperate with Biogen with respect to any such filings, including by executing such authorizations and other documents and taking such other actions as may be reasonably requested by Biogen to obtain such extensions.

**7.5. Enforcement Rights.**

**7.5.1. Notification of Infringement.** If either Party learns of any actual or threatened infringement by a Third Party of a Licensed Patent or Collaboration Patent in the Territory or, other than Prosecution-related matters, any attack by a Third Party on the validity or enforceability of a Licensed Patent or Collaboration Patent in the Territory, including any certification received by such Party under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417, as amended, the "*Hatch-Waxman Act*"), with respect to a Licensed Patent or Collaboration Patent and a Product in the Field (each, an "*Infringement*"), such Party will promptly, and in any event within five (5) days, notify the other Party and will provide the other Party with available evidence of such events.

**7.5.2. Enforcement of Licensed Patents and Joint Collaboration Patents.**

(i) Biogen shall have the first right, but not the obligation, at its own cost and expense and using counsel of its choosing, to institute any action, suit or proceeding against any Infringement of a Licensed Patent or Joint Collaboration Patent. Biogen shall have the right to cause Alkermes to join Biogen as a party plaintiff to any such action, suit or proceeding, at Biogen's sole expense. Biogen will keep Alkermes reasonably informed regarding such action, suit or proceeding and will reasonably consider Alkermes' input regarding such action, suit or proceeding.

(ii) If, after sixty (60) days following the date of notice given pursuant to Section 7.5.1 (or at least twenty (20) days before the expiration of any time limit set forth under 21 U.S.C. §355), Biogen has not provided written notification to Alkermes that Biogen will institute an action, suit or proceeding against the applicable Infringement or provided Alkermes with information and arguments demonstrating that there is insufficient basis for the allegation of such Infringement, then Alkermes shall have the right, but not the obligation, at its own cost and expense and using counsel of its choosing, to institute any action, suit or proceeding against such Infringement, *provided* that, if Biogen provides notice to Alkermes that Biogen has determined, for reasons related to the benefit of the Alkermes 8700 Product in the aggregate not to institute an action, suit or proceeding against such Infringement, Alkermes shall not have the right to institute an action, suit or proceeding against such Infringement. Notwithstanding the foregoing provisions of this Section 7.5.2(ii), if Biogen forms a good faith belief that instituting an action, suit or proceeding against such Infringement would not benefit the Alkermes 8700 Product in the aggregate, then Biogen shall consult with Alkermes in

reasonable detail regarding Biogen's reasonable good faith rationale for such determination, and if after such consultation with Alkermes, Biogen maintains such belief in good faith, then Alkermes shall agree to a reasonable request from Biogen not to institute any such action, suit or proceeding against such Infringement; *provided that*, if the Parties disagree as to whether any such request from Biogen not to institute any such action, suit or proceeding against such Infringement is reasonable, then Alkermes will not institute any such action, suit or proceeding against such Infringement unless and until (a) in the case of an abbreviated new drug application ("ANDA") under the Hatch-Waxman Act, Senior Management has attempted in good faith to discuss and resolve such disagreement at least five (5) days before the expiration of any time limit set forth under 21 U.S.C. §355 (and each Party agrees that it will use its best efforts to make its respective Senior Management available for such discussion within such timeframes) and (b) other than in the case of an ANDA, such request by Biogen is determined not to be reasonable in accordance with the Senior Management escalation and dispute resolution procedure set forth in Section 12.1.2 and, if such dispute remains unresolved after such procedure, then in accordance with the procedure set forth in Section 12.1.3, which escalation and dispute resolution procedures shall be conducted in an expedited manner so as to allow Alkermes to proceed with an action, suit or proceeding against such Infringement if such request by Biogen is determined not to be reasonable. In connection with any action, suit or proceeding pursuant to this Section 7.5.2, the Parties will cooperate with and assist each other in all reasonable respects.

**7.5.3. Recoveries.** In the event that either Party exercises the rights conferred in Section 7.5.2 and recovers any damages or other sums in such action, suit or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to all reasonable out-of-pocket costs and expenses incurred by the Parties in connection therewith, including attorneys' fees. If such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be shared *pro rata* in proportion to the total of such costs and expenses incurred by each Party. If, after such reimbursement, any funds shall remain from such damages or other sums recovered, and (i) if Biogen institutes the action, suit or proceeding pursuant to Section 7.5.2(i) that results in such damages or other sums recovered, then Biogen shall pay Alkermes a payment calculated by multiplying the applicable royalty rate for the Alkermes 8700 Product (that Biogen would have paid to Alkermes if such damages or other sums recovered were treated as Net Sales hereunder) by the amount of such damages or other sums recovered and Biogen shall retain the remainder or (ii) if Alkermes institutes the action, suit or proceeding pursuant to Section 7.5.2(ii) that results in such damages or other sums recovered, then Alkermes shall pay Biogen a payment calculated by multiplying the applicable royalty rate for the Alkermes 8700 Product (that Biogen would have paid to Alkermes if such damages or other sums recovered were treated as Net Sales hereunder) by the amount of such damages or other sums recovered and Alkermes shall retain the remainder.

**7.5.4. Other Patent Rights.** Except as expressly provided in Section 7.5.2, each Party shall have the sole right, in its sole discretion, to institute any action, suit or proceeding against any actual or threatened infringement by a Third Party of any Patent Right owned by such Party.

**7.6. Infringement Defense.**

**7.6.1. Notice.** In the event that a Third Party at any time provides written notice of a claim to, or brings an action, suit or proceeding against, either Party, or any of their respective Affiliates or sublicensees (each Person so sued being referred to herein as a "*Sued Party*"), claiming infringement of such Third Party's Patent Rights or unauthorized use or misappropriation of its Know-How based upon an assertion or claim arising out of the Exploitation of a Product in the Field in the Territory ("*Infringement Claim*"), such Party shall promptly notify the other Party of the Infringement Claim or the commencement of such action, suit or proceeding, enclosing a copy of the Infringement Claim and all papers served.

**7.6.2. Right to Defend.** If the Sued Party with respect to any Infringement Claim is entitled to indemnification under Article 11 with respect to such Infringement Claim, then the terms and conditions of Article 11 and not this Section 7.6.2 shall apply to such Infringement Claim. In all other cases, Biogen shall have the right, but not the obligation, at its own cost and expense and using counsel of its choosing, to defend against any Infringement Claim brought against Biogen or its Affiliates or Sublicensees and Alkermes shall have the right, but not the obligation, at its own cost and expense and using counsel of its choosing, to defend against any Infringement Claim brought against Alkermes or its Affiliates or sublicensees. The Sued Party shall keep the other Party reasonably informed of all material developments in connection with any such suit and shall not, without the other Party's prior written consent, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to the other Party. The other Party shall make available to the Sued Party its advice and counsel regarding any Infringement Claim and shall offer reasonable assistance in connection with any Infringement Claim to the Sued Party, at the Sued Party's cost and expense.

**7.7. Patent Marking.** Biogen agrees to mark, and to require any of its Affiliates or Sublicensees to mark, any Products (or their containers or labels) made, sold, or otherwise distributed by it or them with any notice of Patent Rights required under Applicable Law to enable such Patent Rights to be enforced to their full extent in any country where Products are made, used, sold, or offered for sale.

**7.8. Orange Book Listings.** With respect to patent listings in the FDA Orange Book for issued patents for the Alkermes 8700 Product in the Initial Indication, the Parties shall determine by mutual agreement which patents to list in the FDA Orange Book (a) prior to the submission of the Alkermes 8700 Product 505(b)(2) NDA, or any other NDA for the Alkermes 8700 Product submitted to the FDA and (b) within twenty (20) days after the receipt of Regulatory Approval for the Alkermes 8700 Product in the Initial Indication. If the Parties are unable to reach agreement on any such listings within twenty (20) days before submission of the Alkermes 8700 Product 505(b)(2) NDA, or any other NDA for the Alkermes 8700 Product submitted to the FDA or within twenty (20) days after receipt of Regulatory Approval for the Alkermes 8700 Product in the Initial Indication in the U.S. prior to the Transfer Completion Date, then Alkermes will have the right to make the determination with respect to which patents to list in the FDA Orange Book. After the Transfer Completion Date, Biogen shall have the sole right, in its sole discretion, to determine which patents to list in the FDA Orange Book (or its foreign equivalent in any country in the Territory) for the Alkermes 8700 Product. With respect to patent listings in the FDA Orange Book (or its foreign equivalent in any country in the Territory) for issued patents for any other Product or for the Alkermes 8700 Product in any other indication

than the Initial Indication in the Field, in each case, Biogen shall have the sole right, in its sole discretion, to determine which patents to list.

#### **7.9. Trademark Infringement.**

**7.9.1. Notification of Infringement.** If Alkermes learns that a Third Party is infringing any Product Trademark in the Territory, Alkermes will promptly notify Biogen.

**7.9.2. Infringement Action.** Biogen will have the sole right, at its own cost and expense and in its sole discretion, to take any action with respect to any infringement of a Product Trademark in the Territory, with counsel of its own choice. Any recovery from any settlement or judgment from such action will be retained by Biogen.

### **Article 8**

#### **CONFIDENTIALITY; PUBLICITY**

**8.1. Confidentiality.** Except to the extent authorized by this Agreement or otherwise agreed upon in writing, the Parties agree that the receiving Party will keep confidential and will not publish or otherwise disclose or use for any purpose, any proprietary and confidential information and materials furnished to it by the disclosing Party pursuant to this Agreement or the Confidentiality Agreements (collectively, "**Confidential Information**"), except to the extent that it can be established by the receiving Party that such Confidential Information:

**8.1.1.** was already known to the receiving Party or its Affiliates, as demonstrated by competent written records, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party;

**8.1.2.** was generally available to the public or otherwise part of the public domain at the time of its disclosure by the disclosing Party;

**8.1.3.** became generally available to the public or otherwise part of the public domain after its disclosure by the disclosing Party and other than through any act or omission of the receiving Party or its Affiliates in breach of this Agreement;

**8.1.4.** was disclosed to the receiving Party or its Affiliates, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or

**8.1.5.** was subsequently developed by the receiving Party or its Affiliates without use of or reference to the Confidential Information of the disclosing Party as demonstrated by competent written records.

Licensed Know-How and unpublished Licensed Patents (to the extent that such Licensed Know-How or unpublished Licensed Patents are not subject to any of the foregoing exceptions set forth under this Section 8.1) will be considered Confidential Information of Alkermes, *provided* that Biogen may use or disclose such Licensed Know-How and Licensed Patents in

accordance with Article 8. Notwithstanding anything to the contrary set forth in this Agreement, during the Term Alkermes will use at least the same degree of care to protect the secrecy of such Licensed Know-How and unpublished Licensed Patents that it uses to prevent the disclosure of its own other confidential information of similar importance and in any event a reasonable duty of care.

**8.2. Authorized Use and Disclosure.** Each Party will maintain the Confidential Information of the other Party in confidence and may use the Confidential Information of the other Party only in performance of its obligations under this Agreement and any Supply Agreement. Each Party may disclose such Confidential Information to its employees, Affiliates, sublicensees, agents, consultants or other Third Parties who need to know such Confidential Information in connection with the performance of such Party's obligations under this Agreement or any Supply Agreement and who are bound by obligations of confidentiality and non-use at least substantially equivalent to the obligations of this Article 8. Each Party will be liable for any unauthorized use or disclosure of Confidential Information by its employees, Affiliates, sublicensees, agents, consultants or other Third Parties to which it has disclosed or transferred such Confidential Information.

Without limiting the generality of the foregoing paragraph, a Party may disclose Confidential Information of the other Party to the extent that such disclosure is reasonably necessary in connection with:

- 8.2.1.** filing or prosecuting patent or trademark applications relating to the Products;
- 8.2.2.** prosecuting or defending litigation relating to the Products;
- 8.2.3.** Exploiting the Products;
- 8.2.4.** seeking Regulatory Approval of a Product, including Regulatory Approval of a Manufacturing facility for a Product;
- 8.2.5.** seeking reimbursement or pricing approvals for a Product from Governmental Authorities;
- 8.2.6.** complying with Applicable Laws, including securities laws and the rules of any securities exchange or market on which a Party's or its Affiliates' securities are listed or traded; or
- 8.2.7.** complying with subpoenas or requests for information from Governmental Authorities.

In making any disclosures set forth in Section 8.2.1 through Section 8.2.7 above, the disclosing Party will, except where impracticable for necessary disclosures (as in the event of medical emergency), give such advance notice to the other Party of such disclosure requirement as is reasonable under the circumstances and, except to the extent inappropriate (as in the case of patent applications), use its reasonable efforts to cooperate with the other Party in order to secure confidential treatment of such Confidential Information required to be disclosed, except to the

extent that the disclosing Party receives advice from its legal counsel or independent registered public accounting firm that such information is required to be disclosed under Applicable Laws, including securities laws and the rules of any securities exchange or market on which a Party's or its Affiliates' securities are listed or traded.

**8.3. Disclosure to Investors.** The Parties acknowledge that each Party may, from time to time, engage or have engaged in fundraising or other business activities. The Parties may disclose a copy of this Agreement, under terms of confidentiality no less strict than those contained in this Agreement, to their respective actual or *bona fide* potential investors or business partners (and to their respective bankers, lawyers, accountants and agents); *provided* that any such copy may be redacted to remove any confidential, proprietary or competitive information of the disclosing Party and any other information not necessary in connection with their evaluation of such potential or actual investment.

**8.4. Survival.** This Article 8 will survive the termination or expiration of this Agreement for a period of [\*\*] years.

**8.5. Publications or Presentations.**

**8.5.1. General.** Biogen shall have the sole right, in its sole discretion, to present at symposia, national or regional professional meetings and to publish in journals regarding the Products and any activities under this Agreement, *provided* that any such presentation or publication shall not include any Confidential Information of Alkermes. Alkermes shall have no right to present at symposia, national or regional professional meetings or to publish in journals regarding the Products or any activities under this Agreement.

**8.5.2. Publicity.** A joint press release approved by each Party announcing this Agreement is attached hereto as Exhibit F. Biogen retains the right to make publications about its activities under the Agreement (i) prior to the Transfer Completion Date and with respect to the Alkermes 8700 Product, with the consent of Alkermes, which consent shall not be unreasonably withheld or delayed, and (ii) (a) with respect to any Product other than the Alkermes 8700 Product and, (b) following the Transfer Completion Date, with respect to the Alkermes 8700 Product, in each case (a) and (b), without the consent of Alkermes. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or the arrangements hereunder to the extent the same has already been publicly disclosed by such Party or by the other Party; *provided* that such information remains true, correct and consistent with the most recent information related thereto that has been publically disclosed. Routine references to this Agreement and the arrangements hereunder in the context of disclosures or publications regarding a Party's business in general will be allowed in the usual course of a Party's business, including the use of other Party's name. Each Party may use the other Party's corporate logo(s) or Product Trademarks only with the prior written consent of the other Party.



