Alkermes plc.
Form 10-K
February 17, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10 K

(Mark One)
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
for the fiscal year ended December 31, 2016
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(g) of the Act:

Ordinary shares, $0.01 par value	NASDAQ Global Select Stock Market

Title of each class	Name of each exchange on which registered

Securities registered pursuant to Section 12(b) 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 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b 2 of the Exchange Act. (Check one):

Large accelerated filer	Accelerated filer	Non accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company

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 was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was $6,485,485,798.

As of February 3, 2017, 152,547,458 ordinary shares were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our Annual General Meeting of Shareholders for the fiscal year ended December 31, 2016 are incorporated by reference into Part III of this report.

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ALKERMES PLC AND SUBSIDIARIES

ANNUAL REPORT ON FORM 10 K

FOR THE YEAR ENDED DECEMBER 31, 2016

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CAUTIONARY NOTE CONCERNING FORWARD LOOKING STATEMENTS

This document contains and incorporates by reference "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, these statements can be identified by the use of forward looking terminology such as "may," "will," "could," "should," "would," "expect," "anticipate," "continue," "believe," "plan," "estimate," "intend," or other similar words. These sta 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 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.

Unless otherwise indicated, information contained in this Annual Report concerning the disorders targeted by our products and the markets in which we operate is based on information from various sources (including, without limitation, industry publications, medical and clinical journals and studies, surveys and forecasts, and our internal research), on assumptions that we have made, which we believe are reasonable, based on those data and other similar sources, and on our knowledge of the markets for our products. Our internal research has not been verified by any independent source, and we have not independently verified any third party information. These projections, assumptions and estimates 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." 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 "products" or "our products" in this Annual Report include our marketed products, marketed products using our

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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" are used interchangeably with references to the "biotechnology" and/or "pharmaceutical industries" and (c) references to "licensees" are used interchangeably with references to "collaborative partners" and "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. ("Biogen"); BETASERON®—Bayer Pharma AG; BUNAVAILTM—BioDelivery Sciences; BYDUREON® and BYETTA®—Amylin Pharmaceuticals, LLC ("Amylin"); 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.; SUBOXONE® and SUBUTEX®—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.

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PART I

Item 1.Business

The following discussion contains forward looking statements. Actual results may differ significantly from those expressed or implied in the forward looking statements. See “Cautionary Note Concerning Forward Looking Statements” on pages 3 and 4 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”) facility and corporate offices 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 include:

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”)	

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Summary information regarding products that use our proprietary technologies include:

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.
		Biogen, under sublicense from Acorda	ROW
FAMPYRA			
BYDUREON	Type 2 diabetes	AstraZeneca plc (“AstraZeneca”)	Worldwide

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Proprietary Products

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

ARISTADA

ARISTADA (aripiprazole lauroxil) is an extended-release intramuscular injectable suspension approved in the U.S. for the treatment of schizophrenia. ARISTADA is the first of our products to utilize our proprietary 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 and six-week dosing options to deliver and maintain therapeutic levels of medication in the body. ARISTADA has three dosing options (441 mg, 662 mg and 882 mg) and is packaged in a ready-to-use, pre-filled product format. We developed, manufacture and commercialize ARISTADA 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 the only once monthly, non-addictive, 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 2015 U.S. National Survey on Drug Use and Health, an estimated 2.5 million people aged 18 or older were dependent on pain relievers or heroin in the U.S.

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 2015 U.S. National Survey on Drug Use and Health, an estimated 15 million people aged 18 or older were dependent on alcohol. Adherence to medication is particularly challenging with this patient population.

Products Using Our Proprietary Technologies

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

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

INVEGA SUSTENNA/XEPLION (paliperidone palmitate), INVEGA TRINZA/TREVICTA (paliperidone palmitate) and RISPERDAL CONSTA (risperidone long acting injection) are long-acting atypical antipsychotics owned and commercialized worldwide by Janssen that incorporate our proprietary technologies. INVEGA SUSTENNA is approved in the U.S. for the treatment of schizophrenia and for the treatment of schizoaffective

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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.

