

Alkermes plc.  
Form 10-K  
February 16, 2018  
Table of Contents

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	98 1007018
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Connaught House	

1 Burlington Road

Dublin 4, Ireland  
(Address of principal executive offices) (Zip code)

+353 1 772 8000

(Registrant's telephone number, including area code)

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

Edgar Filing: Alkermes plc. - Form 10-K

Ordinary shares, \$0.01 par value	Nasdaq Global Select Market
Title of each class	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	Smaller reporting company
		(Do not check if a 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.

---

Table of Contents

ALKERMES PLC AND SUBSIDIARIES

ANNUAL REPORT ON FORM 10 K

FOR THE YEAR ENDED DECEMBER 31, 2017

INDEX

PART I

<u>Item 1.</u>	<u>Business</u>	5
<u>Item 1A.</u>	<u>Risk Factors</u>	31
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	49
<u>Item 2.</u>	<u>Properties</u>	49
<u>Item 3.</u>	<u>Legal Proceedings</u>	49
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	49

PART II

<u>Item 5.</u>	<u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	49
<u>Item 6.</u>	<u>Selected Financial Data</u>	52
<u>Item 7.</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	54
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	72
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	73
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosures</u>	74
<u>Item 9A.</u>	<u>Controls and Procedures</u>	74
<u>Item 9B.</u>	<u>Other Information</u>	75

PART III

<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	76
<u>Item 11.</u>	<u>Executive Compensation</u>	76
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	76
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	76
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	76

PART IV

<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	76
<u>Item 16.</u>	<u>Form 10-K Summary</u>	84
<u>SIGNATURES</u>		85

Table of Contents

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” 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

Table of Contents

“products” or “our products” in this Annual Report include our marketed products, marketed products using our proprietary technologies, our product candidates, product candidates using our proprietary technologies, development products and development products using our proprietary technologies, (b) references to the “biopharmaceutical industry” in this Annual Report are intended to include reference to the “biotechnology industry” and/or the “pharmaceutical industry” and (c) references to “licensees” are used interchangeably with references to “partners.”

NOTE REGARDING TRADEMARKS

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

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

Table of Contents

## 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:

Product	Indication(s)	Licensee	Territory
	Schizophrenia	None	Commercialized by Alkermes in the U.S.
	Alcohol dependence and Opioid dependence	None	Commercialized by Alkermes in the U.S.
			Russia and Commonwealth of Independent States (“CIS”)
		Cilag GmbH International (“Cilag”)	





Table of Contents

Summary information regarding products that use our proprietary technologies:

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

BCise

6

---

## Table of Contents

### Proprietary Products

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

#### ARISTADA

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

7

---

## Table of Contents

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

## Table of Contents

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.

9

---

Table of Contents

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:

Preclinical  
Phase 1 Phase 2  
Phase 3 NDA  
Submission

Aripiprazole  
Lauroxil  
NanoCrystal  
Dispersion  
Schizophrenia

ALKS 5461  
Major  
Depressive  
Disorder

ALKS 3831  
Schizophrenia

BIIB098  
(formerly)  
ALKS 8700  
Multiple  
Sclerosis

ALKS 4230  
Cancer  
Immunotherapy

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

## Table of Contents

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

## Table of Contents

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.

## Table of Contents

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

Table of Contents

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,

Table of Contents

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.

## Table of Contents

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.

## Table of Contents

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.

## Table of Contents

**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.

## Table of Contents

### 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.

## Table of Contents

### 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 RISPERDAL CONSTA compete with each other and a number of other injectable products including ZYPREXA RELPREVV ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly; ABILIFY MAINTENA (aripiprazole for extended release injectable suspension), a once-monthly injectable formulation of ABILIFY (aripiprazole) developed by Otsuka Pharm. Co.; oral compounds currently on the market; and generic versions of branded oral and injectable products. In the treatment of bipolar disorder, RISPERDAL CONSTA competes with antipsychotics such as oral aripiprazole, REXULTI, LATUDA, ABILIFY MAINTENA, risperidone, olanzapine,

ziprasidone and clozapine.