**Article 9**

**PAYMENTS**

**9.1. Up-Front Payment.** Within ten (10) Business Days after the Effective Date, as an upfront, one-time, nonrefundable and non-creditable fee in consideration of the grant of the licenses set forth in Section 6.1, Biogen will pay to Alkermes the amount of Twenty Eight Million U.S. Dollars (US\$28,000,000) (the “*Up-Front Payment*”).

**9.2. Option Payment.** Within [\*\*] days after Biogen’s receipt from Alkermes of the Initial GI Tolerability Data Package in accordance with Section 3.2.4(i), subject to any extension pursuant to Section 3.2.4(iii), Biogen will make a one-time, nonrefundable and non-creditable payment to Alkermes in the amount of Fifty Million U.S. Dollars (US\$50,000,000) (the “*Option Payment*”), unless, following the Parties’ discussions as set forth in Section 3.2.4(iv), the Parties jointly agree in writing not to conduct Part B of the GI Tolerability Clinical Trial because the rate of discontinuations due to a GI Event in Part A of the GI Tolerability Clinical Trial is lower in the Tecfidera® arm of such trial (in which case GI Inferiority will be deemed to exist and Biogen will not be obligated to make the Option Payment). If Biogen does not make the Option Payment in accordance with this Section 9.2 for any reason other than the Parties jointly agreeing in writing not to conduct Part B of the GI Tolerability Clinical Trial because the rate of discontinuations due to a GI Event in Part A of the GI Tolerability Clinical Trial is lower in the Tecfidera® arm of such trial, and Biogen fails to make such Option Payment within five (5) Business Days following written notice from Alkermes of such failure, then Biogen will be deemed to have given notice of termination for convenience in accordance with Section 13.3.

**9.3. NDA Approval Payment.** If the Alkermes 8700 Product 505(b)(2) NDA approval is obtained on or prior to December 31, 2021, then within [\*\*] days after the Transfer Completion Date, Biogen will make a one-time, nonrefundable and non-creditable payment to Alkermes in the amount of One Hundred Fifty Million U.S. Dollars (US\$150,000,000).

**9.4. Development Milestones for Products other than the Alkermes 8700 Product.**  
As further consideration of the grant of the licenses set forth in Section 6.1 and the performance of Alkermes’ other obligations hereunder, Biogen shall pay to Alkermes the amounts set forth below no later than [\*\*] days after the earliest date on which the corresponding milestone event has first been achieved with respect to the first two Products other than the Alkermes 8700 Product:

<b>Development Milestone Event</b>	<b>Amount</b>
The first administration to the first patient in a Clinical Trial of such Product.	[**]
The first administration of such Product to the first patient in a phase 3 Clinical Trial.	[**]
Receipt of Regulatory Approval of an NDA from the FDA in the U.S. for such Product.	[**]

The milestone payments set forth in this Section 9.4 will be paid on a Product-by-Product basis on the first occurrence of each such applicable milestone for each of the first two Products (other than the Alkermes 8700 Product).

**9.5. Royalties.**

**9.5.1. Royalty Payments for Alkermes 8700 Product.**

(i) **Royalty Percentages.** As further consideration of the grant of the licenses set forth in Section 6.1 and the performance of Alkermes' other obligations hereunder, Biogen will pay to Alkermes royalty payments on Net Sales of the Alkermes 8700 Product in the Territory on a country-by-country basis during the applicable Royalty Term at the rate of [\*\*] percent ([\*\*]%) of Net Sales. Notwithstanding the foregoing, in the event of a determination of GI Inferiority, if Biogen has made the Option Payment to Alkermes, then the royalty rate during each Royalty Term for the Alkermes 8700 Product in each country in the Territory shall be [\*\*] percent ([\*\*]%) of Net Sales until such time as the aggregate royalty payments paid to Alkermes across all countries equal Fifty Million U.S. Dollars (\$50,000,000), after which time such royalty rate shall return to its prior level, before the determination of GI Inferiority that resulted in such royalty rate of [\*\*] percent ([\*\*]%) (but subject in any event to Section 9.5.5, Section 9.5.6 and Section 9.5.7).

(ii) **Minimum Annual Payments.** As further consideration for the grant of the licenses set forth in Section 6.1 and the performance of Alkermes' other obligations hereunder, Biogen will pay Alkermes a minimum aggregate royalty payment during each twelve (12)-month period (each, a "*Minimum Annual Payment*" and together, the "*Minimum Annual Payments*") in the amounts set forth in the table below, commencing on the first day of the first month following the date of the First FDA Approval (such first day of such first month, the "*Minimum Payment Commencement Date*") and continuing for a period of five (5) years, unless earlier terminated as set forth in Section 9.5.1(iii) (the "*Minimum Annual Payment Term*").

For clarity, for each twelve (12)-month period during the Minimum Annual Payment Term in which the aggregate amount payable to Alkermes as royalties under Section 9.5.1(i) is less than the applicable Minimum Annual Payment, Biogen shall pay Alkermes an amount equal to the applicable Minimum Annual Payment for such twelve (12)-month period, *minus* the aggregate amount already paid to Alkermes as royalties under Section 9.5.1(i) for such twelve (12)-month period.

<b>Twelve (12)-Month Period</b>	<b>Minimum Annual Payment</b>
First twelve (12)-month period following the Minimum Payment Commencement Date	[**]
Second twelve (12)-month period following the Minimum Payment Commencement Date	[**]
Third twelve (12)-month period following the Minimum Payment Commencement Date	[**]
Fourth twelve (12)-month period following the Minimum Payment Commencement Date	[**]
Fifth twelve (12)-month period following the Minimum Payment Commencement Date	[**]

**(iii) Termination of Minimum Annual Payments.**

Notwithstanding anything to the contrary in Section 9.5.1(ii), the Minimum Annual Payment Term shall immediately terminate, and no further Minimum Annual Payments shall be payable under this Agreement, if any of the following conditions is met:

- (A) (i) [\*\*] and (ii) [\*\*];
- (B) [\*\*]; or
- (C) [\*\*].

Notwithstanding anything to the contrary, if any of the foregoing conditions in clauses (A) through (C) exist prior to the Minimum Payment Commencement Date, then the Minimum Annual Payment Term shall be deemed not to commence and no Minimum Annual Payments shall be payable under this Agreement.

**9.5.2. Royalty Payments for Products other than the Alkermes 8700 Product.** As further consideration of the grant of the licenses set forth in Section 6.1 and the performance of Alkermes' other obligations hereunder, Biogen will pay to Alkermes tiered royalty payments on annual aggregate worldwide Net Sales of Products, other than the Alkermes 8700 Product, on a Product-by-Product basis during the applicable Royalty Term as follows: (i) for Net Sales less than or equal to [\*\*] U.S. Dollars (US\$[\*\*]), [\*\*] percent ([\*\*]%) of such Net Sales and (ii) for Net Sales greater than [\*\*] U.S. Dollars (US\$[\*\*]), [\*\*] percent ([\*\*]%) of such Net Sales.

**9.5.3. Duration of Royalty Payments.** Biogen will pay royalties to Alkermes, as set forth in Section 9.5.1(i) and Section 9.5.2, on a country-by-country and

Product-by-Product basis, during the period commencing on the First Commercial Sale of a Product in a country and ending on the later of (i) the expiration of all Valid Claims of the Joint Collaboration Patents and Licensed Patents that Cover the use or sale of such Product in such country and (ii) [\*\*] years after the First Commercial Sale of such Product in such country (any such period, a “**Royalty Term**”). Following expiration of the Royalty Term for any Product in a country, no further royalties shall be payable in respect of sales of such Product in such country and, thereafter, the license granted to Biogen under Section 6.1.1 with respect to such Product in such country shall be non-exclusive, fully paid-up, perpetual, irrevocable and royalty-free.

**9.5.4. Cumulative Royalties.** The obligation to pay royalties under this Agreement shall be imposed only once with respect to a single unit of a Product regardless of how many Valid Claims of the Licensed Patents Cover the use or sale of such Product in the applicable country.

**9.5.5. No Valid Claim.** On a country-by-country and Product-by-Product basis, in any country in which a Product is Commercialized and there are no remaining Valid Claims of the Licensed Patents that Cover the use or sale of such Product in such country, the royalties payable to Alkermes on Net Sales of such Product pursuant to (i) Section 9.5.1(i) will be reduced to [\*\*] percent ([\*\*]%) of such Net Sales for the Alkermes 8700 Product and (ii) Section 9.5.2 will be reduced to [\*\*] percent ([\*\*]%) of the applicable royalty rate for any Product (other than the Alkermes 8700 Product).

**9.5.6. Third Party Payment Obligations.** If Biogen or its Affiliates or Sublicensees are required to make any payments (including upfront fees, milestones or royalties) to a Third Party to obtain rights to any intellectual property that is necessary to Exploit a Product in the Field in any country, then Biogen may deduct up to [\*\*] percent ([\*\*]%) of such Third Party payments as and when incurred from any royalty payment or Minimum Annual Payment due to Alkermes under Section 9.5.1 or Section 9.5.2 with respect to such Product and such country; *provided* that Biogen may not deduct from any payments due to Alkermes hereunder any such Third Party payments due under any arrangement entered into prior to the Effective Date.

**9.5.7. Royalty Floor.** Notwithstanding anything to the contrary herein, in no event shall the royalty payments or Minimum Annual Payments due to Alkermes under Section 9.5.1 or Section 9.5.2 for any Product in a given Calendar Quarter be reduced as a result of the application of the reductions and offsets described in this Section 9.5 below [\*\*] percent ([\*\*]%) of the amounts otherwise payable to Alkermes under Section 9.5.1 or Section 9.5.2 with respect to such Product. Any reductions or offsets that are not used to reduce payments under Section 9.5.1 or Section 9.5.2 in a given Calendar Quarter as a result of the foregoing limitations may be carried over to reduce payments due under Section 9.5.1 and Section 9.5.2 in subsequent Calendar Quarters.

**9.6. Reporting and Paying Net Sales.** For each Calendar Quarter for which royalties are payable by Biogen to Alkermes pursuant to Section 9.5.1(i) or Section 9.5.2, Biogen will (i) deliver to Alkermes, within five (5) days after the end of each such Calendar Quarter, a non-binding estimated report prepared in good faith, (ii) deliver to Alkermes, within forty-five (45) days after the end of each such Calendar Quarter a true and accurate report, in each case,

providing in reasonable detail (A) an accounting of all Net Sales made on a country-by-country and Product-by-Product basis in the Territory during such Calendar Quarter, including the amount of gross sales of Products and the aggregate allowable deductions therefrom, (B) the number of units of Products sold, (C) the currency conversion rates used, (D) the U.S. Dollar-equivalent of such Net Sales during such Calendar Quarter and (E) a calculation of the amount of royalty payment due on such Net Sales, and (iii) within forty-five (45) days after the end of each such Calendar Quarter, pay Alkermes the royalties due under Section 9.5.1(i) and Section 9.5.2 with respect to such Calendar Quarter as provided for in the report delivered under (ii) above. In addition, within forty-five (45) days of the end of the first Calendar Quarter following each twelve (12)-month period during the Minimum Annual Payment Term, Biogen shall pay Alkermes any amount due under Section 9.5.1(ii) for such twelve (12)-month period of the Minimum Annual Payment Term. Each report delivered hereunder shall be considered Confidential Information of Biogen, subject to the terms and conditions of Article 8 hereof. Any payments due hereunder for less than a full Calendar Quarter will be prorated.

#### **9.7. Records and Reporting; Audits.**

**9.7.1. Records and Reporting.** Each Party shall keep, and shall cause its Affiliates and Sublicensees to keep, such accurate and complete records of Net Sales and its Development Costs as are necessary to determine the amounts due to Alkermes under this Agreement, including time records. Records of Net Sales and Development Costs shall be retained by each Party or any of its Affiliates and Sublicensees (in such capacity, the “**Recording Party**”) for three (3) years following the end of the Calendar Year to which they pertain.

**9.7.2. Audits.** During normal business hours and with reasonable advance notice to the Recording Party, such records shall be made available for inspection, review and audit, at the request and expense of the other Party (the “**Auditing Party**”), by an independent certified public accountant, appointed by such Auditing Party and reasonably acceptable to the Recording Party, for the sole purpose of verifying the accuracy of the Recording Party’s accounting reports and payments made or to be made pursuant to this Agreement or any Supply Agreement; *provided, however*, that such audits may not be performed by the Auditing Party more than once per Calendar Year, that such audits may only cover records pertaining to any period commencing not more than two (2) Calendar Years prior to the date of such audit, and that such Auditing Party shall not be permitted to audit the same period of time more than once. Such accountants, prior to any review hereunder, shall have entered into an appropriate confidentiality agreement with the Recording Party on mutually acceptable terms and shall have been instructed not to reveal to the Auditing Party the details of their review, except for (i) such information as is required to be disclosed under this Agreement and (ii) such information presented in a summary fashion as is necessary to report the accountants’ conclusions to the Auditing Party. The report prepared by such accountants shall be sent or otherwise provided to the Recording Party by such accountants at the same time it is sent or otherwise provided to the Auditing Party. All costs and expenses incurred in connection with performing any such audit shall be paid by the Auditing Party unless the audit uncovers a net underpayment of amounts owed or overreporting of expenses by a Recording Party of five percent (5%) of total amounts owed or expenses reported by such Recording Party for any Calendar Year period covered by the audit, in which case the Recording Party will bear the full cost of such audit. If either Party is found to have been underpaid any amounts payable to such

Party hereunder or to have overpaid to the other Party any amounts payable hereunder, such first Party will be entitled to recover any undisputed discrepancy, plus interest calculated in accordance with Section 9.9, within forty-five (45) days after receipt of such audit report. If either Party disagrees with any discrepancy identified during the course of any audit conducted pursuant to this Section 9.7.2, then either Party may submit the issue for resolution in accordance with Article 12.

**9.8. Manner of Payments.** All sums due to Alkermes or Biogen under this Agreement shall be payable in U.S. Dollars by bank wire transfer in immediately available funds to such bank account(s) as Alkermes and Biogen, respectively, shall designate from time to time. Each Party shall endeavor to notify the other Party as to the date and amount of any such wire transfer to the other Party at least two (2) Business Days prior to such transfer, but in no event later than the Business Day of such transfer.

**9.9. Interest on Late Payments.** Without limitation on other available rights or remedies, any payments or portions thereof due hereunder that are not paid at the latest five (5) days following the date such payments are due under this Agreement will bear interest at the lower of (i) the Prime Rate as determined by Bank of America in effect on the due date, or (ii) the maximum rate permitted by Applicable Law, calculated on the number of days such payment is delinquent.