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, the first schizophrenia treatment to be taken once every three months, became commercially available in the U.S. in June 2015.

In May 2016, TREVICTA (paliperidone palmitate a 3-monthly injection), was approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION. INVEGA TRINZA/TREVICTA use our proprietary technology and are 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 36%, 40% and 41% of our consolidated revenues for the fiscal years ended December 31, 2016, 2015 and 2014, 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 for the improvement of walking in adults with MS. This authorization was renewed as of August 2016. AMPYRA and FAMPYRA incorporate our oral controlled-release technology. AMPYRA and FAMPYRA are manufactured by us.

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

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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

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.

What is type 2 diabetes?

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

Key Development Programs

Our R&D is focused on leveraging our formulation expertise and proprietary product platforms to develop novel, competitively advantaged medications designed to enhance patient outcomes in major CNS disorders, such as schizophrenia, addiction, depression and MS. As part of our ongoing R&D efforts, we have devoted, and will continue to devote, significant resources to conducting pre-clinical work and clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our key current 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 “Item 1A—Risk Factors” of this Annual Report. Refer to the “Patents and Proprietary Rights” section of this Annual Report for information with respect to the intellectual property protection for our development products.

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

Aripiprazole Lauroxil Two-Month Dose

Aripiprazole lauroxil, an intramuscular injectable atypical antipsychotic, which is currently commercially available as ARISTADA, with once monthly and six-week dosing options, for the treatment of schizophrenia, is also in development with a two-month dosing interval. In February 2016, we announced positive topline results from a randomized, open-label, pharmacokinetic study evaluating a two-month dosing interval of aripiprazole lauroxil extended-release injectable suspension for the treatment of schizophrenia. Based on these phase 1 results, we submitted a supplemental New Drug Application ("sNDA") to the U.S. Food and Drug Administration ("FDA") in August 2016 and the sNDA was accepted for filing by the FDA in October 2016 with a Prescription Drug User Fee Act ("PDUFA") date in June 2017.

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ALKS 5461

ALKS 5461 is a proprietary, once-daily, oral sublingual investigational medicine, with a novel mechanism of action, in development for the adjunctive treatment of Major Depressive Disorder ("MDD") in patients with an inadequate response to standard antidepressant therapies. ALKS 5461 is composed of samidorphan in combination with buprenorphine. Samidorphan is a proprietary oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. 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.

In January 2016, we announced the topline results of FORWARD-3 and FORWARD-4 from the FORWARD (Focused on Results With a Rethinking of Depression) pivotal program. Neither study met the prespecified 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 (2mg/2mg and 0.5mg/0.5mg) compared to placebo, showed a clear trend toward efficacy with the 2mg/2mg dose of ALKS 5461 on the primary endpoint, and post hoc analyses achieved statistical significance for the 2mg/2mg 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 (2mg/2mg) 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 in MDD from the FORWARD pivotal program. ALKS 5461 2mg/2mg met the prespecified primary endpoint of significantly reducing depression scores compared to placebo, as measured by the 6-item Montgomery—Åsberg Depression Rating Scale ("MADRS-6"). ALKS 5461 2mg/2mg also demonstrated statistically significant reductions in MADRS-10 scores compared to placebo. The 1mg/1mg 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.

Based on the results of FORWARD-5, the supportive evidence from FORWARD-4 and the successful phase 2 study of ALKS 5461, we recently met with the FDA's Division of Psychiatric Products at a Type C meeting to discuss ALKS 5461. We will request a pre-NDA meeting with the FDA and plan to submit the New Drug Application ("NDA") for ALKS 5461 in the second half of 2017.

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 efficacy of olanzapine and a differentiated safety profile from olanzapine with favorable weight and metabolic properties and to have utility in the treatment of schizophrenia in patients with co-occurring alcohol use disorder.