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

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

## Table of Contents

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:



Edgar Filing: Alkermes plc. - Form 10-K

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.

21

---

Table of Contents

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:

U.S. Patent No.	Product Candidate(s) Covered	Expiration Date
7,956,187	ALKS 5461	2021
	ALKS 3831	

Edgar Filing: Alkermes plc. - Form 10-K

8,252,929	ALKS 5461	2021
	ALKS 3831	
7,262,298	ALKS 5461	2025
	ALKS 3831	
8,680,112	ALKS 5461	2030
	ALKS 3831	
9,119,848	ALKS 5461	2031
	ALKS 3831	
9,126,977	ALKS 3831	2031
9,517,235	ALKS 3831	2031
8,778,960	ALKS 3831	2032
8,822,488	ALKS 5461	2032
9,498,474	ALKS 5461	2032

Table of Contents

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.”

Table of Contents

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

## Table of Contents

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,

## Table of Contents

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

## Table of Contents

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

Table of Contents

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

28

---

## Table of Contents

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”).

## Table of Contents

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

## Table of Contents

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.

## Table of Contents

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;

Table of Contents

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

Table of Contents

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

## Table of Contents

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

## Table of Contents

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

Table of Contents

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

## Table of Contents

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.

## Table of Contents

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

## Table of Contents

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.

## Table of Contents

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

## Table of Contents

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

Table of Contents

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:

43

---

Table of Contents

- 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

## Table of Contents

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.

45

---

## Table of Contents

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.

46

---

## Table of Contents

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.

## Table of Contents

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.

48

---

## Table of Contents

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.

49

---

Table of Contents

	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.

## Table of Contents

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.

Table of Contents

## 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.

## Comparison of Cumulative total Returns

Alkermes plc

Nasdaq Composite Total Returns

Nasdaq Biotechnology Index

Nasdaq Stock Market (U.S. and Foreign) Index

	Year Ended March 31, 2013	Nine Months Ended December 31, 2013	Year Ended December 31,			
			2014	2015	2016	2017
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

Table of Contents

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
	2017	2016	2015	2014	Months Ended December 31, 2013
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
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	903,374	745,694	628,335	618,789	432,911
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	1,051,274	954,359	852,636	705,933	417,417
OPERATING (LOSS) INCOME	(147,900)	(208,665)	(224,301)	(87,144)	15,494
OTHER INCOME (EXPENSE), NET(1)	4,626	(5,722)	296	73,115	(10,097)
(LOSS) INCOME BEFORE INCOME TAXES	(143,274)	(214,387)	(224,005)	(14,029)	5,397
PROVISION (BENEFIT) FOR INCOME TAXES	14,671	(5,943)	3,158	16,032	(12,252)
NET (LOSS) INCOME	\$ (157,945)	\$ (208,444)	\$ (227,163)	\$ (30,061)	\$ 17,649
(LOSS) EARNINGS PER ORDINARY SHARE:					
BASIC	\$ (1.03)	\$ (1.38)	\$ (1.52)	\$ (0.21)	\$ 0.13



Edgar Filing: Alkermes plc. - Form 10-K

DILUTED WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:	\$ (1.03)	\$ (1.38)	\$ (1.52)	\$ (0.21)	\$ 0.12
BASIC	153,415	151,484	149,206	145,274	135,960
DILUTED	153,415	151,484	149,206	145,274	144,961
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	\$ 590,716	\$ 619,165	\$ 798,849	\$ 801,646	\$ 449,995
Total assets(2)	1,797,227	1,726,423	1,855,744	1,919,058	1,574,848
Long-term debt(2)	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	2017–2016	2016–2015
Manufacturing and royalty revenues:					

Edgar Filing: Alkermes plc. - Form 10-K

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	\$ 505.3	\$ 487.2	\$ 475.3	\$ 18.1	\$ 11.9

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

Table of Contents

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.

Table of Contents

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,

Table of Contents

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 Favorable/(Unfavorable)	
	2017	2016	2015	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 Favorable/(Unfavorable)	
	2017	2016	2015	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 Favorable/(Unfavorable)
	2017	2016	2015	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.