**9.10. Currency of Payments/Exchange Rates.** All payments to be made under this Agreement will be made in U.S. Dollars. The royalty due on Net Sales and the price for any applicable Product sold in the Territory (other than in the U.S.) will be calculated on the basis of the local currency sales figures translated into U.S. Dollars according to Biogen's standard currency translation methodology. As of Effective Date, Biogen converts revenue in local currency using the average FX rates for the month downloaded from the Bloomberg end of day rates on the second last business day of the month. The methodology employed by Biogen will be that methodology used by Biogen from time to time in the translation of its foreign currency operating results for external reporting and will be consistent with GAAP, and in any event will not be impacted by Biogen's hedging program.

**9.11. Taxes.**

**9.11.1. Withholding.** Biogen will make all payments to Alkermes under this Agreement without deduction or withholding except to the extent that any such deduction or withholding is required by Applicable Law. It is the intention of the Parties that all payments will be made by Biogen hereunder from its offices in Zug, Switzerland. No such payments will be made by Biogen hereunder from any other jurisdiction, unless Biogen and Alkermes agree in advance that such payments would not adversely affect the withholding tax position of such payments. In the event of Biogen's breach of this Section 9.11.1 resulting in an adverse effect on Alkermes' withholding tax position of such payments, Biogen shall make true-up payments to Alkermes as compensation for such adverse effect.

**9.11.2. Payment of Taxes.** Any tax required to be withheld by Applicable Law on amounts payable under this Agreement will promptly be paid by Biogen on behalf of Alkermes or Alkermes on behalf of Biogen, as applicable, to the appropriate Governmental

Authority, and the Party making such payment will furnish the other Party with proof of payment of such tax within one (1) calendar month of such payment. The Party making tax payments hereunder will give ten (10) days' advance notice of its intention to begin withholding any such tax in advance of such withholding.

**9.11.3. Cooperation and Documentation.** Biogen and Alkermes will cooperate (i) in all respects necessary to take advantage of any double taxation agreements or similar agreements as may, from time to time, be available in order for the payments under this Agreement to be made without any deduction or withholding and (ii) with respect to producing all documentation required by any Governmental Authority including an IRS Form W-8BEN-E with respect to taxes or as reasonably requested by Biogen or Alkermes, as applicable, to secure a reduction in the rate of applicable withholding taxes or to secure a credit or refund for withheld taxes. Alkermes shall prepare and deliver to Biogen a complete, accurate IRS Form W-8BEN-E for the Up-Front Payment within three (3) days after the Effective Date.

**9.11.4. Value Added Tax.** All payments to Alkermes under this Agreement are exclusive of any applicable value added tax ("*VAT*"), for which, if applicable, Biogen will be responsible; *provided* that Alkermes will issue an appropriate VAT invoice to Biogen.

**9.11.5. Pharmaceutical Excise Taxes.** Biogen may invoice Alkermes each Calendar Quarter for its pro rata share of any pharmaceutical excise taxes (based on the applicable Product royalty rate(s) in effect at the time of such Product sales to which the tax applies) imposed by the United States Patient Protection and Affordable Care Act of 2010 due with respect to sales of the Products in the U.S. at the time Biogen accrues such taxes in accordance with GAAP. Biogen will provide a summary of the amount invoiced and a roll-forward of the accrual balance. Alkermes will, within forty-five (45) days after the receipt of an invoice from Biogen for such pharmaceutical excise taxes, pay Biogen the undisputed amounts set forth in such invoice. Alkermes will notify Biogen of any disputed amounts within ten (10) days of receipt of any such invoice and will work with Biogen to resolve such issues on a timely basis. If such issue cannot be resolved by the Parties, then such matter will be resolved in accordance with the dispute resolution process set forth in Article 12. If the amount of such pharmaceutical excise taxes owed by Biogen differs from the amount accrued by Biogen in respect of such taxes for the applicable period, then Biogen will reflect such differences in Alkermes' next accrual payment.

## Article 10

### REPRESENTATIONS AND WARRANTIES; COVENANTS; DISCLAIMER

**10.1. Disclaimer.** EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, EACH PARTY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF COMMERCIAL UTILITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR SCOPE OF PATENT RIGHTS OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS. Each Party acknowledges and agrees that nothing in this Agreement will be construed as representing any estimate or projection of (a) the successful Development or

Commercialization of any Product under this Agreement, (b) the number of Products that will or may be successfully Developed or Commercialized under this Agreement, (c) anticipated sales or the actual value of any Products that may be successfully Developed or Commercialized under this Agreement or (d) the damages, if any, that may be payable if this Agreement is terminated for any reason. Without limiting the foregoing, Biogen makes no representation, warranty or covenant, either express or implied, that (i) it will successfully Develop, Manufacture, Commercialize or continue to Commercialize any Product in any country, (ii) if Commercialized, that any Product will achieve any particular sales level, whether in any individual country or cumulatively throughout the Territory or (iii) other than is expressly required under Section 4.2, that it will devote, or cause to be devoted, any level of diligence or resources to Developing or Commercializing any Product in any country, or in the Territory in general.

**10.2. Mutual Representations, Warranties and Covenants.** Each Party represents, warrants and covenants to the other as of the Effective Date as follows:

**10.2.1.** this Agreement has been duly executed and delivered by such Party and constitutes the valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other Applicable Laws relating to or affecting creditors' rights generally and by general equitable principles;

**10.2.2.** such Party has the full right, power and authority to execute, deliver and perform this Agreement;

**10.2.3.** the execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of such Party and its officers and directors;

**10.2.4.** the execution, delivery and performance of this Agreement do not breach, violate, contravene or constitute a default under any contracts, arrangements or commitments to which such Party is a party or by which it is bound nor do the execution, delivery and performance of this Agreement by such Party violate any order or Applicable Law of any court or Governmental Authority having authority over it; and

**10.2.5.** such Party will not enter into any contract, arrangement or commitment in the future that conflicts with or violates any term or provision of this Agreement.

**10.3. Alkermes Representations and Warranties.** Alkermes further represents and warrants to Biogen as of the Effective Date as follows:

**10.3.1.** Exhibit B contains a complete and correct list of all Patent Rights Controlled by Alkermes or its Affiliates as of the Effective Date that (i) are necessary for the Exploitation of the Alkermes 8700 Product in the Field in the Territory or (ii) Cover any Know-How Controlled by Alkermes or its Affiliates on the Effective Date that (a) is or was used in the Development or Manufacture of Products or (b) is or was embodied in Products;



**10.3.2.** Alkermes has and will have the full right, power and authority to grant, and is not required to obtain the consent of any Third Party to grant, the rights and licenses granted to Biogen under Article 6;

**10.3.3.** Except as set forth in Schedule 10.3.3, Alkermes owns the entire right, title and interest in and to the Licensed Patents and the Licensed Know-How, free of any encumbrance, lien, charge, license grant, option grant or other burden, and any such encumbrance, lien, charge, license grant, option grant or other burden set forth in Schedule 10.3.3 will not negatively affect Alkermes' right to grant the license to Biogen pursuant to Article 6;

**10.3.4.** the polymorph used by Alkermes in the Alkermes 8700 Product was disclosed in WO2014/152494, which published September 25, 2014 and is owned or otherwise Controlled by Alkermes, as compound (14) of Example 1, and which is further characterized in Example 7 and Figure 7 therein;

**10.3.5.** the data provided by Alkermes to Biogen that characterizes the polymorph used by Alkermes in the Alkermes 8700 Product, including the x-ray powder diffraction data, is true and complete and correct in all material respects;

**10.3.6.** Alkermes has complied in all material respects with all Applicable Laws in connection with the Prosecution of the Licensed Patents, including, with respect to any issued patents and pending patent applications, any disclosure requirements of the United States Patent and Trademark Office or any other Governmental Authority and has timely paid all filing and renewal fees payable with respect thereto;

**10.3.7.** Alkermes has obtained, or caused its Affiliates, as applicable, to obtain, assignments from the inventors of all inventorship rights to the Licensed Patents, and all such assignments are valid and enforceable, and the inventorship of the Licensed Patents is properly identified on each patent or patent application;

**10.3.8.** to Alkermes' Knowledge, no Third Party is infringing any Licensed Patent;

**10.3.9.** to Alkermes' Knowledge, the Exploitation of the Alkermes 8700 Product in the Field in the Territory does not infringe any issued Patent Right of any Third Party and Alkermes has disclosed to Biogen, to Alkermes' Knowledge, any pending Patent Rights that, if issued, may be infringed by the Exploitation of the Alkermes 8700 Product in the Field in the Territory;

**10.3.10.** Alkermes has not received notice of any claims, and there are no judgments or settlements against or owed by Alkermes or, to Alkermes' Knowledge, any pending or threatened claims or litigation, in each case, claiming that a Patent Right owned by such Third Party would be infringed by Exploitation of the Products in the Field in the Territory;

**10.3.11.** to Alkermes' Knowledge, Alkermes has the right to use, and to permit Biogen, Biogen's Affiliates and Biogen's Sublicensees to use, the Licensed Know-How for all permitted purposes under this Agreement;

**10.3.12.** to Alkermes' Knowledge, the Manufacture of the Alkermes 8700 Product as conducted or as currently planned to be conducted (including for Commercial Supplies), in each case, as of the Effective Date does not and will not infringe any Patent Right of any Third Party or misappropriate any Know-How of any Third Party (for clarity, this provision applies to Patent Rights and Know-How of Third Parties that Cover the process of manufacturing the Alkermes 8700 Product);

**10.3.13.** Alkermes and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Licensed Know-How that constitutes trade secrets under Applicable Law (including requiring all employees, consultants and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants and independent contractors to maintain the confidentiality of such Licensed Know-How) and, to Alkermes' Knowledge, such Licensed Know-How has not been used, disclosed to or discovered by any Third Party except pursuant to such confidentiality agreements and there has not been a breach by any party to such confidentiality agreements;

**10.3.14.** the Licensed Patents are, to Alkermes' Knowledge, valid and enforceable, and no Third Party has made any claim made against Alkermes or its Affiliates asserting the invalidity, unenforceability or non-infringement of any Licensed Patents (including, by way of example, through the institution or written threat of institution of interference, nullity, opposition, *inter partes* or post-grant review or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Governmental Authority);

**10.3.15.** Except as set forth in Schedule 10.3.3, the Licensed Patents and Licensed Know-How are not subject to any funding agreement with any Governmental Authority or any other Third Party, and are not subject to the requirements of the Bayh-Dole Act or any similar provision of any Applicable Law;

**10.3.16.** neither Alkermes nor any of its Affiliates (i) are subject to any obligation to or with any Third Party that causes Alkermes or its Affiliates not to Control (or otherwise not have rights to) any Patent Right or Know-How that would, but for such obligation, be included in the Licensed Patents or the Licensed Know-How or (ii) hold for use or otherwise have rights to, but do not Control, any Patent Rights or Know-How that would otherwise be included in the Licensed Patents or Licensed Know-How if such Patent Rights or Know-How were Controlled by Alkermes or an Affiliate;

**10.3.17.** there is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to Alkermes' Knowledge, threatened, with any judicial or arbitral body against Alkermes or any of its Affiliates in connection with the Licensed Patents, the Licensed Know-How or the Products;

**10.3.18.** the Development and Manufacture of the Alkermes 8700 Product have been conducted in all material respects in accordance with Applicable Law;

**10.3.19.** in the Development and Manufacture of the Alkermes 8700 Product, Alkermes is not, as of the Effective Date, using any employee who is debarred by the FDA or any other Regulatory Authority, or who is the subject of debarment proceedings by the FDA or any such Regulatory Authority;

**10.3.20.** to Alkermes' Knowledge, in the Development and Manufacture of the Alkermes 8700 Product, Alkermes has not previously used any employee and has not previously used, and is not currently using, any consultant, in each case, who is or has been debarred by the FDA or any other Regulatory Authority, or, to Alkermes' Knowledge, who is or has been the subject of debarment proceedings by the FDA or any such Regulatory Authority; and

**10.3.21.** Alkermes has not knowingly withheld from Biogen information relating to the Licensed Patents, the Licensed Know-How and the Alkermes 8700 Product, in each case, that Alkermes reasonably believes would be material to Biogen's decision to enter into this Agreement and undertake the commitments and obligations set forth herein.

**10.4. Biogen Representations and Warranties.** Biogen further represents and warrants to Alkermes that, as of the Effective Date, Biogen has undertaken an assessment of the reportability of the transactions contemplated by this Agreement under the HSR Act, and following such assessment, Biogen has concluded that pursuant to 16 CFR 801.10, a filing under the HSR Act is not required as of the Effective Date.

**10.5. Responsibility for Government Approvals.** Biogen, as the acquirer of the licenses granted in Article 6, shall determine, control and direct strategy regarding requesting Governmental Approvals in connection with the transactions contemplated by this Agreement, including with respect to determining the necessity of requesting Governmental Approvals for the transactions contemplated by this Agreement by any Governmental Authority, and if applicable, all matters relating to any review by any Governmental Authority, or any litigation by, or negotiations with, any Governmental Authority related thereto, and will take the lead in all meetings, discussions, and communications, if any, with any Governmental Authority relating to requesting or obtaining all Governmental Approvals for the transactions contemplated by this Agreement (provided that this Section 10.5 shall not apply to any Regulatory Approvals that may be required to Exploit the Alkermes 8700 Product prior to the Transfer Completion Date).

## **Article 11**

### **LIABILITY**

**11.1. Limitation of Liability.** EXCEPT FOR (i) LIABILITY FOR EITHER PARTY'S BREACH OF ARTICLE 8, (ii) THE PARTIES' INDEMNIFICATION OBLIGATIONS PURSUANT TO SECTIONS 11.2 AND 11.3 OR (iii) ANY LIABILITY ARISING FROM A PARTY'S FRAUD OR WILLFUL MISCONDUCT, NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY OR ANY OF SUCH OTHER PARTY'S REPRESENTATIVES OR STOCKHOLDERS FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES OR LOST PROFITS OR LOST REVENUES ARISING OUT OF OR RESULTING FROM THIS

AGREEMENT, REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

**11.2. Biogen Indemnification.** Biogen will indemnify, defend and hold harmless Alkermes and its Affiliates and their respective directors, officers, employees and agents (each an “*Alkermes Indemnified Party*”) from and against all costs, losses, liabilities, expenses (including reasonable attorneys’ fees, experts’ fees and other costs of investigation or defense at any stage of the proceedings) and damages (collectively, “*Losses*”) to the extent relating to a claim, action or demand (“*Claim*”) by a Third Party or Governmental Authority arising out of or resulting from:

- 11.2.1. any breach of this Agreement by Biogen;
- 11.2.2. the violation of any Applicable Law by or on behalf of Biogen, its Affiliates or its Sublicensees;
- 11.2.3. Development or Commercialization of any Product in the Field in the Territory by or on behalf of Biogen, its Affiliates or its Sublicensees, including use of the Products by Third Parties;
- 11.2.4. a trademark infringement action pursuant to Section 7.9.2; or
- 11.2.5. the gross negligence or willful misconduct of any Biogen Indemnified Party;

except to the extent such Claim is subject to an indemnification, defense or hold harmless obligation of Alkermes set forth in Section 11.3 or in any Supply Agreement.