In December 2015 and February 2016, we announced the initiation of ENLIGHTEN-1 and ENLIGHTEN-2, respectively, the two phase 3 studies from the ENLIGHTEN pivotal program for ALKS 3831. ENLIGHTEN-1 is a multicenter, randomized, double-blind study to evaluate the antipsychotic efficacy of ALKS 3831 compared to placebo over four weeks in patients experiencing acute exacerbation of schizophrenia. ENLIGHTEN-2 is designed to assess weight gain with ALKS 3831 compared to olanzapine in patients with schizophrenia over a six month period. The ENLIGHTEN pivotal program will also include supportive studies to evaluate the pharmacokinetic, metabolic and long-term safety profile of ALKS 3831. Results from ENLIGHTEN-1 are expected by the end of 2017

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and results from ENLIGHTEN-2 are expected in mid-2018. We expect to use safety and efficacy data from the ENLIGHTEN pivotal program, if successful, to serve as the basis for an NDA to be submitted to the FDA.

In October 2016, we announced the initiation of a phase 1 metabolic study of ALKS 3831 to assess the effects of ALKS 3831 on whole body insulin sensitivity, lipid metabolism and other important metabolic parameters compared to olanzapine. Subjects will be randomized to receive ALKS 3831, olanzapine or placebo for 21 days. Results from the study are expected in mid-2017.

In January 2017, we announced plans to initiate a phase 3 study of ALKS 3831 in young adult patients. The study will assess the impact of ALKS 3831 on weight compared to treatment with olanzapine. The study is expected to initiate in the second quarter of 2017.

ALKS 8700

ALKS 8700 is a novel, proprietary, oral investigational monomethyl fumarate ("MMF") molecule in development for the treatment of MS. ALKS 8700 is designed to rapidly and efficiently convert to MMF in the body and to offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA.

We plan to file a 505(b)(2) NDA using pharmacokinetic bridging data from studies comparing ALKS 8700 and TECFIDERA and a two-year, multicenter, open-label study designed to assess the safety of ALKS 8700, which we initiated in December 2015. Additionally, we plan to initiate a randomized, head-to-head phase 3 study of the gastrointestinal tolerability of ALKS 8700 compared to TECFIDERA in the first quarter of 2017. We expect to complete ALKS 8700 registration studies and file the NDA in 2018.

For more information about 505(b)(2) NDAs, see “Item 1—Business, Regulatory, Hatch-Waxman Act”.

ALKS 6428

ALKS 6428 is designed to help healthcare providers transition patients from physical dependence on opioids to initiation with VIVITROL. ALKS 6428 is an investigational regimen of ascending doses of oral naltrexone administered in conjunction with ancillary medications during a seven-day treatment period, prior to first VIVITROL injection. In February 2017, we announced that the study did not meet its primary endpoint, and no statistically significant difference between treatment groups was observed. Patients in each of the three treatment arms (ALKS

6428 plus tapering doses of buprenorphine, ALKS 6428 plus placebo, and placebo) performed equally well, with a similar percentage of patients successfully transitioning to initiation with VIVITROL. The company is continuing to analyze the full data set from the study.

A second phase 3 study of ALKS 6428 is ongoing in patients who want to transition from buprenorphine maintenance therapy to initiation with VIVITROL for the treatment of opioid dependence.

ALKS 4230

ALKS 4230 is our selective effector cell activator ("SECA") that is designed to harness a patient's immune system to preferentially activate and increase the number of tumor killing immune cells. SECA proteins selectively target immune cells to avoid expansion of immune regulatory cells which interfere with the anti-tumor response. SECA molecules are engineered using our proprietary fusion protein technology platform to modulate the natural mechanism of action of a biologic product. We filed an Investigational New Drug ("IND") application with the FDA in the first quarter of 2016 and initiated a phase 1 clinical trial in May 2016. This phase 1 study 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 results from the first stage of the phase 1 study are expected in 2017.

ALKS 7119

ALKS 7119 is a novel, proprietary, oral investigational medicine that has a multivalent mechanism of action that acts on key receptors in the brain involved in several CNS diseases, including agitation in Alzheimer's disease, MDD

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and others. In January 2016, we announced the initiation of a phase 1, double-blind, placebo-controlled study designed to evaluate the safety and tolerability of single ascending doses of ALKS 7119 in healthy subjects. In April 2016, we announced that early results of the single-ascending-dose study demonstrated a favorable tolerability profile and pharmacokinetic properties consistent with potential once-daily dosing.