Table of Contents

## 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 Favorable/(Unfavorable)	
	2017	2016	2015	2017 - 2016	2016 - 2015
External R&D Expenses:					
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)
Internal R&D expenses:					
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.

Table of Contents

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	(Unfavorable) 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.

Table of Contents

## Other Income (Expense), Net

(In millions)	Year Ended December 31,			Change Favorable/(Unfavorable)	
	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 Favorable/(Unfavorable)	
	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.

## Table of Contents

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.

Edgar Filing: Alkermes plc. - Form 10-K

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

## Table of Contents

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.



Table of Contents

## Contractual Obligations

The following table summarizes our obligations to make future payments under our current contracts at December 31, 2017:

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

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.

## Table of Contents

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

Table of Contents

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
Balance, December 31, 2015	\$ 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)
Balance, December 31, 2016	\$ 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)
Balance, December 31, 2017	\$ 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.

Table of Contents

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.

## Table of Contents

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

Table of Contents

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 %	39 %	38 %
Risk-free interest rate	47 %	- 53 %	- 46 %
Expected annual dividend yield	1.69 %	0.95 %	1.29 %
	-	% -	% -
	2.38	2.14	2.02
	%	%	%
	—	—	—

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

## Table of Contents

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.

## Table of Contents

### 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

## Table of Contents

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.

Table of Contents

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



INCOME TAX PROVISION (BENEFIT)					
NET LOSS	\$ (68,881)	\$ (42,999)	\$ (36,276)	\$ (9,789)	\$ (157,945)
LOSS PER SHARE—BASIC AND DILUTED	\$ (0.45)	\$ (0.28)	\$ (0.24)	\$ (0.06)	\$ (1.03)

Table of Contents

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Year Ended December 31, 2016					
REVENUES:					
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	156,774	195,165	180,241	213,514	745,694
EXPENSES:					
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	233,658	242,282	241,368	237,051	954,359
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	(77,019)	(47,713)	(65,342)	(24,313)	(214,387)
INCOME TAX (BENEFIT)					
PROVISION	404	(520)	(2,655)	(3,172)	(5,943)
NET LOSS	\$ (77,423)	\$ (47,193)	\$ (62,687)	\$ (21,141)	\$ (208,444)
LOSS PER SHARE—BASIC AND DILUTED	\$ (0.51)	\$ (0.31)	\$ (0.41)	\$ (0.14)	\$ (1.38)

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

Table of Contents

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.

Table of Contents

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
-------------	------------------------	---------------------------------------	------

Edgar Filing: Alkermes plc. - Form 10-K

- 2.1 \* Purchase and Sale Agreement, dated March 7, 2015, by and among Alkermes Pharma Ireland Limited, Daravita Limited, Eagle Holdings USA, Inc., Recro Pharma, Inc., and Recro Pharma LLC. Exhibit 2.1 of the Alkermes plc Current Report on Form 8-K/A (File No. 001-35299) April 16, 2015
- 2.1.1 First Amendment to Purchase and Sale Agreement, dated December 8, 2016 by and among Alkermes Pharma Ireland Limited, Daravita Limited, Eagle Holdings USA, Inc., Recro Pharma, Inc., and Recro Gainesville LLC. Exhibit 2.1.1 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299) February 17, 2017
- 3.1 Memorandum and Articles of Association of Exhibit 3.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299) May 26, 2016

Alkermes  
plc.

76

---

Table of Contents

Exhibit No.	Description of Exhibit	Incorporated by reference herein Form	Date
10.1	<u>Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of April 22, 2009.</u>	Exhibit 10.5 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 28, 2009
10.1.1	<u>First Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009.</u>	Exhibit 10.2 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	August 6, 2009
10.1.2	<u>Second Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of November 12, 2013.</u>	Exhibit 10.74 of the Alkermes plc Transition Report on Form 10-KT (File No. 001-35299)	February 27, 2014
10.1.3	<u>Third Amendment to Lease Agreement between Alkermes, Inc. and PDM 850 Unit, LLC, dated as of May 15,</u>	Exhibit 10.2 of the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 31, 2014