**11.3. Alkermes Indemnification.** Alkermes will indemnify, defend and hold harmless Biogen and its Affiliates and their respective directors, officers, employees and agents (each a “*Biogen Indemnified Party*”) from and against all Losses relating to a Claim by a Third Party or Governmental Authority to the extent arising out of or resulting from:

- 11.3.1. any breach of this Agreement by Alkermes;
- 11.3.2. the violation of any Applicable Law by or on behalf of Alkermes or its Affiliates;
- 11.3.3. Development of any Product in the Field in the Territory by or on behalf of Alkermes or its Affiliates;
- 11.3.4. Development or Commercialization of the Alkermes 8700 Product by or on behalf of Alkermes or its Affiliates after the effective date of termination of this Agreement with respect to the Alkermes 8700 Product or in its entirety; or
- 11.3.5. the gross negligence or willful misconduct of any Alkermes Indemnified Party;

except to the extent such Claim is subject to an indemnification, defense or hold harmless obligation of Biogen set forth in Section 11.2 or in any Supply Agreement.

**11.4. Indemnification Procedures.** In the event of any Claim by a Third Party or Governmental Authority against any Alkermes Indemnified Party or Biogen Indemnified Party (individually, an “*Indemnitee*”), the indemnified Party shall promptly notify the other Party in writing of the Claim and the indemnifying Party shall manage and control, at its sole expense, the defense of the Claim and any settlement thereof. The Indemnitee shall cooperate with the indemnifying Party and may, at its option and expense, be represented in any such action or proceeding. The indemnifying Party shall not be liable for any settlements, litigation costs or expenses incurred by any Indemnitee without the indemnifying Party’s prior written authorization. Notwithstanding the foregoing, if the indemnifying Party believes that any of the exceptions to its obligation of indemnification of the Indemnitees set forth in Sections 11.2 or 11.3, as applicable, may apply, the indemnifying Party shall promptly notify the Indemnitees, which may be represented in any such action or proceeding by separate counsel at their expense; *provided, however*, that the indemnifying Party shall be responsible for payment of such expenses if the Indemnitees are ultimately determined to be entitled to indemnification from the indemnifying Party. Notwithstanding any other provision of this Article 11 to the contrary, no Indemnitee under this Agreement shall be required to waive a conflict of interest under any applicable rules of professional ethics or responsibility if such waiver would be required for a single law firm to defend both the indemnifying Party and one or more Indemnitees. In such case, the indemnifying Party shall provide a defense of the affected Indemnitees through a separate law firm reasonably acceptable to the affected Indemnitees at the indemnifying Party’s expense. Except with the approval of an Indemnitee, which approval will not be unreasonably withheld or delayed, the indemnifying Party will not consent to entry of any judgment or enter into any settlement that would admit any wrongdoing by, or result in injunctive or other relief being imposed against, an Indemnitee.

**11.5. Cooperation.** The indemnified Party and each Indemnitee will cooperate in the defense or prosecution of any action or proceeding with respect to which it is being indemnified and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested by the indemnifying Party in connection with such action or proceeding. Such cooperation will include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the indemnified Party and the Indemnitee of, records and information that are reasonably relevant to such action or proceeding, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party will reimburse the indemnified Party for all its reasonable out-of-pocket expenses incurred in connection with such cooperation.

**11.6. Insurance.** As of the Effective Date each Party shall procure and maintain, at its sole cost and expense, commercial general liability insurance and products liability coverage in amounts not less than Ten Million U.S. Dollars (US\$10,000,000) per incident and Twenty Million U.S. Dollars (US\$20,000,000) annual aggregate. In the event of an indemnification claim pursuant to Sections 11.2 or 11.3 above, such insurance will be primary to any insurance owned, secured or put in place by the Indemnitee. All such policies will be written by insurance

companies with an A.M. Best's rating (or its equivalent) of A-VII or higher. In the event that any of these policies are written on a claims-made basis, then such policies shall be maintained during the Term and until the later of (i) three (3) years after expiration of Term or (ii) sixty (60) days following expiration of all applicable statutes of limitation for any potential Claims that may be indemnified Losses pursuant to Sections 11.2 or 11.3, as applicable. Upon written request, each Party will provide the other Party with a certificate of insurance attesting to such coverage. The minimum amounts of insurance coverage required under this Section 11.6 shall not be construed to create a limit of either Party's liability with respect to its indemnification obligation under Sections 11.2 or 11.3 above, as applicable. Notwithstanding the foregoing, Biogen and Alkermes may self-insure to the extent that such Party self-insures for its other products.

## Article 12

### DISPUTE RESOLUTION

#### 12.1. Disputes.

**12.1.1. Objective.** The Parties recognize that disputes, controversies or claims arising out of or relating to this Agreement or any Supply Agreement, or the interpretation, breach, termination or invalidity hereof or thereof (each a "**Dispute**"), may from time to time occur during the Term. It is the objective of the Parties to establish procedures to facilitate the resolution of Disputes occurring with respect to this Agreement or any Supply Agreement, in an expedient manner by mutual cooperation and without resorting to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 12 if and when a Dispute occurs with respect to this Agreement or any Supply Agreement. Notwithstanding the foregoing or anything to the contrary in this Agreement, with respect to any matter under this Agreement, (a) if such matter is within the scope of the JSC's authority, the dispute resolution provisions of Section 2.1.4 and not this Article 12 shall apply with respect to such matter and (b) if this Agreement expressly provides that such matter is subject to a Party's sole discretion or to a Party's sole or final decision-making authority, such matter shall not be subject to dispute resolution under this Article 12, but may be finally determined by such Party in accordance with the terms of this Agreement.

**12.1.2. Escalation.** With respect to any Dispute under this Agreement, other than any Dispute relating to the scope, validity or enforceability of a Licensed Patent or a Collaboration Patent (which may only be determined in accordance with Section 12.3 hereof), either Party (the "**Complaining Party**") may present such Dispute for resolution by senior management of each of Alkermes and Biogen (in the case of Alkermes, its Chief Executive Officer or a designee, and in the case of Biogen, its Chief Executive Officer or a designee) (collectively, "**Senior Management**") by providing a dispute notice (the "**Dispute Notice**") to Senior Management and the other Party. The Dispute Notice will concisely set forth the Dispute, the Parties' respective positions, and the specific relief requested. Within ten (10) days after receipt of a Dispute Notice, the Party receiving the Dispute Notice will provide a concise written response (the "**Response**") to such Dispute Notice to Senior Management and the Complaining Party. Senior Management will attempt to resolve such Dispute within ten (10) days after receipt by Senior Management of the Response. In the event that Senior Management cannot resolve a

Dispute within the ten (10)-day period, unless otherwise agreed by the Parties, such Dispute may be referred by either Party to arbitration in accordance with Section 12.1.3 upon written notice to the other Party.

**12.1.3. Arbitration.** The Parties agree that any Dispute referred for arbitration by a Party pursuant to Section 12.1 will be resolved through binding arbitration in accordance with the CPR International Institute for Conflict Prevention and Resolution Rules for Non-Administered Arbitration, as amended from time to time (the “*CPR Rules*”). If either Party receives a Dispute Notice, then any associated time to cure will be stayed pending the resolution of the issue pursuant to this Section 12.1.3. Any Dispute in which either Party seeks in excess of Twenty Million U.S. Dollars (US\$20,000,000) in damages will be resolved by an arbitral tribunal consisting of three (3) arbitrators, one (1) of whom will be designated by each Party in accordance with the CPR Rules, and a third arbitrator who will chair the tribunal and who will be selected as provided in the CPR Rules. Any other Dispute, aside from those seeking equitable relief, will be submitted to a sole arbitrator, appointed pursuant to the CPR Rules. Any suit seeking equitable relief shall be heard by a court of competent jurisdiction pursuant to Section 12.2. The arbitrator(s) will render a written opinion setting forth findings of fact and conclusions of law with the reasons therefor stated. Arbitration pursuant to this Section 12.1.3 will be governed by the Federal Arbitration Act, 9 U.S.C. §§ 1-16, and judgment upon the award rendered by the arbitrators may be entered by any court having jurisdiction thereof. The arbitration proceedings for all Disputes will be conducted in New York, New York in English and will be confidential in nature. Each Party will continue to perform its obligations under the Agreement pending final resolution of any Dispute unless to do so would be impossible or impracticable under the circumstances. The Parties agree that they will share equally the cost of the arbitration filing and hearing fees, and the cost of the arbitrators. Each Party must bear its own attorneys’ fees and associated costs and expenses.

**12.2. Jurisdiction.** The Parties agree to the exclusive jurisdiction of the federal courts located in the State of New York for the purposes of enforcing awards entered pursuant to this Article 12 and for enforcing the agreements reflected in this Article 12.

**12.3. Determination of Disputes Relating to Patents.** Notwithstanding anything to the contrary herein, any Dispute relating to the determination of scope, validity or enforceability of a Licensed Patent or Collaboration Patent will be submitted exclusively to the national court or other tribunal having jurisdiction over the disputed patent.

**12.4. Equitable Relief.** The Parties agree that irreparable harm may occur in the event any of the provisions of Article 6, Article 7, Article 8, in each case, are not performed in accordance with the terms of this Agreement or are otherwise breached and that money damages may not be a sufficient remedy for such a breach of this Agreement. Therefore, in addition to, and not in limitation of, any other remedy available to either Party, a Party will be entitled to seek, at its sole expense, injunctive relief or other equitable relief in the event of any such breach or threatened breach of this Agreement by the other Party from a court of competent jurisdiction, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding. Such remedies, and all other remedies provided for in this Agreement, shall be cumulative and not exclusive and will be in addition to any other remedies a Party may have under Applicable Law or in equity or otherwise.

## Article 13

### TERM AND TERMINATION

**13.1. Term.** This Agreement will commence as of the Effective Date and, unless sooner terminated as provided in this Article 13, will continue in effect until the expiration of the last Royalty Term as set forth in Section 9.5.3 (such period, the “*Term*”).

**13.2. Right to Terminate for Government Prohibition.** Either Party will have the right to terminate this Agreement effective immediately upon written notice to the other Party, following the issuance of any order, decree or judgment by any Governmental Authority that makes illegal, enjoins or prohibits the transactions effected by this Agreement.

**13.3. Biogen’s Right to Terminate for Convenience.** Biogen may terminate this Agreement, on a Product-by-Product basis or in its entirety, for any reason or for no reason, upon fifteen (15) days’ prior written notice to Alkermes; *provided that*, from and after the date of the First FDA Approval, Biogen may only terminate this Agreement, with respect to the Alkermes 8700 Product or in its entirety, upon one hundred and eighty (180) days’ prior written notice to Alkermes. Notwithstanding anything to the contrary set forth in this Agreement, from and after any notice of termination provided by Biogen to Alkermes under this Section 13.3 that terminates the Agreement with respect to the Alkermes 8700 Product or in its entirety, Biogen will not be obligated to make any further Minimum Annual Payments.

**13.4. Right to Terminate Upon Bankruptcy.** Either Party may, in addition to any other remedies available to it under Applicable Law or in equity, terminate this Agreement, effective immediately upon written notice to the other Party in the event (i) the other Party has made an assignment for the benefit of its creditors; (ii) there has been appointed an administrator, trustee or receiver for the other Party or for all or a substantial part of its property; or (iii) any case or proceeding has been commenced or other action taken by or against the other Party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or other similar act or Applicable Law of any jurisdiction now or hereafter in effect, and any such event has continued for sixty (60) days undismissed.

#### **13.5. Effects of Termination.**

**13.5.1. Termination of License Grants.** Upon any termination (but not expiration) of this Agreement in its entirety, except for the licenses and rights granted under Sections 13.5.2 and 13.5.3, all other licenses and rights granted by a Party to the other Party hereunder will terminate. Upon any termination of this Agreement with respect to a Product pursuant to Section 13.3, except for the licenses and rights granted under Sections 13.5.2 and 13.5.3, all other licenses and rights granted by a Party to the other Party hereunder with respect to such Product(s) (as applicable) shall terminate.

**13.5.2. Alkermes 8700 Product Rights.** In the event of a termination (but not expiration) of this Agreement with respect to the Alkermes 8700 Product or in its entirety, so



long as at such time (1) GI Inferiority does not exist or GI Inferiority exists and Biogen has Commercialized the Alkermes 8700 Product, and (2) Alkermes is not then in breach of its obligations under this Agreement (unless such breach is curable and has been cured no later than sixty (60) days after written notice from Biogen to Alkermes requesting cure of such breach), then at Alkermes' written request, Biogen shall:

(i) within a reasonable time period, transfer to Alkermes all ongoing Clinical Trials being conducted by the Parties for the Alkermes 8700 Product as of the effective date of such termination of this Agreement, if permitted by Applicable Law and the applicable Regulatory Authorities (or any data monitoring review board or internal safety review board), and provide cooperation reasonably requested by Alkermes in connection with such transfer;

(ii) if such termination occurs after the Transfer Completion Date, then no later than one (1) Business Day following the effective date of such termination, (a) send a letter to the FDA to transfer and assign to Alkermes all Regulatory Approvals and regulatory filings related to the Alkermes 8700 Product, including the Alkermes 8700 Product 505(b)(2) NDA and (b) transfer to Alkermes a complete copy of the Alkermes 8700 Product 505(b)(2) NDA and any other application for Regulatory Approval of the Alkermes 8700 Product and all regulatory filings, regulatory documentation and other supplements and records related to such NDA and applications that are required to be kept under 21 C.F.R. § 314.81, in each case, in Biogen's possession and Control as of the effective date of such termination of this Agreement;

(iii) no later than one (1) Business Day following the effective date of such termination, transfer to Alkermes a true and complete copy of (a) all data and results generated from any Development activities conducted by or on behalf of Biogen with respect to the Alkermes 8700 Product prior to the effective date of such termination of this Agreement, (b) all Trial Master Files (including any Trial Master File plans, tables of contents or indices and any evidence or certification of related quality checks) or equivalents thereof, for all completed or ongoing Clinical Trials of the Alkermes 8700 Product conducted by or on behalf of Biogen and (c) all other tangible embodiments of the Collaboration Know-How, in each case, in Biogen's possession and Control as of the effective date of such termination of this Agreement;

(iv) as of the effective date of such termination, grant to Alkermes an exclusive (even as to Biogen and its Affiliates), fully paid-up, perpetual, irrevocable and royalty-free, worldwide license, with the right to grant sublicenses through multiple tiers, under Biogen Collaboration Know-How and Biogen Collaboration Patents to Exploit the Alkermes 8700 Product in the Initial Indication in the Territory; and

(v) as of the effective date of such termination, grant to Alkermes a non-exclusive, fully paid-up, perpetual, irrevocable and royalty-free, worldwide license, with the right to grant sublicenses through multiple tiers, under any Know-How and Patent Rights that (a) are Controlled by Biogen or its Affiliates as of the effective date of such termination, (b) are invented after the Effective Date and prior to the effective date of such termination in the course of performance of activities by Biogen or its Affiliates or Sublicensees under this Agreement and (c) relate to (with respect to Know-How) or Cover (with respect to Patent Rights) the Alkermes 8700 Product in the form such product exists as of the effective date of such termination to

Exploit the Alkermes 8700 Product in the form such product exists as of the effective date of such termination in the Initial Indication in the Territory.