Based on these early results, we initiated the multiple-ascending-dose study in healthy volunteers in July 2016. In October 2016, due to tolerability issues observed in a small number of subjects in the study, we ceased further development of ALKS 7119. The effects observed were not observed in the single-ascending dose study or anticipated based on pre-clinical models.

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 fiscal years ended December 31, 2016, 2015 and 2014.

Collaborative Arrangements

We have entered into several collaborative arrangements to develop and commercialize products and, in so doing, to access technological, financial, marketing, manufacturing and other resources. Refer to the “Patents and Proprietary Rights” section 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 our 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 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 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

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2.5% of Janssen's net sales of RISPERDAL CONSTA in each country where the license is in effect based on the quarter when the product is sold by Janssen. This royalty may be reduced in any country based on lack of patent coverage and significant competition from generic versions of the product. Janssen can terminate the license agreements upon 30 days' prior written notice to us. Either party may terminate the license agreements by written notice following a breach which continues for 90 days after the delivery of written notice thereof or upon the other party's insolvency. The licenses granted to Janssen expire on a country by country basis upon the later of (i) the expiration of the last patent claiming the product in such country or (ii) 15 years after the date of the first commercial sale of the product in such country, provided that in no event will the license granted to Janssen expire later than the twentieth anniversary of the first commercial sale of the product in such country, with the exception of Canada, France, Germany, Italy, Japan, Spain and the United Kingdom, in each case, where the fifteen year limitation 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 calendar year. This percentage is determined based on Janssen's unit demand for the 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.

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

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

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

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

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

market competition. These financial obligations survive termination of the agreement.

AstraZeneca

In May 2000, we entered into a development and license agreement with Amylin for the development of exendin products falling within the scope of our patents, including the once weekly formulation of exenatide marketed as BYDUREON. In August 2012, Bristol Myers Squibb Company ("Bristol-Myers") acquired Amylin. From August 2012 through January 2014, Bristol Myers and AstraZeneca jointly developed and commercialized Amylin's exendin products, including BYDUREON, through their diabetes collaboration. In April 2013, Bristol Myers completed its assumption of all global commercialization responsibility related to the marketing of BYDUREON from Amylin's former collaborative 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 product sales. Upon the achievement of certain development and commercialization goals, we received milestone payments consisting of cash and warrants for Amylin common stock;

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there are no further milestones to be earned under the agreement. In October 2005 and in July 2006, we amended the development and license agreement. Under the amended development and license agreement (i) we are responsible for formulation and are principally responsible for non clinical development of any products that may be developed pursuant to the agreement and for manufacturing these products, except to the extent manufacturing rights have been transferred to Amylin, and (ii) we transferred certain of our technology related to the manufacture of BYDUREON to Amylin and agreed to the manufacture of BYDUREON by Amylin. Under our amended development and license agreement, AstraZeneca is responsible for conducting clinical trials, securing regulatory approvals and commercializing exenatide products, including BYDUREON, on a worldwide basis.

Until December 31, 2021, we will receive royalties equal to 8% of net sales from the first 40 million units of BYDUREON 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 this 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.

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

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includes technologies for tailored pharmacokinetic profiles including SODAS technology, CODAS technology, IPDAS technology and the MXDAS drug absorption system, each as described below:

SODAS Technology: SODAS ("Spheroidal Oral Drug Absorption System") technology involves producing uniform spherical beads of 1 mm to 2 mm in diameter containing drug plus excipients and coated with product specific modified release polymers. Varying the nature and combination of polymers within a selectively permeable membrane enables varying degrees of modified release depending upon the required product profile.

CODAS Technology: CODAS ("Chronotherapeutic Oral Drug Absorption System") technology enables the delayed onset of drug release incorporating the use of specific polymers, resulting in a drug release profile that more accurately complements circadian patterns.