Edgar Filing: Alkermes plc. - Form 10-K

- 2014.
- 10.1.4 Fourth Exhibit 10.7 to the Alkermes plc Quarterly Report on Form 10-Q (File No. July 30, 2015  
Amendment 001-35299)  
to Lease  
Agreement  
between  
Alkermes,  
Inc. and Gl  
TC 850  
Winter  
Street, LLC,  
dated as of  
December  
30, 2014.
- 10.2 License Exhibit 10.2 to the Alkermes plc Annual Report on Form 10-K (File No. February 25,  
Agreement, 001-35299) 2016  
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).
- 10.2.1 Third Exhibit 10.5 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File February 8, 2005  
\* Amendment No. 001-14131)  
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).

10.2.2 Second Exhibit 10.3 of the Alkermes plc Quarterly Report on Form 10-Q (File  
\* Amendment, No. 001-35299)

November 1,  
2012

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

	<p><u>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.</u></p>		
10.3	<p><u>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).</u></p>	<p>Exhibit 10.3 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)</p>	<p>February 25, 2016</p>

Table of Contents

Exhibit No.	Description of Exhibit	Incorporated by reference herein Form	Date
10.4	<u>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).</u>	Exhibit 10.4 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.4.1 *	<u>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).</u>	Exhibit 10.4 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.4.2	<u>Addendum to the Manufacturing and Supply Agreement by</u>	Exhibit 10.4.2 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016

- and among JPI  
Pharmaceutica  
International,  
Janssen  
Pharmaceutica  
Inc. and  
Alkermes  
Controlled  
Therapeutics  
Inc. II, dated  
August 1, 2001.
- 10.4.3 Letter  
Agreement and  
Exhibits to  
Manufacturing  
and Supply  
Agreement,  
dated February  
1, 2002, by and  
among JPI  
Pharmaceutica  
International,  
Janssen  
Pharmaceutica  
Inc. and  
Alkermes  
Controlled  
Therapeutics  
Inc. II (assigned  
to Alkermes,  
Inc. in July  
2006). Exhibit 10.4.3 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299) February 25, 2016
- 10.4.4 Amendment to  
Manufacturing  
and Supply  
Agreement by  
and between JPI  
Pharmaceutica  
International,  
Janssen  
Pharmaceutica  
Inc. and  
Alkermes  
Controlled  
Therapeutics  
Inc. II, dated  
December 22,  
2003 (assigned  
to Alkermes,  
Inc. in July  
2006). Exhibit 10.6 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299) July 30, 2015
- \*

Edgar Filing: Alkermes plc. - Form 10-K

<p>10.4.5 * <u>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).</u></p>	<p>Exhibit 10.9 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)</p>	<p>February 8, 2005</p>
<p>10.5 * <u>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).</u></p>	<p>Exhibit 10.28 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)</p>	<p>May 21, 2010</p>
<p>10.6 * <u>Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated</u></p>	<p>Exhibit 10.6 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)</p>	<p>February 8, 2005</p>

10.6.1 *	<p><u>December 21, 2002 (assigned to Alkermes, Inc. in July 2006).</u></p> <p><u>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).</u></p>	<p>Exhibit 10.7 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)</p>	<p>February 8, 2005</p>
10.7	<p><u>Amended and Restated License Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc.</u></p>	<p>Exhibit 10.14 of the Acorda Therapeutics, Inc. Quarterly Report on Form 10-Q/A (File No.000-50513; film No. 11821367)</p>	<p>July 20, 2011</p>

Table of Contents

Exhibit No.	Description of Exhibit	Incorporated by reference herein Form	Date
10.7.1	<u>Supply Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc.</u>	Exhibit 10.22 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.7.2	<u>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,</u>	Exhibit 10.56 to Acorda Therapeutics, Inc.'s Quarterly Report on Form 10-Q (File No.000-50513; film No. 09999376)	August 10, 2009



- plc).  
Acorda  
Therapeutics,  
Inc. and  
Biogen Idec  
International  
GmbH.
- 10.7.3 Amendment Exhibit 10.46 of the Acorda Therapeutics, Inc. Annual Report on Form February 28,  
No. 2, dated 10-K (File No.000-50513; film no. 13653677) 2013  
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).
- 10.7.4 Amendment Exhibit 10.1 of the Acorda Therapeutics, Inc. Quarterly Report on Form May 10, 2013  
No. 3, dated 10-Q (File No. 000-50513; film No. 13831684)  
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).