**13.5.3. License to Biogen Know-How and Biogen Patents.** In the event of a termination (but not expiration) of this Agreement with respect to the Alkermes 8700 Product or in its entirety, so long as at such time (i) GI Inferiority does not exist or GI Inferiority exists and Biogen has Commercialized the applicable Product and (ii) Alkermes is not then in breach of its obligations under this Agreement (unless such breach is curable and has been cured no later than sixty (60) days after written notice from Biogen to Alkermes requesting cure of such breach), then at Alkermes' written request, the Parties will negotiate in good faith the terms and conditions of the grant of a license to Alkermes under Know-How and Patent Rights Controlled by Biogen prior to the Effective Date that Cover the Alkermes 8700 Product and that are not licensed to Alkermes pursuant to Sections 13.5.2(iv) or Section 13.5.2(v).

**13.5.4. Costs of Product Reversion to Alkermes.** Alkermes shall be responsible for all costs and expenses incurred [\*\*] in connection with the activities set forth in Section 13.5.2, and thereafter Biogen shall be responsible for all such costs and expenses incurred.

**13.5.5. Surviving Sublicensee.** Following the effective date of any termination of this Agreement, at the request of any Sublicensee with a market capitalization (or other independent valuation) of at least Ten Billion U.S. Dollars (US\$10,000,000,000), and who is not then in breach of its Sublicense Agreement and is otherwise in good standing, subject to Alkermes' receipt of a copy from such Sublicensee of the Sublicense Agreement with such Sublicensee (together with all modifications or amendments); *provided* that any such copy may be redacted to remove any confidential, proprietary or competitive information of Biogen, Alkermes will enter into, without any assistance by Biogen, a direct license agreement with such Sublicensee under the Licensed Know-How and Licensed Patents that are sublicensed to such Sublicensee on substantially the same terms, *i.e.*, provides Sublicensee and Alkermes (as a substitute thereunder for Biogen) the same rights and obligations, as set forth in such Sublicense Agreement between Biogen and such Sublicensee effective as of the date of termination of the Sublicense Agreement granted to Sublicensee by Biogen; *provided, however,* that (a) such direct license agreement would not impose on Alkermes any obligations over and above its obligations under this Agreement and would not impose on any such Sublicensee any obligations over and above its obligations under the applicable Sublicense Agreement, and (b) as consideration for such direct license, the direct license agreement would require Sublicensee to pay Alkermes the same amount as Alkermes would have received from Biogen (had this Agreement survived) as a result of the Sublicensee's performance under such Sublicense Agreement. During the pendency of any negotiation of a direct license agreement between Alkermes and the applicable Sublicensee in accordance with this Section 13.5.5, so as to ensure no disruption in the rights granted to such Sublicensee, such Sublicensee is hereby licensed to continue to exercise its rights and will continue to perform its obligations, in each case, as set forth under such Sublicense Agreement and the applicable terms under such Sublicense Agreement will apply *mutatis mutandis* to Alkermes rather than Biogen, except that Alkermes will not have any obligations over and above its obligations under this Agreement. As provided in this Section 13.5.5, in the event of any termination of this Agreement, Alkermes will not have the right to terminate or otherwise restrict any rights granted to a Sublicensee that is not also in breach of this Agreement

or the applicable Sublicense Agreement. For any Sublicensee with a market capitalization (or other independent valuation) of less than Ten Billion U.S. Dollars (US\$10,000,000,000) and who is not then in breach of its Sublicense Agreement and is otherwise in good standing, Alkermes agrees to discuss in good faith with such Sublicensee a direct license agreement with such Sublicensee under the Licensed Know-How and Licensed Patents that are sublicensed to such Sublicensee.

### **13.6. Bankruptcy.**

**13.6.1.** All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code or analogous provisions of Applicable Law outside the U.S., licenses of right to “intellectual property” as defined under Section 101 of the Bankruptcy Code or analogous provisions of Applicable Law outside the U.S. (hereinafter “*IP*”). The Parties agree that the licensee of any such rights under this Agreement shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code or any other provisions of Applicable Law outside the U.S. that provide similar protection for IP. The license-granting Party shall, during the Term, create and maintain current copies of all IP licensed to the other Party under this Agreement. Upon the bankruptcy of a Party, the other Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such IP, and such IP, if not already in such other Party’s possession, shall be promptly delivered to such other Party. Each Party acknowledges and agrees that “embodiments” of such IP within the meaning of Section 365(n) include, without limitation, laboratory notebooks, product samples and inventory, research studies and data, all Regulatory Approvals and rights of reference therein, and all embodiments of any Licensed Know-How. If (a) a case under the Bankruptcy Code is commenced by or against a license-granting Party, (b) this Agreement is rejected as provided in the Bankruptcy Code, and (c) the other Party elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, the license-granting Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall:

(i) provide to the other Party all such IP (including all embodiments thereof) in such license-granting Party’s possession on terms agreed by the Parties, promptly upon the other Party’s written request; and

(ii) not interfere with the other Party’s rights under this Agreement, or any agreement supplemental hereto, to such IP (including such embodiments), including any right to obtain such IP (or such embodiments) from another entity, to the extent provided in Section 365(n) of the Bankruptcy Code.

**13.6.2.** All rights, powers and remedies provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code with respect to either Party. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, and to be enforceable under Bankruptcy Code Section 365(n) upon any rejection of this Agreement: (a) the right of access to any IP (including all embodiments thereof) of the license-granting Party or any Third Party with whom the license-granting Party contracts to perform any of its obligations

under this Agreement; and (b) the right to contract directly with any such Third Party to complete the contracted work.

**13.7. Survival of Certain Provisions.** Termination of this Agreement for any reason or expiration of this Agreement will not release either Party from any obligation arising prior to the date of expiration or termination. The rights and obligations under Section 3.8.1 and Section 3.8.3 (in each case solely with respect to amounts accruing prior to the effective date of termination or expiration of this Agreement and record-keeping and audits with respect to such amounts), Section 6.1.3, Section 7.1, Section 10.1, Section 13.5 and this Section 13.7 and Article 1 (solely to the extent necessary to give effect to the other surviving provisions), Article 8, Article 9 (solely with respect to amounts accruing prior to the effective date of termination or expiration of this Agreement, and record-keeping and audits with respect to such amounts), Article 11, Article 12 and Article 14, in each case, only in the event and to the extent applicable, and subject to the terms and conditions stated therein, will survive any expiration or termination of this Agreement. Any right to terminate this Agreement, and any rights a Party has under Section 13.5, as applicable, shall be cumulative and not exclusive and will be in addition to any other rights or remedies that the Party giving notice of termination may have under Applicable Law or in equity or otherwise.

#### **Article 14**

##### **GENERAL PROVISIONS**

**14.1. Notices.** All notices, reports, requests or demands required or permitted under this Agreement will be sent by hand or overnight courier, properly addressed to the respective Parties as follows:

If to Alkermes:

Alkermes Pharma Ireland Limited  
Connaught House  
1 Burlington Road  
Dublin 4, Ireland  
Attention: President

With a copy to:

Alkermes Public Limited Company  
Connaught House  
1 Burlington Road  
Dublin 4, Ireland  
Attention: Chief Legal Officer

If to Biogen:

Biogen MA Inc.  
225 Binney Street  
Cambridge, MA 02142  
Attention: Executive Vice President, Head of R&D

With a copy to:

Biogen MA Inc.  
225 Binney Street  
Cambridge, MA 02142  
Attention: Chief Legal Officer

and

Ropes & Gray LLP  
Prudential Tower, 800 Boylston Street  
Boston, MA 02199-3600  
Attention: Susan Galli, Esq.

or to such address or addresses as the Parties hereto may designate for such purposes during the Term. Notices will be deemed to have been sufficiently given or made: (i) if by hand, when delivered, and (ii) if by overnight courier, upon receipt by the applicable Party.

**14.2. Governing Law.** This Agreement and all questions regarding the existence, validity, interpretation, breach or performance of this Agreement will be governed by and construed in accordance with the laws of the State of New York (other than its choice of law principles).

**14.3. Entire Agreement; Amendment.** This Agreement, together with the Exhibits hereto, represent the entire agreement between the Parties regarding the subject matter hereof, and supersedes all prior or contemporaneous written or oral promises or representations relating such subject matter not incorporated herein (including the Confidentiality Agreements). The Parties are not relying, and have not relied, on any representations or warranties whatsoever regarding the subject matter of this Agreement, express or implied, except for the representations and warranties set forth in this Agreement. No amendment or modification of the terms and conditions of this Agreement will be binding on either Party unless reduced to writing referencing this Agreement and signed by a duly authorized officer of each Party.

**14.4. Binding Effect and Assignment.** This Agreement will be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns. This Agreement will not be assignable by either Party without the other Party's prior written consent; *provided, however*, that either Party may assign its rights or obligations under this Agreement (in whole or in part), without the other Party's written consent but with notice to the other Party, to an Affiliate. If any Affiliate to which a Party has assigned its rights or obligations under this Agreement thereafter ceases to be an Affiliate of such Party, then such assignment will be deemed to require the consent of the other Party pursuant to this Section 14.4. To the extent that the assigning Party survives as a legal entity, the assigning Party shall remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned to such assignee. Either Party may also assign this Agreement (in whole or in part) without the other Party's written consent, but with notice to the other Party, to any successor pursuant to a Change of Control, and Biogen may assign this Agreement (in whole or in part), without Alkermes' written consent but with notice to Alkermes in connection with the sale or other

transfer to a Third Party of all or substantially all of Biogen's assets to which this Agreement relates (i.e., Tecfidera®, Fumaderm® and any Product).

**14.5. Waiver.** No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. A waiver by either Party of any of the terms and conditions of this Agreement in any instance will not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement will be cumulative and none of them will be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

**14.6. Severability.** If any part of this Agreement will be found to be invalid, illegal or unenforceable under Applicable Law in any jurisdiction, such part will be ineffective only to the extent of such invalidity, illegality or unenforceability in such jurisdiction, without in any way affecting the remaining parts of this Agreement in that jurisdiction or the validity, legality or enforceability of the Agreement as a whole in any other jurisdiction. In addition, the part that is ineffective will be reformed in a mutually agreeable manner so as to as nearly approximate the intent of the Parties as possible.

**14.7. Counterparts and Signatures.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original for all purposes, but all of which together will constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

**14.8. Force Majeure.** Neither Party will be held liable or responsible to the other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in performing its obligations hereunder (except for payment of money) to the extent, and as long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party (a "**Force Majeure Delay**"), including fire, floods, embargoes, war, civil commotions, terrorism, strikes, lockouts or other labor disturbances, acts of God, acts of a Governmental Authority or judicial orders or decrees. In the event of a Force Majeure Delay, the affected Party will give prompt notice thereof to the other Party (to the extent possible), will use commercially reasonable efforts to mitigate the adverse consequences thereof and will resume performance hereunder with dispatch whenever the consequences of the Force Majeure Delay have been mitigated.

**14.9. Ambiguities.** Ambiguities, if any, in this Agreement will not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

**14.10. Headings.** Headings are for the convenience of reference only and will not control the construction or interpretation of any of the provisions of this Agreement.

**14.11. No Partnership.** Nothing in this Agreement is intended or will be deemed to constitute a partnership, agency, or joint venture relationship between the Parties.

Notwithstanding any of the provisions of this Agreement, neither Party will at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever.

**14.12. No Third Party Beneficiaries.** No Person other than Alkermes, Biogen and their respective successors and permitted assigns shall be deemed an intended beneficiary hereunder or have any right to enforce any provision of this Agreement.

**14.13. Performance by an Affiliate.** Each of Biogen and Alkermes acknowledges that obligations under this Agreement may be performed by Affiliates of Biogen and Alkermes. Each of Biogen and Alkermes will remain responsible for any obligations of such Party under this Agreement undertaken by one or more of its Affiliates.

**14.14. Further Assurances.** Each Party agrees to do and perform all such further acts and things and shall execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may deem advisable in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

*[Signature page follows]*

**In Witness Whereof**, each of the Parties has caused this Agreement to be executed and delivered by its duly authorized representatives to be effective as of the Effective Date.