IPDAS Technology: IPDAS ("Intestinal Protective Drug Absorption System") technology conveys gastrointestinal protection by a wide dispersion of drug in a controlled and gradual manner, through the use of numerous high density controlled release beads compressed into a tablet form. Release characteristics are modified by the application of polymers to the micro matrix and subsequent coatings, which form a rate limiting semi permeable membrane.

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

Manufacturing and Product Supply

We own and occupy a 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 Practice ("cGMP") regulations and other regulatory agency 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 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 third party service providers involved in the manufacture of our products 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"), 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 ARISTADA in our Wilmington, Ohio facility. We are currently operating two RISPERDAL CONSTA lines, two VIVITROL lines and one ARISTADA line at commercial scale. Janssen has granted us an option, which we exercised, to purchase the most recently constructed and validated RISPERDAL CONSTA manufacturing line at its then current net book value. 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

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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.

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 at our Wilmington, Ohio facility and NanoCrystal and OCR technology products at our Athlone, Ireland facility. We have also contracted with third party manufacturers to formulate certain products for clinical use. We require that our contract manufacturers adhere to cGMP in the manufacture of products for clinical use.

Research & Development

We devote significant resources to R&D programs. We focus our R&D efforts on developing novel therapeutics in areas of high unmet medical need. Our R&D efforts include, but are not limited to, areas such as pharmaceutical formulation, analytical chemistry, process development, engineering, scale up and drug optimization/delivery. Please see “Management’s Discussion and Analysis of Financial Condition and Results of Operations” for our R&D expenditures for our years ended December 31, 2016, 2015 and 2014.

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 certain 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 are developing 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 use customary pharmaceutical company practices to market our product and to educate physicians, such as sales representatives calling on individual physicians, 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 90 individuals. VIVITROL is sold directly to pharmaceutical wholesalers, specialty pharmacies and a specialty distributor. Product sales of VIVITROL during the year ended December 31, 2016 to AmerisourceBergen Corporation (“AmerisourceBergen”), McKesson Corporation,

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Cardinal Health and CVS Caremark Corporation represented approximately 19%, 18%, 13% and 12%, respectively, of total VIVITROL sales.

Our sales force for ARISTADA in the U.S. consists of approximately 210 individuals. ARISTADA is primarily sold to pharmaceutical wholesalers. Product sales of ARISTADA during the year ended December 31, 2016 to Cardinal Health, McKesson Corporation and AmerisourceBergen represented approximately 45%, 23% and 21%, 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, these companies are responsible for the commercialization of any products developed under such agreements if and when regulatory approval is obtained.

Competition

We face intense competition in the development, manufacture, marketing and commercialization of our products from many and varied sources, such as academic institutions, government agencies, research institutions and biotechnology and pharmaceutical 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 biotechnology and pharmaceutical industries are characterized by intensive research, development and commercialization efforts and rapid and significant technological change. Many of our competitors are larger and have significantly greater financial and other resources than we do. We expect our competitors to develop new technologies, products and processes that may be more effective than those we develop. The development of technologically improved or different products or technologies may make our products or product platforms obsolete or noncompetitive before we recover expenses incurred in connection with their development or realize any revenues from any marketed product.

There are other companies developing extended release product platforms. In many cases, there are products on the market or in development that may be in direct competition with our products. In addition, we know of new chemical

entities that are being developed that, if successful, could compete against our products. These chemical entities are being designed to work differently than our products and may turn out to be safer or to be more effective than our products. Among the many experimental therapies being tested around the world, there may be some that we do not now know of that may compete with our proprietary product platforms or products. Our licensees could choose a competing technology to use with their drugs instead of one of our product platforms and could develop products that compete with our products.

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

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended release delivery systems for pharmaceutical products, including, but not limited to Luye Pharma Group Ltd. (“Luye Pharma”), which is developing risperidone formulated as extended release microspheres for intramuscular injection for the treatment of schizophrenia and/or schizoaffective disorders. In the treatment of schizophrenia, ARISTADA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA

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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, 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 methadone, oral naltrexone, SUBOXONE (buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE (buprenorphine/naloxone) Sublingual Film, and SUBUTEX (buprenorphine HCl sublingual tablets), each of which is marketed and sold by Indivior plc, and BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences, PROBUPHINE (buprenorphine), marketed and sold by Braeburn Pharmaceuticals and ZUBSOLV (buprenorphine and naloxone) marketed by Orexo US, Inc. It also competes with 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 competes 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 also competes 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.