10.7.5\* Development Exhibit 10.21 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299) May 23, 2013

and  
Supplemental  
Agreement  
between  
Elan  
Pharma  
International  
Limited and  
Acorda  
Therapeutics,  
Inc. dated  
January 14,  
2011.

10.8 \* License Exhibit 10.23 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299) May 23, 2013

Agreement  
by and  
among Elan  
Pharmaceutical  
Research  
Corp., d/b/a  
Nanosystems  
and Elan  
Pharma

10.8.1	<p><u>International Limited and Janssen Pharmaceutica N.V. dated as of March 31, 1999.</u></p> <p><u>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.</u></p>	<p>Exhibit 10.24 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)</p>	<p>May 23, 2013</p>
10.8.2	<p><u>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</u></p>	<p>Exhibit 10.25 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)</p>	<p>May 23, 2013</p>

\*

10.9	<p><u>Pharmaceutica</u> <u>N.V. dated</u> <u>as of March</u> <u>31, 1999, as</u> <u>amended by</u> <u>the First</u> <u>Amendment,</u> <u>dated as of</u> <u>July 31,</u> <u>2003.</u> <u>Amendment</u> <u>to First Lien</u> <u>Credit</u> <u>Agreement,</u> <u>dated</u> <u>September</u> <u>25, 2012,</u> <u>among</u> <u>Alkermes,</u> <u>Inc.,</u> <u>Alkermes</u> <u>plc, the</u> <u>guarantors</u> <u>party</u> <u>thereto, the</u> <u>lenders</u> <u>party</u> <u>thereto,</u> <u>Morgan</u> <u>Stanley</u> <u>Senior</u> <u>Funding,</u> <u>Inc. as</u> <u>Administrative</u> <u>Agent and</u> <u>Collateral</u> <u>Agent and</u> <u>the</u> <u>arrangers</u> <u>and agents</u> <u>party</u> <u>thereto.</u></p>	Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 25, 2012
------	---	--	-----------------------

Table of Contents

Exhibit No.	Description of Exhibit	Incorporated by reference herein Form	Date
10.9.1	<u>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.</u>	Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	February 19, 2013
10.9.2	<u>Amendment No. 3 and</u>	Exhibit 10.52 of the Alkermes plc Annual Report on Form 10-K (File No. 011-35299)	May 23, 2013

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.

- 10.9.3 Amendment Exhibit 10.2 of the Alkermes plc Quarterly Report on Form 10-Q (File November 2, 2016  
No. 4, dated No. 011-35299)  
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,  
10.10 License and  
#\* Collaboration  
Agreement,  
dated  
November  
27, 2017,  
by and  
between  
Alkermes  
Pharma  
Ireland

Limited and  
Biogen  
Swiss  
Manufacturing  
GmbH.

- |           |   |   |                    |
|-----------|---|---|--------------------|
| 10.11 †   | <u>Employment agreement, dated as of December 12, 2007, by and between Richard F. Pops and Alkermes, Inc.</u>               | Exhibit 10.1 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131) | February 11, 2008  |
| 10.11.1 † | <u>Amendment to Employment Agreement, dated as of October 7, 2008, by and between Alkermes, Inc. and Richard F. Pops.</u>   | Exhibit 10.5 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)    | October 7, 2008    |
| 10.11.2 † | <u>Amendment No. 2 to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops, dated September 10, 2009.</u> | Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)    | September 11, 2009 |
| 10.12 †   | <u>Form of Employment Agreement, dated as of December 12, 2007, entered into by and between Alkermes,</u>                   | Exhibit 10.3 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131) | February 11, 2008  |



Inc. and  
each of  
Kathryn L.  
Biberstein,  
Elliot W.  
Ehrich,  
M.D.,  
James M.  
Frates and  
Michael J.  
Landine.

10.12.1 † Form of Exhibit 10.7 to the Alkermes, Inc. Current Report on Form 8-K (File October 7, 2008  
Amendment No. 001-14131)

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.