**ALKERMES PHARMA IRELAND  
LIMITED**

**BIOGEN SWISS MANUFACTURING  
GMBH**

By: /s/ Shane Cooke

By: /s/ Fred Lawson

Name: Shane Cooke

Name: F. Lawson

Title: Director

Title: Director

Date: November 27, 2017

Date: 26/11/2017

**Signature Page to License and Collaboration Agreement**

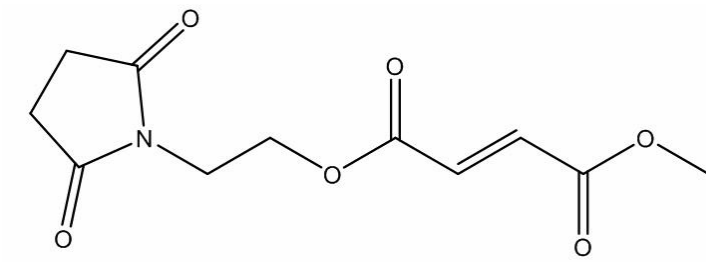
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**EXHIBIT A**

**Alkermes 8700 Chemical Structure**

The chemical structure of the active ingredient in the Alkermes 8700 Product:



**EXHIBIT B**  
**Licensed Patents**

B-1

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EPLG DOCKET NO.	COUNTRY	TYPE	STATUS	APPLICATION NO.	FILING DATE	PUBLICATION NO.	PATENT NO.	GRANT DATE
<b>Prodrugs of Fumarates and Their Use in Treating Various Diseases</b>								
4165.3059 AE	AE	NSPCT (Patent)	Pending	12192015	Mar 14, 2014			
4165.3059 AU	AU	NSPCT (Patent)	Issued	2014239641	Mar 14, 2014		2014239641	Feb 2, 2017
4165.3059 AUD	AU	DIV (Patent)	Pending	2016222363	Mar 14, 2014			
4165.3059 BR	BR	NSPCT (Patent)	Pending	1120150228542	Mar 14, 2014			
4165.3059 CA	CA	NSPCT (Patent)	Pending	2906580	Mar 14, 2014			
4165.3059 CAD	CA	DIV (Patent)	Pending		Mar 14, 2014			
4165.3059 CN	CN	NSPCT (Patent)	Issued	2014800244589	Mar 14, 2014	CN 105452213 A	201480024458.9	Sep 22, 2017
4165.3059 CND	CN	DIV (Patent)	Pending	2017105365373	Mar 14, 2014			
4165.3059 EA	EA	NSPCT (Patent)	Pending	201500926	Mar 14, 2014			
4165.3059 EP	EP	NSPCT (Patent)	Pending	147678924	Mar 14, 2014		2970101	
4165.3059 HKEP	HK	ORG (Patent)	Pending	161008869	Mar 14, 2014		1212966	
4165.3059 ID	ID	NSPCT (Patent)	Pending	P00201506474	Mar 14, 2014		2017/03745	
4165.3059 IL	IL	NSPCT (Patent)	Pending	241440	Mar 14, 2014			
4165.3059 IN	IN	NSPCT (Patent)	Pending	83190ELNP2015	Mar 14, 2014			
4165.3059 JP	JP	NSPCT (Patent)	Pending	2016-502423	Mar 14, 2014		2016-520524	
4165.3059 JPD	JP	DIV (Patent)	Pending	2017070509	Mar 14, 2014		2017-149735	
4165.3059 KR	KR	NSPCT (Patent)	Allowed	1020157029339	Mar 14, 2014		10-2015-0131284	
4165.3059 MO	MO	CONF (Patent)	Pending		Mar 14, 2014			
4165.3059 MX	MX	NSPCT (Patent)	Pending	MXa2015011897	Mar 14, 2014			
4165.3059 NZ	NZ	NSPCT (Patent)	Issued	631337	Mar 14, 2014		631337	Apr 28, 2017
4165.3059 NZD	NZ	DIV (Patent)	Pending	723459	Mar 14, 2014			
4165.3059 NZD1	NZ	DIV (Patent)	Pending		Mar 14, 2014			
4165.3059 SG	SG	NSPCT (Patent)	Abandoned	11201507371R	Mar 14, 2014			
4165.3059 SGD	SG	DIV (Patent)	Allowed	10201707543P	Mar 14, 2014			
4165.3059 SGD1	SG	DIV (Patent)	Pending	10201707547T	Mar 14, 2014			

EPLG DOCKET NO.	COUNTRY	TYPE	STATUS	APPLICATION NO.	FILING DATE	PUBLICATION NO.	PATENT NO.	GRANT DATE
4165.3059 UA	UA	NSPCT (Patent)	Pending	a201509885	Mar 14, 2014			
4165.3059 US	US	ORG (Patent)	Expired	61782445	Mar 14, 2013			
4165.3059 US1	US	ORG (Patent)	Issued	14032736	Sep 20, 2013		8669281	Mar 11, 2014
4165.3059 US2	US	ORG (Patent)	Expired	61934365	Jan 31, 2014			
4165.3059 US3	US	DIV (Patent)	Issued	14180687	Feb 14, 2014	2014/0275205	9090558	Jul 28, 2015
4165.3059 US4	US	ORG (Patent)	Issued	14212745	Mar 14, 2014	2014/0275048	9505776	Nov 29, 2016
4165.3059 US5	US	CON (Patent)	Abandoned	14744325	Jun 19, 2015	2016/0137660		
4165.3059 US6	US	CON (Patent)	Issued	15295370	Oct 17, 2016	2017/0095439	9775823	Oct 3, 2017
4165.3059 US7	US	DIV (Patent)	Pending	15683189	Aug 22, 2017			
4165.3059 US8	US	CON (Patent)	Pending	15704219	Sep 14, 2017			
4165.3059 US9	US	CON (Patent)	Pending	15782128	Oct 12, 2017			
4165.3059 WO	WO	ORG (Patent)	Completed	PCTUS2014027401	Mar 14, 2014	WO2014/152494		
4165.3059 ZA	ZA	NSPCT (Patent)	Pending	201506754	Mar 14, 2014			
4165.3059 ZAD	ZA	DIV (Patent)	Pending	201706118	Mar 14, 2014			
<b>Monomethylfumurate Prodrug Compositions</b>								
4165.1000 AE	AE	NSPCT (Patent)	Pending	P60008962017	Mar 10, 2015			
4165.1000 AU	AU	NSPCT (Patent)	Pending	2015381240	Mar 10, 2015			
4165.1000 BR	BR	NSPCT (Patent)	Pending	1120170163780	Mar 10, 2015			
4165.1000 CA	CA	NSPCT (Patent)	Pending	2972179	Mar 10, 2015			
4165.1000 CN	CN	NSPCT (Patent)	Pending	2015800746607	Mar 10, 2015	CN 107205985 A		
4165.1000 EA	EA	NSPCT (Patent)	Pending	201791432	Mar 10, 2015			
4165.1000 EG	EG	NSPCT (Patent)	Pending	20171208	Mar 10, 2015			
4165.1000 EP	EP	NSPCT (Patent)	Pending	157605080	Mar 10, 2015			
4165.1000 ID	ID	NSPCT (Patent)	Pending	P00201704824	Mar 10, 2015			
4165.1000 IL	IL	NSPCT (Patent)	Pending	252962	Mar 10, 2015			

EPLG DOCKET NO.	COUNTRY	TYPE	STATUS	APPLICATION NO.	FILING DATE	PUBLICATION NO.	PATENT NO.	GRANT DATE
4165.1000 IN	IN	NSPCT (Patent)	Pending	201727027097	Mar 10, 2015			
4165.1000 JP	JP	NSPCT (Patent)	Pending	2017539611	Mar 10, 2015			
4165.1000 KR	KR	NSPCT (Patent)	Pending	1020177020434	Mar 10, 2015			
4165.1000 MX	MX	NSPCT (Patent)	Pending	MXa2017009849	Mar 10, 2015			
4165.1000 NZ	NZ	NSPCT (Patent)	Pending	732807	Mar 10, 2015			
4165.1000 SG	SG	NSPCT (Patent)	Pending	11201705124Q	Mar 10, 2015			
4165.1000 UA	UA	NSPCT (Patent)	Pending	a201707666	Mar 10, 2015			
4165.1000 US	US	ORG (Patent)	Expired	62113496	Feb 8, 2015			
4165.1000 US1	US	ORG (Patent)	Pending	15017817	Feb 8, 2016	2016/0228376		
4165.1000 WO	WO	ORG (Patent)	Completed	PCTIB20150000731	Mar 10, 2015	WO2016/124960		
4165.1000 ZA	ZA	NSPCT (Patent)	Pending	201705169	Mar 10, 2015			
<b>Sulfonamide and Sulfonamide Prodrugs of Fumarates and Their Use in Treating Various Diseases</b>								
4165.1001 AU	AU	NSPCT (Patent)	Issued	2015218587	Feb 24, 2015		2015218587	Aug 10, 2017
4165.1001 CA	CA	NSPCT (Patent)	Pending	2940845	Feb 24, 2015			
4165.1001 EP	EP	NSPCT (Patent)	Pending	157514837	Feb 24, 2015	3110793		
4165.1001 HKEP	HK	ORG (Patent)	Pending	171014487	Feb 24, 2015	1227839A		
4165.1001 JP	JP	NSPCT (Patent)	Pending	2016553405	Feb 24, 2015	2017-511799		
4165.1001 NZ	NZ	NSPCT (Patent)	Issued	723269	Feb 24, 2015		723269	Aug 1, 2017
4165.1001 US	US	ORG (Patent)	Expired	61943699	Feb 24, 2014			
4165.1001 US1	US	ORG (Patent)	Issued	14630248	Feb 24, 2015	2015/0239829	9604922	Mar 28, 2017
4165.1001 US2	US	CON (Patent)	Pending	15363610	Nov 29, 2016	2017/0129851		
4165.1001 WO	WO	ORG (Patent)	Completed	PCTUS1517322	Feb 24, 2015	WO2015/127450		

**EXHIBIT C**  
**Initial Development Plan**

C-1

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**ALKS 8700 Product High-Level Development Plan**

\* The activities that are allocated to Alkermes, unless otherwise agreed in writing by the Parties, are (1) all activities prior to the Transfer Completion Date and (2) transition of the P3 Long-Term Safety Study (-A301) to Biogen following the Transfer Completion Date.

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**Detailed ALKS 8700 Product Plan – Multiple Sclerosis (505b2)**

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\* The activities that are allocated to Alkermes, unless otherwise agreed in writing by the Parties, are (1) all activities prior to the Transfer Completion Date and (2) t



**ALKS 8700 Development Plan Budget – Multiple Sclerosis**

Spend in \$M	FY'17	FY'17	FY'17	FY'17	FY'17	FY'18	FY'18	FY'18	FY'18	FY'18	FY'19	FY'19	FY'19	FY'19	FY'19
	Total	Q1	Q2	Q3	Q4	Total	Q1	Q2	Q3	Q4	Total	Q1	Q2	Q3	Q4
<b>Base ALKS 8700 Development (FY16 - FY'21)</b>	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Clinical															
Phase 1 PK and Clinical Pharmacology Studies	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
ALKS 8700 FIH Study (-001)	[**]					[**]					[**]				
ALKS 8700 MAD / FE Study (-A102)	[**]					[**]					[**]				
ALKS 8700 Relative BA Study Fasted Condition (-A103)	[**]					[**]					[**]				
ALKS 8700 Relative BA Study Fed (HF) Condition (-A104)	[**]					[**]					[**]				
ALKS 8700 Mass Balance Study (-A105)	[**]	[**]	[**]	[**]	[**]	[**]					[**]				
ALKS 8700 Alcohol Dose Dumping Study (-A106)	[**]	[**]	[**]	[**]	[**]	[**]					[**]				
ALKS 8700 DDI Study (-A107)	[**]	[**]	[**]	[**]	[**]	[**]					[**]				
ALKS 8700 Renal Study (-A108)	[**]	[**]	[**]	[**]	[**]	[**]					[**]				
ALKS 8700 Additional Food Effect Study (-A109)	[**]	[**]	[**]	[**]	[**]	[**]					[**]				
ALKS 8700 Potential IQT Study	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]			[**]				
Phase 3 Long-term Safety Study (-A301)	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Phase 3 Tolerability Study (-A302)	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Clinical CRO Credits	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Translational Medicine	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Non-Clinical															
2-Yr Rat Study	[**]	[**]			[**]	[**]	[**]				[**]				
Mouse Carci Studies	[**]	[**]	[**]	[**]	[**]	[**]					[**]				
Additional Non-Clinical Studies/Activities	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]				
CMC															
API & Drug Product Development, Manufacturing, and Supply	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Medical Affairs															
PRO Development & Additional Medical Affairs Activities	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
NDA Submission Fee & supporting preparation spend	[**]					[**]	[**]	[**]	[**]	[**]	[**]				
Other – All	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
<b>Pediatric Plan Activities</b>	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Non-clinical Studies	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]				
Adult PK Sprinkling Study	[**]					[**]					[**]				
Pediatric PK Study	[**]					[**]					[**]				
Pediatric Extension	[**]					[**]					[**]				
<b>ALKS 8700 External Spend Projection</b>	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
<b>ALKS 8700 Internal Spend Projection</b>	[**]					[**]	[**]			[**]	[**]				
<b>Total R&amp;D</b>	[**]					[**]					[**]				

<b>Name of Sponsor/ Company:</b> Alkermes, Inc.	
<b>Name of Investigational Product:</b> ALKS 8700	
<b>Name of Active Ingredient:</b> ALKS 8700	
<b>Title of study:</b> A Phase 3 Open Label Study to Evaluate the Long-term Safety and Tolerability of ALKS 8700 in Adults with Relapsing Remitting Multiple Sclerosis	
<b>Investigators:</b> This study will be conducted at approximately 125 sites in North America and Europe.	
<b>Study Period:</b> Estimated date of first subject's consent: Q4 2015 Estimated date of last subject's last visit: Q4 2020	<b>Phase of Development:</b> 3
<b>Objectives:</b> <ul style="list-style-type: none"><li>• Evaluate the long-term safety and tolerability of ALKS 8700 for up to 96 weeks of treatment in adult subjects with relapsing remitting multiple sclerosis (RRMS)</li><li>• Evaluate treatment effect over time in adult subjects with RRMS treated with ALKS 8700</li></ul>	
<b>Methodology:</b> [**]	

<b>Study Design Schematic</b> [**]
<b>Number of Subjects Planned:</b> [**]
<b>Main Criteria for Inclusion:</b> [**]
<b>Investigational Product, Dosage, Duration and Mode of Administration:</b> [**]
<b>Reference Therapy, Dosage, Duration and Mode of Administration:</b> [**]
<b>Duration of Study:</b> [**]

**Criteria for Evaluation:**

**Safety and Tolerability:**

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**Efficacy:**

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**Pharmacokinetics:**

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**Statistical Methods:** [\*\*]

**Study Populations:** [\*\*]

**Safety: [\*\*]**

**Efficacy: [\*\*]**

**Pharmacokinetics: [\*\*]**

**Sample Size Considerations: [\*\*]**

<b>Name of Sponsor/ Company:</b> Alkermes, Inc.	
<b>Name of Investigational Product:</b> ALKS 8700	
<b>Name of Active Ingredient:</b> ALKS 8700	
<b>Title of study:</b> A Phase 3 Study in Subjects with Relapsing Remitting Multiple Sclerosis to Evaluate the Tolerability of ALKS 8700 and Dimethyl Fumarate	
<b>Investigators:</b> This study will be a multicenter study.	
<b>Study Period:</b> Estimated date of first subject's consent: Q1 2017 Estimated date of last subject's last visit: [**]	<b>Phase of Development:</b> 3
<b>Objectives:</b> <ul style="list-style-type: none"> <li>• Evaluate the utility of two GI symptom scales (IGISIS and GGISIS) and endpoints derived from the scales in assessing GI tolerability in adult subjects with relapsing remitting multiple sclerosis (RRMS) (after administration of ALKS 8700 or DMF in Part A</li> <li>• Compare the GI tolerability of ALKS 8700 and DMF in adult subjects with RRMS using two GI symptom scales (IGISIS and GGISIS) in Part B with endpoints informed from Part A</li> <li>• Evaluate the safety and tolerability of ALKS 8700 in adult subjects with RRMS in Parts A and B</li> </ul>	
<b>Methodology (Part A and Part B):</b> [**]	