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; 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, 2016, 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.

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ARISTADA

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

U.S. Patent No. 8,431,576, having claims to a class of compounds that includes aripiprazole lauroxil, expiring in 2030;

U.S. Patent No. 8,796,276, having claims to methods of treating schizophrenia using a class of compounds that includes aripiprazole lauroxil, expiring in 2030;

U.S. Patent No. 9,034,867, having claims to pharmaceutical compositions, expiring in 2032;

U.S. Patent No. 9,193,685, having claims to pharmaceutical compositions that confer long-term stability, expiring in 2033;

U.S. Patent No. 9,452,131, having claims to methods of treatment for schizophrenia, expiring in 2035; and

U.S. Patent No. 9,526,726, having claims to kits comprising pharmaceutical compositions of aripiprazole lauroxil and instructions for intramuscular injection, expiring in 2035.

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

VIVITROL, RISPERDAL CONSTA and BYDUREON

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 and BYDUREON. The latest of our patents covering VIVITROL, RISPERDAL CONSTA and BYDUREON expire in 2029, 2023 and 2026 in the U.S., respectively, and 2021, 2021 and 2024 in the EU, respectively, and we own 20, 7, and 10 Orange-Book listed U.S. patents covering VIVITROL, RISPERDAL CONSTA and BYDUREON, 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, such as Australia and South Korea, in 2023. The latest of the patents covering INVEGA TRINZA/TREVICTA expire in November 2017 in the U.S. and 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.

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 May 2027 in the U.S. and April 2025 in the EU. For a discussion of legal proceedings related to the patents covering AMPYRA, see “Item 3—Legal Proceedings.”

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:

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U.S. Patent No.	Product Candidate(s) Covered	Expiration Date
7,956,187	ALKS 5461	2021
8,252,929	ALKS 3831 ALKS 5461	2021
7,262,298	ALKS 3831 ALKS 5461	2025
8,680,112	ALKS 3831 ALKS 5461	2030
9,119,848	ALKS 3831 ALKS 5461	2031
9,126,977	ALKS 3831 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

ALKS 8700

We have U.S. patents and patent applications, and a number of corresponding foreign counterparts, that cover ALKS 8700. Our U.S. patents and expiration dates for ALKS 8700 are:

U.S. Patent No. 8,669,281, having claims to a composition of matter that covers ALKS 8700, 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.

We know of several U.S. patents issued to other parties that may 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 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.

We also know of patent applications filed by other parties in the U.S. and various other countries that may 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 are issued to any of these applicants, 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 biotechnology and pharmaceutical 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

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these countries. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed outside the scope of our patents. The laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the U.S.

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

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

Revenues and Assets by Region

For the fiscal years ended December 31, 2016, 2015 and 2014, our revenue and assets are presented below by geographic area:

	Year Ended December 31,		
(In thousands)	2016	2015	2014
Revenue by region:			
U.S.	$ 557,312	$ 448,639	$ 398,189
Ireland	4,407	3,902	7,691
Rest of world	183,975	175,794	212,909
Assets by region:			
Current assets:			

U.S.	$ 382,168	$ 360,154	$ 385,715
Ireland	407,761	394,281	490,577
Rest of world	749	527	501
Long-term assets:			
U.S.:			
Intangible assets	$ —	$ —	$ —
Goodwill	—	—	3,677
Other	236,175	294,158	226,479
Ireland:			
Intangible assets	$ 318,227	$ 379,186	$ 479,412
Goodwill	92,873	92,873	90,535
Other	288,470	334,565	242,162

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

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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 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 a 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.

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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, 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 potential 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 new 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.