10.13 † Form of Exhibit 10.15 to the Alkermes, Inc. Annual Report on Form 10-K (File May 30, 2008  
Covenant No. 001-14131)

Not to  
Compete,  
of various  
dates, by  
and  
between  
Alkermes,  
Inc. and  
each of  
Kathryn L.  
Biberstein  
and James  
M. Frates.

Table of Contents

Exhibit No.	Description of Exhibit	Incorporated by reference herein Form	Date
10.14 †	<u>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.</u>	Exhibit 10.15(a) to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 30, 2008
10.15 †	<u>Shane Cooke Offer Letter, dated as of September 15, 2011.</u>	Exhibit 10.5 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.15.1 †	<u>Employment Agreement by and between Alkermes Pharma Ireland Limited and Shane Cooke, dated as of September 16, 2011.</u>	Exhibit 10.6 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.16 †	<u>Offer Letter between Alkermes, Inc. and Mark P. Stejbach, effective as of February 15, 2012.</u>	Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	March 5, 2012
10.16.1 †	<u>Employment Agreement by and between Alkermes, Inc. and Mark P. Stejbach, dated as of February 29, 2012.</u>	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	March 5, 2012

Edgar Filing: Alkermes plc. - Form 10-K

10.16.2 †	<u>Amendment to Employment Agreement, dated as of July 21, 2015, by and between Mark P. Stejbach and Alkermes, Inc.</u>	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 30, 2015
10.17 †	<u>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.</u>	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	November 2, 2016
10.17.1# †	<u>Offer Letter between Alkermes, Inc. and Craig C. Hopkinson M.D., effective as of April 24, 2017.</u>		
10.18 †	<u>Form of Indemnification Agreement by and between Alkermes, Inc. and each of its directors and executive officers.</u>	Exhibit 10.1 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	March 25, 2010
10.19 †	<u>Form of Deed of Indemnification for Alkermes plc Officers.</u>	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.20 †	<u>Form of Deed of Indemnification for Alkermes</u>	Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011

	<u>plc</u>		
	<u>Directors/Secretary.</u>		
10.21 †	<u>Form of Deed</u>	Exhibit 10.3 to the Alkermes plc Current Report on Form 8-K (File	September 20,
	<u>of</u>	No. 011-35299)	2011
	<u>Indemnification</u>		
	<u>for Alkermes,</u>		
	<u>Inc. and</u>		
	<u>Subsidiaries</u>		
	<u>Directors/Secretary.</u>		

Table of Contents

Exhibit No.	Description of Exhibit	Incorporated by reference herein Form	Date
10.22 †	<u>Alkermes, Inc. Amended and Restated 1999 Stock Option Plan.</u>	Appendix A to the Alkermes, Inc. Definitive Proxy Statement on Form DEF 14/A (File No. 001-14131)	July 27, 2007
10.22.1 †	<u>Form of Incentive Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended.</u>	Exhibit 10.35 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	June 14, 2006
10.22.2 †	<u>Form of Non-Qualified Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended.</u>	Exhibit 10.36 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	June 14, 2006
10.23 †	<u>Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.</u>	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 †	<u>Alkermes plc 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee</u>	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

Edgar Filing: Alkermes plc. - Form 10-K

10.23.2 †	<u>Director).</u> <u>Alkermes</u> <u>plc 2008</u> <u>Stock</u> <u>Option and</u> <u>Incentive</u> <u>Plan.</u> <u>Restricted</u> <u>Stock Unit</u> <u>Award</u> <u>Certificate</u> <u>(Time</u> <u>Vesting</u> <u>Only - Irish).</u>	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 †	<u>Alkermes</u> <u>plc 2008</u> <u>Stock</u> <u>Option and</u> <u>Incentive</u> <u>Plan.</u> <u>Restricted</u> <u>Stock Unit</u> <u>Award</u> <u>Certificate</u> <u>(Time</u> <u>Vesting</u> <u>Only – U.S.).</u>	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 †	<u>Alkermes</u> <u>plc 2008</u> <u>Stock</u> <u>Option and</u> <u>Incentive</u> <u>Plan, Stock</u> <u>Option</u> <u>Award</u> <u>Certificate</u> <u>(Time</u> <u>Vesting</u> <u>Non-Qualified</u> <u>Option –</u> <u>Irish).</u>	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