<b>Number of Subjects Planned (Part A and Part B): [**]</b>
<b>Main Criteria for Inclusion (Part A and Part B): [**]</b>
<b>Investigational Product, Dosage, Duration and Mode of Administration (Part A and Part B): [**]</b>
<b>Reference Therapy, Dosage, Duration and Mode of Administration (Part A and Part B): [**]</b>

<b>Duration of Study (Part A and Part B):</b> [**]
<b>Criteria for Evaluation (Part A and Part B):</b> <b>Endpoints:</b> <b>Primary Endpoint:</b> [**] <b>Secondary Endpoints:</b> [**] <b>Safety and Tolerability (Part A and Part B):</b> [**]
<b>Exploratory Efficacy (Part A and Part B):</b> [**]
<b>Pharmacokinetics (Part A):</b> [**]



**Statistical Methods (Part A and Part B):**  
**Sample Size Considerations (Part A and Part B):** [\*\*]

**Study Populations (Part A and Part B):** [\*\*]

**Safety Analyses (Part A and Part B):** [\*\*]

**GI Tolerability Analyses (Part A and Part B):** [\*\*]

**Exploratory Efficacy Analyses (Part A and Part B):** [\*\*]

**Pharmacokinetics Analyses (Part A):** [\*\*]

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<b>Name of Sponsor/ Company:</b> Alkermes, Inc.	
<b>Name of Investigational Product:</b> ALKS 8700	
<b>Name of Active Ingredient:</b> ALKS 8700	
<b>Title of study:</b> A Phase 1 Study of the Pharmacokinetics, Safety and Tolerability of ALKS 8700 in Subjects with Renal Impairment	
<b>Investigators:</b> This study will be conducted at multiple centers study in the United States.	
<b>Study Period:</b> Estimated date of first subject's consent: Q4 2016 Estimated date of last subject's last visit: Q2 2017	<b>Phase of Development:</b> 1
<b>Objectives:</b> The objective of this study is to compare the pharmacokinetics (PK), safety and tolerability of ALKS 8700 in subjects with mild, moderate and severe renal impairment versus healthy control subjects following single dose administration.	
<b>Methodology:</b> [**]	

<b>Study Design Schematic</b> [**]
<b>Number of Subjects Planned:</b> [**]
<b>Main Criteria for Inclusion:</b> [**]
<b>Investigational Product, Dosage, Duration and Mode of Administration:</b> [**]
<b>Reference Therapy, Dosage, Duration and Mode of administration:</b> [**]

<b>Duration of Study:</b> [**]
<b>Criteria for Evaluation:</b> <b>Pharmacokinetics:</b> [**] <b>Safety:</b> [**]
<b>Statistical Methods:</b> [**] <b>Analyses Populations:</b> [**] <b>Pharmacokinetic Analysis:</b> [**]

**Safety Analysis: [\*\*]**

**Sample Size Considerations: [\*\*]**

<b>Name of Sponsor/ Company:</b> Alkermes, Inc.	
<b>Name of Investigational Product:</b> ALKS 8700	
<b>Name of Active Ingredient:</b> Monomethyl fumarate	
<b>Title of study:</b> A Phase 1 Study to Evaluate the Effect of Multiple Doses of ALKS 8700 on QTc Interval in Healthy Volunteers	
<b>Investigator(s):</b> Single center study in the US	
<b>Study Period (years):</b> Estimated date of first patient visit: Q4 2017 Estimated date of last patient completed: Q1 2018	<b>Phase of Development:</b> 1
<p><b>Objectives:</b></p> <p><b>Primary:</b> To evaluate the effects of multiple doses of therapeutic and suprathreshold oral dose strengths of ALKS 8700 on the heart rate-corrected QT interval using Fridericia's formula (QTcF)</p> <p><b>Secondary:</b></p> <ul style="list-style-type: none"> <li>• To evaluate the effect of ALKS 8700 on other electrocardiogram (ECG) parameters: heart rate, PR and QRS intervals, and T-wave morphology and U-wave presence</li> <li>• To demonstrate sensitivity of the study to detect a small QT effect using moxifloxacin as a positive control</li> <li>• To evaluate the safety and tolerability of ALKS 8700</li> <li>• To evaluate the pharmacokinetic/pharmacodynamic relationship between the effect of ALKS 8700 on ECG and plasma concentrations of the metabolites monomethyl fumarate (MMF) and RDC-6567</li> </ul>	
<p><b>Methodology:</b> [**]</p>	

<b>Number of Subjects Planned:</b> [**]
<b>Main Criteria for Inclusion:</b> [**]
<b>Investigational Product, Dosage, Duration, and Mode of Administration:</b> [**]
<b>Reference Therapy, Dosage, Duration, and Mode of Administration:</b> [**]
<b>Duration of Study:</b> [**]
<b>Criteria for Evaluation:</b> <b>Primary Endpoint:</b> [**] <b>Secondary Endpoints:</b> [**]



**Pharmacokinetics/Pharmacodynamics:**

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**Safety:** [\*\*]

**Statistical Methods:** [\*\*]

**Analyses Populations:**  
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**Baseline:** [\*\*]

**Safety Analyses:** [\*\*]

**Concentration-Response Analysis:** [\*\*]

**Criteria for Negative QT Assessment: [\*\*]**

**Investigation of Hysteresis: [\*\*]**

**Assessment of Appropriateness of Model: [\*\*]**

**Assay Sensitivity: [\*\*]**

**By-Time Point Analysis: [\*\*]**

**Categorical Analyses: [\*\*]**

**Safety: [\*\*]**

**Sample Size Considerations: [\*\*]**

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**EXHIBIT D**  
**Clinical Supply Agreement Terms**

**Clinical Supply Agreement and Quality Agreement**

- The Parties will negotiate and execute a Clinical Supply Agreement and an associated Technical and Quality Agreement (“*Clinical Supply Quality Agreement*”) in accordance with Section 5.1.1 of the Agreement.

**Program of Manufacturing, Forecasts and Delivery of Products**

- A detailed program of Manufacture with a rolling Calendar Quarter forecast and order and delivery mechanisms will be outlined in the Clinical Supply Agreement.
- Biogen to supply Tecfidera® [\*\*].
- Alkermes shall have no liability as a result of any failure or delay in Manufacturing Clinical Supplies.

**Quality Assurance**

- Alkermes will Manufacture the Products in accordance with Applicable Law and cGMPs, the specifications for the Products and the terms and conditions of the Clinical Supply Agreement and the Clinical Supply Quality Agreement.
- Alkermes will perform and document those tests and checks required to assure the quality of the Product that are established by the Clinical Supply Quality Agreement.
- The Clinical Supply Agreement will contain terms establishing standards for the release, acceptance and rejection of the Products and will establish a minimum shelf life for the Products.
- In accordance with the terms of the Clinical Supply Agreement and the Clinical Supply Quality Agreement, Biogen will be entitled to inspect or have inspected those portions of the facilities that are used by Alkermes in the Manufacture of the Products as well as the relevant Manufacturing records.
- Validation batches will be treated as Clinical Supplies until such time as they are utilized in the Commercialization of Product, at which time Biogen will pay Alkermes the difference between the clinical and commercial supply prices.

**Supply Price for Clinical Supplies of Products**

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## EXHIBIT E

### Commercial Supply Agreement Terms

#### Clinical Supply Agreement and Quality Agreement

- The Parties will negotiate and execute a Commercial Supply Agreement and an associated Technical and Quality Agreement (“*Commercial Supply Quality Agreement*”) in accordance with Section 5.1 of the Agreement.

#### Program of Manufacturing, Forecasts and Delivery of Products

- A detailed program of Manufacture with a rolling Calendar Quarter forecast and order and delivery mechanisms will be outlined in the Commercial Supply Agreement.
- Product in the form of “finished goods” to be delivered Ex Works (Incoterms 2010) Athlone, Ireland.
- Biogen to provide (A) 3-year rolling forecasts and (B) 4-quarter rolling forecasts, the proximate two quarters of which shall be binding and the subsequent two quarters of which may be increased or decreased by 20% prior to becoming binding.

#### Quality Assurance

- Alkermes will Manufacture the Products in accordance with Applicable Law and cGMPs, the specifications for the Products and the terms and conditions of the Commercial Supply Agreement and the Commercial Supply Quality Agreement.
- Alkermes will perform and document those tests and checks required to assure the quality of the Products that are established by the Commercial Supply Quality Agreement.
- The Commercial Supply Agreement will contain terms establishing standards for the release, acceptance and rejection of the Products and will establish a minimum shelf life for the Products.
- In accordance with the terms of the Commercial Supply Agreement and the Commercial Supply Quality Agreement, Biogen will be entitled to inspect or have inspected those portions of the facilities that are used by Alkermes in the Manufacture of the Products as well as the relevant Manufacturing records.

#### Supply Price for Commercial Supplies of Products

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#### Products in Process upon Termination

- For any Product that Alkermes has commenced the Manufacture of, but for which Manufacture is incomplete on the Commercial Supply Agreement termination date, Biogen shall either request that Alkermes (i) complete the Manufacture of such incomplete Product, in which case Biogen shall pay Alkermes [\*\*] or (ii) cease the



Manufacture of such incomplete Product, in which case Biogen shall pay Alkermes the costs incurred by Alkermes for such incomplete Product, as calculated in accordance with GAAP.

**Indemnification and Liability for Manufacture of Commercial Supplies of Products**

- Customary toll manufacturer indemnification provisions.
- Limitation of liability equal to one year of amounts paid to Alkermes under the Commercial Supply Agreement.
- In the event of a Serious Failure to Supply, Alkermes shall transfer to Biogen or its designee, at Biogen's cost and expense, the Manufacturing technology to enable Biogen or its designee to Manufacture Commercial Supplies.

**EXHIBIT F**

**Press Release**

Biogen Contacts:  
For Investors: Matt Calistri +1 781 464 2442  
For Media: Matt Fearer +1 781 464 3260

Alkermes Contacts:  
For Investors: Sandy Coombs +1 781 609 6377  
Eva Stroynowski +1 781 609 6823  
For Media: Jennifer Snyder +1 781 609 6166

**BIOGEN AND ALKERMES ANNOUNCE LICENSE AND COLLABORATION  
AGREEMENT TO DEVELOP AND COMMERCIALIZE ALKS 8700 FOR THE  
TREATMENT OF MULTIPLE SCLEROSIS**

— *Novel, Oral, Fumarate Therapy Intended to Provide a Differentiated Gastrointestinal Tolerability Profile* —

— *Biogen Brings Multiple Sclerosis Expertise to Commercialization of ALKS 8700* —

— *New Drug Application Anticipated for Submission in 2018* —

**Cambridge, Mass and Dublin, Ireland., Nov. 27, 2017** — Biogen (Nasdaq: BIIB) and Alkermes plc (Nasdaq: ALKS) today announced that they have entered into a global license and collaboration agreement to develop and commercialize ALKS 8700, a novel, oral, monomethyl fumarate (MMF) small drug molecule in Phase 3 development for the treatment of relapsing forms of multiple sclerosis (MS).

“This partnership is further evidence of Biogen’s ongoing commitment to multiple sclerosis and builds upon our deep experience in neuroscience and particularly in MS,” stated Michel Vounatsos, Chief Executive Officer at Biogen. “We aim to provide patients with a new oral therapy which may bring differentiated benefits.”

“This collaboration has the potential to provide important benefits to patients with multiple sclerosis and immediately increases the value of ALKS 8700 to Alkermes,” said Richard Pops, Chief Executive Officer at Alkermes. “Biogen has a broad product portfolio and a highly experienced commercial team. In Biogen’s hands, we believe that patients will have broader and more rapid access to this important medicine. Meanwhile, we will focus our growing commercial capabilities on our expanding portfolio of medicines in psychiatry, including addiction, schizophrenia and depression.”

Under the terms of the agreement, Biogen will receive an exclusive, worldwide license to commercialize ALKS 8700 and will pay Alkermes a mid-teens royalty on worldwide net sales of ALKS 8700.

This collaboration aligns the interests of Alkermes and Biogen in the successful development and commercialization of ALKS 8700 as an important potential treatment option for patients

suffering from MS. Biogen will reimburse Alkermes for fifty percent (50%) of the 2017 ALKS 8700 development costs, with Alkermes receiving an upfront payment of \$28 million representing Biogen's share of development expenses already incurred in 2017. Beginning Jan. 1, 2018, Biogen will be responsible for all development expenses related to ALKS 8700. Alkermes may also receive milestone payments for ALKS 8700 with a maximum aggregate value of \$200 million upon certain clinical and regulatory achievements. Biogen anticipates the initial milestone payment of \$50 million will be recorded as an expense in 2017.

Alkermes will maintain responsibility for regulatory interactions with the U.S. Food and Drug Administration (FDA) through the potential approval of the New Drug Application (NDA) for ALKS 8700 for the treatment of MS. Biogen shall be responsible for all commercialization activities for ALKS 8700.

ALKS 8700 is currently in Phase 3 development for MS. Alkermes plans to seek approval of ALKS 8700 under the 505(b)(2) regulatory pathway referencing Biogen's TECFIDERA® (dimethyl fumarate). The registration package for ALKS 8700 will include pharmacokinetic bridging studies that establish bioequivalence to TECFIDERA and data from a two-year safety study known as EVOLVE-MS-1. Initial safety data from EVOLVE-MS-1 were recently presented at MSParis2017, the 7<sup>th</sup> Joint Meeting of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) and the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) in October. Safety data from the first month of the EVOLVE-MS-1 study (N=580) showed that treatment with ALKS 8700 was associated with low rates of gastrointestinal (GI) adverse events (AEs) leading to discontinuation and no occurrence of serious GIAEs. The most common AEs during the first month of treatment with ALKS 8700 were flushing, pruritus and diarrhea.

Also, currently underway is a head-to-head study (EVOLVE-MS-2) evaluating the GI tolerability of ALKS 8700 compared to TECFIDERA. Initial data from EVOLVE-MS-2 are expected in the first half of 2018.

**About the EVOLVE-MS Clinical Development Program**

The key components of the EVOLVE-MS (Endeavoring to Advance Treatment for Patients Living with Multiple Sclerosis) clinical development program of ALKS 8700 include a two-year safety study and pharmacokinetic bridging studies comparing ALKS 8700 and TECFIDERA. In addition, the program includes an elective head-to-head study comparing the GI tolerability of ALKS 8700 and TECFIDERA.

**About ALKS 8700**

ALKS 8700 is an oral, novel and proprietary monomethyl fumarate (MMF) prodrug candidate in development for the treatment of relapsing forms of multiple sclerosis (MS). ALKS 8700 is designed to rapidly and efficiently convert to MMF in the body and to offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA®.