Table of Contents

Exhibit No.	Description of Exhibit	Incorporated by reference herein Form	Date
10.23.5 †	<u>Alkermes plc 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Time Vesting Non-Qualified Option – U.S.)</u>	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 †	<u>Alkermes plc 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option – U.S.)</u>	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 †	<u>Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only)</u>	Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	May 22, 2009
10.24 †	<u>Alkermes plc 2011 Stock Option and Incentive</u>	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299)	May 24, 2017

Edgar Filing: Alkermes plc. - Form 10-K

10.24.1 †	<u>Plan, as amended.</u> <u>Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option – U.S.), as amended.</u>	Exhibit 10.26.1 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.24.2 †	<u>Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Time Vesting Non-Qualified Option – U.S.), as amended.</u>	Exhibit 10.26.2 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.24.3 †	<u>Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Performance Vesting Non-Qualified Option – U.S.),</u>	Exhibit 10.26.3 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.24.4 †	<u>Alkermes plc 2011 Stock Option and Incentive Plan,</u>	Exhibit 10.75 of the Alkermes plc Transition Report on Form 10-KT (File No. 011-35299)	February 27, 2014



	<u>Restricted</u> <u>Stock Unit</u> <u>Award</u> <u>Certificate</u> <u>(Time</u> <u>Vesting</u> <u>Only –</u> <u>U.S.), as</u> <u>amended.</u>		
10.24.5	<u>Alkermes</u> <u>plc 2011</u> <u>Stock</u> <u>Option and</u> <u>Incentive</u> <u>Plan.</u> <u>Restricted</u> <u>Stock Unit</u> <u>Award</u> <u>Certificate</u> <u>(Performance</u> <u>Vesting</u> <u>Only –</u> <u>U.S.), as</u> <u>amended.</u>	Exhibit 10.26.5 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
†			
10.24.6	<u>Alkermes</u> <u>plc 2011</u> <u>Stock</u> <u>Option and</u> <u>Incentive</u> <u>Plan.</u> <u>Restricted</u> <u>Stock Unit</u> <u>Award</u> <u>Certificate</u> <u>(Time</u> <u>Vesting</u> <u>Only -</u> <u>Irish), as</u> <u>amended.</u>	Exhibit 10.77 of the Alkermes plc Transition Report on Form 10-KT (File No. 011-35299)	February 27, 2014
†			
10.24.7	<u>Alkermes</u> <u>plc 2011</u> <u>Stock</u> <u>Option and</u> <u>Incentive</u> <u>Plan.</u> <u>Restricted</u> <u>Stock Unit</u> <u>Award</u> <u>Certificate</u> <u>(Performance</u> <u>Vesting</u>	Exhibit 10.26.7 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
†			

Only -  
Irish).

83

---

Table of Contents

Incorporated by reference herein		Date
Exhibit No.	Description of Exhibit	
10.24.8 †	<u>All Exhibits</u> 10.3 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299) <u>2011</u> <u>Stock</u> <u>Option</u> <u>and</u> <u>Incentive</u> <u>Plan.</u> <u>Stock</u> <u>Option</u> <u>Award</u> <u>Certificate</u> <u>(Non-Employee</u> <u>Director).</u>	April 28, 2016
10.24.9 †	<u>All Exhibits</u> 10.26.9 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299) <u>2011</u> <u>Stock</u> <u>Option</u> <u>and</u> <u>Incentive</u> <u>Plan.</u> <u>Stock</u> <u>Option</u> <u>Award</u> <u>Certificate</u> <u>(Time</u> <u>Vesting</u> <u>Non-Qualified</u> <u>Option</u> <u>= Irish).</u>	February 25, 2016
10.24.10 †	<u>All Exhibits</u> 10.26.10 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299) <u>2011</u> <u>Stock</u> <u>Option</u> <u>and</u> <u>Incentive</u> <u>Plan.</u> <u>Stock</u> <u>Option</u> <u>Award</u> <u>Certificate</u> <u>(Performance</u>	February 25, 2016