**About Multiple Sclerosis**

Multiple sclerosis (MS) is an unpredictable, often disabling disease of the central nervous system (CNS), which interrupts the flow of information within the brain, and between the brain and

body.<sup>1</sup> MS symptoms can vary over time and from person to person. Symptoms may include extreme fatigue, impaired vision, problems with balance and walking, numbness or pain and other sensory changes, bladder and bowel symptoms, tremors, problems with memory and concentration and mood changes, among others.<sup>1</sup> Approximately 400,000 individuals in the U.S. and 2.5 million people worldwide have MS, and most are diagnosed between the ages of 15 and 50.<sup>2</sup>

#### **About Alkermes plc**

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes' website at [www.alkermes.com](http://www.alkermes.com).

#### **About Biogen**

At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases. Founded in 1978 as one of the world's first global biotechnology companies by Charles Weissman, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp, today Biogen has the leading portfolio of medicines to treat multiple sclerosis; has introduced the first and only approved treatment for spinal muscular atrophy; and is focused on advancing neuroscience research programs in Alzheimer's disease and dementia, neuroimmunology, movement disorders, neuromuscular disorders, pain, ophthalmology, neuropsychiatry, and acute neurology. Biogen also manufactures and commercializes biosimilars of advanced biologics.

We routinely post information that may be important to investors on our website at [www.biogen.com](http://www.biogen.com).

To learn more, please visit [www.biogen.com](http://www.biogen.com) and follow us on social media Twitter, LinkedIn, Facebook, YouTube.

#### **Biogen Safe Harbor**

This press release contains forward-looking statements, made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements relating to the potential benefits and results, including financial and operating results, that may be achieved through Biogen's license agreement with Alkermes, risks and uncertainties associated with drug development and commercialization, the potential benefits, safety, efficacy and clinical effects of ALKS 8700, the timing and status of regulatory filings, and the potential of Biogen's commercial business and pipeline programs, including ALKS 8700. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "will," and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure

regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation: uncertainty as to whether the anticipated benefits and potential of Biogen's license agreement with Alkermes can be achieved; risks that Biogen and/or Alkermes may not fully enroll the clinical trials for ALKS 8700 or will take longer than expected; risks of unexpected costs or delays; uncertainty of success in the development and potential commercialization of ALKS 8700, which may be impacted by, among other things, unexpected concerns that may arise from additional data or analysis, the occurrence of adverse safety events, failure to obtain regulatory approvals in certain jurisdictions, failure to protect and enforce Biogen's data, intellectual property, and other proprietary rights and uncertainties relating to intellectual property claims and challenges; third party collaboration risks; and uncertainty of Biogen's success in developing, licensing, or acquiring other product candidates or additional indications for existing products. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this press release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

**Alkermes Note Regarding Forward-Looking Statements**

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the continued expansion of Alkermes' portfolio of medicines in psychiatry, the continued clinical development and the potential therapeutic and commercial value of ALKS 8700 for the treatment of relapsing forms of MS, the number of patients enrolled in the ALKS 8700 Phase 3 studies, the timing of expected initial data from EVOLVE-MS-2, the regulatory strategy for filing of an NDA for ALKS 8700 and the adequacy of the EVOLVE-MS development program for ALKS 8700 to serve as the basis for an NDA, the timing of the submission of an NDA to the FDA for ALKS 8700 and the potential financial, commercial and therapeutic benefits that may be achieved through collaboration with Biogen under the license and collaboration agreement between Alkermes and Biogen. Alkermes cautions that forward-looking statements are inherently uncertain. Although Alkermes believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether the results from the head-to-head study to evaluate the GI tolerability of ALKS 8700 compared to TECFIDERA will show that ALKS 8700 has more favorable GI tolerability; whether preclinical and early clinical results for ALKS 8700 will be predictive of future clinical study results or real-world results; whether clinical trials for ALKS 8700 will be completed on time or at all; changes in the cost, scope and duration of the ALKS 8700 clinical trials; whether

ALKS 8700 could be shown ineffective or unsafe during clinical studies, and whether, in such instances, Alkermes may not be permitted by regulatory authorities to undertake new or additional clinical studies of ALKS 8700; whether regulatory submissions for ALKS 8700 will be submitted on time or at all; whether adverse decisions by regulatory authorities will occur; whether the pharmacokinetic, Phase 3 and other studies conducted for ALKS 8700 will meet the FDA's requirements for approval; whether the potential financial, commercial and therapeutic benefits of collaboration with Biogen under the license and collaboration agreement between Alkermes and Biogen will be achieved; and those risks described in the Alkermes Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017 and September 30, 2017 and in subsequent filings made by Alkermes with the U.S. Securities and Exchange Commission (SEC), which are available on the SEC's website at [www.sec.gov](http://www.sec.gov). Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

TECFIDERA® is a registered trademark of Biogen Inc.

<sup>1</sup> National Multiple Sclerosis Society. Multiple Sclerosis: Just the Facts. Accessed from <http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Brochure-Just-the-Facts.pdf> on Nov. 27, 2017.

<sup>2</sup> Multiple Sclerosis Association of America. MS Overview. Accessed from <http://mymsaa.org/ms-information/overview/who-gets-ms/> on Nov. 27, 2017.

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**Schedule 1.1.26**  
**GI Tolerability Data Package**

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Schedule 1.1.26

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**Schedule 5.1**  
**Change of Control - Competitors**

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Schedule 5.1

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**Schedule 10.3.3**

Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012, as further amended by that certain Amendment No. 2 to Amended and Restated Credit Agreement dated as of February 14, 2013, and as amended by that certain Amendment No. 3 and Waiver to Amended and Restated Credit Agreement dated as of May 22, 2013 and by that certain Amendment No. 4 to Amended and Restated Credit Agreement dated as of October 12, 2016, among ALKERMES, INC., a corporation organized under the laws of the Commonwealth of Pennsylvania, ALKERMES PLC, a company incorporated under the laws of the Republic of Ireland (registered number 498284) (“Holdings”), ALKERMES PHARMA IRELAND LIMITED, a private limited company organized under the laws of the Republic of Ireland (registered number 448848) and a wholly owned indirect subsidiary of Holdings (the “Intermediate Holdco”), ALKERMES US HOLDINGS, INC., a Delaware corporation and a wholly owned subsidiary of Intermediate Holdco, certain other subsidiaries of Holdings, the several banks and other financial institutions or entities from time to time parties to the Credit Agreement as lenders, MORGAN STANLEY SENIOR FUNDING, INC., as administrative agent, MORGAN STANLEY SENIOR FUNDING, INC., Citigroup Global Markets, Inc. and JPMorgan Chase Bank, N.A. as co-syndication agents, and MORGAN STANLEY SENIOR FUNDING, INC., as collateral agent.

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Schedule 10.3.3

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April 24, 2017

Dear Craig,

On behalf of Alkermes Inc., I am pleased to offer you the position of Senior Vice President, Clinical Development and Medical Affairs, Chief Medical Officer, reporting to Elliot Ehrich, Executive Vice President, Research and Development. This is a full-time exempt position and will be located in Waltham, MA.

This letter, and its accompanying documents, confirms the terms of the offer.

- Base Pay:** Your starting annual salary will be \$550,000, subject to applicable taxes and withholdings. You will be paid bi-weekly.
- Annual Bonus:** You will be eligible to participate in the 2017 Performance Pay Plan. Your annual Performance Pay target will be 50% and will not be prorated. Your actual Performance Pay will be based on individual and company performance. You must be actively employed by Alkermes on the date the bonus is paid to receive a Performance Pay bonus.
- Sign-On Bonus:** You will receive a sign-on bonus of \$250,000. This is a one-time payment that is considered wages and is therefore subject to supplemental income tax rates. Your sign-on bonus should be paid within thirty (30) days of your start date.
- If you voluntarily separate your employment with Alkermes prior to the first anniversary of your start date, you will be expected to return to Alkermes a prorated amount of your sign-on bonus. The prorated amount shall be calculated by multiplying 1/12th of your sign-on bonus amount (\$250,000) by the total number of uncompleted months of service in the one year period from your start date. Repayment of the prorated amount will be due to Alkermes within thirty (30) days of your last day of employment with Alkermes.
- Equity Participation:** Subject to approval by the Compensation Committee of the Board of Directors of Alkermes plc, you will be granted the following equity grant;
- A stock option grant of 80,000 stock options of Alkermes plc ordinary shares which will ratably vest over four (4) years on the anniversary of the grant date, provided that you remain employed by an Alkermes plc affiliated company. The options shall expire on the earlier to occur of: the 10th anniversary of the date of grant or three months after termination of your service relationship with the Company.
  - A restricted stock unit award for 5,000 shares of Alkermes plc ordinary shares which will ratably vest over four (4) years on the anniversary of the grant date, provided that you remain employed by an Alkermes plc affiliated company. In the event you cease to be employed by an Alkermes plc affiliated company, vesting shall cease.
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In addition, Alkermes currently has a Performance Share Grant which all employees who begin working at Alkermes before December 31, 2017 are eligible for. Subject to approval by the Compensation Committee of the Board of Directors of Alkermes plc, you will be granted a target grant of 8,000 Alkermes plc Performance Share Units that vest based on the company's performance against stated milestones. The number of shares is based on your anticipated start date with Alkermes. If your start date changes, the number of Performance Share Units may be adjusted. In the event you cease to be employed by an Alkermes plc affiliated company, vesting shall cease. Please see the attached information sheet for further information about this grant.

The above equity grants will be made from the Alkermes plc 2011 Stock Option and Incentive Plan, as amended (the "Plan") and will be subject to the terms and conditions of that Plan. The Compensation Committee generally meets once per month to approve grants for employees who began employment at the company during the previous month. The price of the stock option grant will be the closing price of the stock on the date of grant. You will receive notice of your equity award grant via Alkermes/Merrill Lynch's Benefits Online system. Information regarding your equity grant including the grant award certificate(s) can also be found in the Alkermes/Merrill Lynch's Benefits Online system and in the Plan. We will provide you with a copy of the Plan for complete details.

- Vacation:** In addition to location specific paid holidays, you are entitled to 3 weeks of annual vacation. During this year, your vacation allotment will be prorated in accordance with Alkermes policy.
- Benefits:** You will also be eligible to participate in the Alkermes benefits program as described in the accompanying *Decision Guide*. Medical, Dental, and Vision coverage will begin on your start date. Complete details and enrollment information will be included with your New Employee Welcome Packet.
- Offer Contingencies:** This employment offer is contingent upon successful completion of all aspects of the Alkermes pre-employment screening process. This process includes the verification of information you will provide to us for a background check.
- Background Verification Process:** This process will verify the information you have provided concerning your prior employment and education. As Alkermes is concerned with the security of our customers, employees, business partners and the general public, we will perform a criminal history check to determine whether you have criminal convictions of record and to verify your identity. For positions within our Finance department, a credit check will also be performed.
- Employment Eligibility Verification:** Please note that all persons in the United States are required to complete an Employment Eligibility Verification Form on the first day of employment and submit an original document or documents that establish identity and employment eligibility within three (3) business days of employment. For your convenience, we are enclosing Form I-9 for your review. You will need to complete Section 1 and present original document(s) of your choice as listed on the reverse side of the form once you begin work.
- Alkermes participates in the E-Verify program. E-Verify is a Social Security Administration/Department of Homeland Security program which allows employers to electronically verify each new employee's work authorization using information provided on Form I-9. The verification process will occur within three (3) business days of employment. If you would like further information regarding E-Verify, please contact Alkermes Human Resources department.
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**Proprietary  
Information,  
No Conflicts:**

You agree to execute the Company's standard Employee Agreement With Respect to Inventions and Proprietary Information and Non-Solicitation and to be bound by all of the provisions thereof. A copy is enclosed with this letter. You hereby represent that you are not presently bound by any employment agreement, confidential or proprietary information agreement or similar agreement with any current or previous employer that would impose any restriction on your acceptance of this offer or that would interfere with your ability to fulfill the responsibilities of your position with the Company.

**Employment Period:**

This letter, and its accompanying documents, set out the complete terms of our offer of employment but are not intended as, and should not be considered, a contract of employment for a fixed period of time. If you accept this offer of employment with the Company, you accept that your employment is at-will, which means that you or Alkermes are free to end the employment relationship at any time, with or without cause.

Craig, all of us here at Alkermes are very enthusiastic about the prospect of you joining the Company and have the highest expectation of your future contributions.

Please indicate your acceptance of the foregoing with your signature, and return all completed documents to the Company no later than April 28, 2017. After that date, the offer will lapse. The other duplicate original is for your records.

Best Regards,

Madeline Coffin  
Senior Vice President, Human Resources  
Alkermes Inc.

The foregoing is signed and accepted as of the date first above written by:

/s/ Craig Hopkinson  
Craig Hopkinson

25 April 2017  
Date

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## SUBSIDIARIES

<b>Name</b>	<b>Jurisdiction</b>
Alkermes Ireland Holdings Limited	Ireland
Alkermes Pharma Ireland Limited	Ireland
Alkermes Finance Ireland Limited	Ireland
Daravita Pharma Ireland Limited	Ireland
Alkermes Finance Ireland (No. 3) Limited	Ireland
Alkermes Science Four Limited	Ireland
Alkermes Science Five Limited	Ireland
Alkermes Science Six Limited	Bermuda
Daravita Limited	Ireland
Alkermes Finance S.à r.l.	Luxembourg
Alkermes Finance Ireland (No. 2) Limited	Ireland
Alkermes US Holdings, Inc.	Delaware
Alkermes, Inc.	Pennsylvania
Alkermes Controlled Therapeutics, Inc.	Pennsylvania
Alkermes Europe, Ltd.	United Kingdom

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-179545, 333-184621, 333-200777 and 333-214952) of Alkermes plc of our report dated February 16, 2018 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
February 16, 2018

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## CERTIFICATIONS

I, Richard F. Pops, certify that:

1. I have reviewed this annual report on Form 10-K of Alkermes plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Richard F. Pops

Richard F. Pops

*Chairman and Chief Executive Officer  
(Principal Executive Officer)*

February 16, 2018

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## CERTIFICATIONS

I, James M. Frates, certify that:

1. I have reviewed this annual report on Form 10-K of Alkermes plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ James M. Frates

James M. Frates

*Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)*

February 16, 2018

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Alkermes plc (the "Company") for the period ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Richard F. Pops, Chairman and Chief Executive Officer of the Company, and James M. Frates, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to our knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Richard F. Pops

Richard F. Pops  
*Chairman and Chief Executive Officer*  
*(Principal Executive Officer)*

/s/ James M. Frates

James M. Frates  
*Senior Vice President and Chief Financial Officer*  
*(Principal Financial Officer)*

February 16, 2018

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