- Vesting  
Non-Qualified  
Option  
- Irish).
- 21.1 # List  
of  
subsidiaries
- 23.1 # Consent  
of  
PricewaterhouseCoopers  
LLP,  
an  
independent  
registered  
public  
accounting  
firm
- 24.1 # Power  
of  
Attorney  
(included  
on  
the  
signature  
pages  
hereto)
- 31.1 # Certification  
Pursuant  
to  
Rule  
13a-14(a)  
or  
Rule  
15d-14(a)  
of  
the  
Securities  
Exchange  
Act  
of  
1934
- 31.2 # Certification  
Pursuant  
to  
Rule  
13a-14(a)  
or  
Rule  
15d-14(a)  
of  
the

32.1 ‡ Securities  
Exchange  
Act  
of  
1934  
Certification  
Pursuant  
to  
18  
U.S.C.  
Section  
1350.  
as  
adopted  
pursuant  
to  
Section  
906  
of  
the  
Sarbanes-Oxley  
Act  
of  
2002

101.INS XBRL  
+# Instance  
Document

101.SCH XBRL  
+# Taxonomy  
Extension  
Schema  
Document

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.

Table of Contents

SIGNATURES

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

ALKERMES PLC

By: /s/ Richard F. Pops

Richard F. Pops  
Chairman and Chief Executive Officer

February 16, 2018

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Richard F. Pops Richard F. Pops	Chairman and Chief Executive Officer (Principal Executive Officer)	February 16, 2018
/s/ James M. Frates James M. Frates	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	February 16, 2018
/s/ Iain M. Brown Iain M. Brown	Senior Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 16, 2018
/s/ David W. Anstice David W. Anstice	Director	February 16, 2018
/s/ Floyd E. Bloom	Director	February 16, 2018

Floyd E. Bloom

/s/ Robert A. Breyer

Director

February 16,  
2018

Robert A. Breyer

/s/ Wendy L. Dixon

Director

February 16,  
2018

Wendy L. Dixon

/s/ Paul J. Mitchell

Director

February 16,  
2018

Paul J. Mitchell

/s/ Nancy L. Snyderman

Director

February 16,  
2018

Nancy L. Snyderman

/s/ Nancy J. Wysenski

Director

February 16,  
2018

Nancy J. Wysenski



Table of Contents

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

F-1

---

Table of Contents

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.

F-2

---

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

December 31, 2017 and 2016

	December 31, 2017	December 31, 2016
	(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	808,844	790,678
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>\$ 1,797,227</b>	<b>\$ 1,726,423</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	291,122	211,993
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	594,419	516,942
<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 (89,347)	1,539 (72,639)

Edgar Filing: Alkermes plc. - Form 10-K

Treasury shares, at cost (2,048,176 and 1,760,767 shares at December 31, 2017 and 2016, respectively)		
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	1,202,808	1,209,481
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,797,227	\$ 1,726,423

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

F-3

---

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

Years Ended December 31, 2017, 2016 and 2015

	Year Ended December 31,		
	2017	2016	2015
	(In thousands, except per share amounts)		
<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	903,374	745,694	628,335
<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	1,051,274	954,359	852,636
<b>OPERATING LOSS</b>	<b>(147,900)</b>	<b>(208,665)</b>	<b>(224,301)</b>
<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	4,626	(5,722)	296
<b>LOSS BEFORE INCOME TAXES</b>	<b>(143,274)</b>	<b>(214,387)</b>	<b>(224,005)</b>
<b>INCOME TAX PROVISION (BENEFIT)</b>	<b>14,671</b>	<b>(5,943)</b>	<b>3,158</b>
<b>NET LOSS</b>	<b>\$ (157,945)</b>	<b>\$ (208,444)</b>	<b>\$ (227,163)</b>
<b>LOSS PER ORDINARY SHARE:</b>			
Basic and diluted	\$ (1.03)	\$ (1.38)	\$ (1.52)
<b>WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:</b>			
Basic and diluted	153,415	151,484	