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

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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 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

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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 for five years from the date of approval of the NCE, or four years in the case of an ANDA or 505(b)(2) application containing a patent challenge. A 505(b)(2) application is an NDA wherein the applicant relies, in part, on data and the FDA's findings of safety and efficacy from studies not conducted by or for it and for which the applicant has not obtained a right of reference. Hatch-Waxman Act exclusivities will not prevent the submission or approval of a full NDA (e.g., under 505(b)(1)), as opposed to an ANDA or 505(b)(2) application, for any drug, including, for example, a drug with the same active ingredient, dosage form, route of administration, strength and conditions of use.

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

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

Sales and Marketing

We are subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti kickback laws and false claims laws. Anti kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the broad scope of the U.S. statutory provisions, the general absence of

guidance in the form of regulations, and few court decisions addressing industry practices, it is possible that our practices might be challenged under anti kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third party payers (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil 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

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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 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 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

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

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

In addition, on January 21, 2016, CMS released the final Medicaid covered outpatient drug regulation, which became effective on April 1, 2016. This regulation implements those changes made by the Affordable Care Act 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 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.

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Other Regulations

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

UK Bribery Act: We are also subject to the UK Bribery Act, which proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official and failing to have adequate procedures to prevent employees and other agents from giving bribes. Foreign corporations that conduct business in the UK generally will be subject to the UK Bribery Act. Penalties under the UK Bribery Act include potentially unlimited fines for corporations and criminal sanctions for corporate officers under certain circumstances.

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

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 3, 2017, we had approximately 1,750 full time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biotechnology 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

Our principal executive offices are located at Connaught House, 1 Burlington Road, Dublin 4, Ireland. Our telephone number is +353 1 772 8000 and our website address is www.alkermes.com. Information that is contained in, and can be accessed through, our website is not incorporated into, and does not form a part of, this Annual Report. We make available free of charge through the Investors section of our website our Annual Reports on Form 10 K, Quarterly Reports on Form 10 Q, Current Reports on Form 8 K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. We also make available on our

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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.

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Item 1A. Risk Factors

Investing in our company involves a high degree of risk. In deciding whether to invest in our ordinary shares, 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 operating results. This could cause the market price of our ordinary shares to decline, and could cause you to lose all or a part of your investment. Except as otherwise suggested by the context, references to "products" or "our products" include our marketed products, marketed products using our proprietary technologies, product candidates, product candidates using our proprietary technologies, development products and development products using our proprietary technologies.

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

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

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

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- perception of physicians and other members of the healthcare community as to our products' safety and efficacy relative to that of competing products;
- 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;
- unfavorable publicity concerning our products, similar classes of drugs or the industry generally;
- 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;
- 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 than our competitors.

We launched ARISTADA in October 2015 into a highly competitive market with companies larger than us and with more experience than us marketing and selling competing long-acting injectable atypical antipsychotic products for the treatment of schizophrenia.

We have less experience commercializing ARISTADA in a competitive market of this type. If we are not able to continue to attract and retain qualified personnel to serve in our sales and marketing organization, to maintain an effective distribution network and reimbursement for ARISTADA, or to otherwise effectively and efficiently support our commercialization activities, we may not be able to successfully commercialize ARISTADA 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.

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We rely solely on our manufacturing facility in Wilmington, Ohio for the manufacture of RISPERDAL CONSTA, VIVITROL, ARISTADA, polymer for BYDUREON 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 or packaging services, storage and product distribution services, customer service activities and product returns processing. These third parties must comply with federal, state and local regulations applicable to their business, including FDA and, as applicable, DEA regulations. Although we actively manage these third-party relationships to ensure continuity, quality and compliance with regulations, some events beyond our control could result in the complete or partial failure of these goods and services. Any such failure could materially adversely affect our business, financial condition, cash flows and results of operations.

The manufacture of products and product components, including the procurement of bulk drug product, packaging, storage and distribution of our products, requires successful coordination among us and multiple third-party providers. For example, we are responsible for the entire supply chain for both ARISTADA and VIVITROL, up to the sale of final product and including the sourcing of key raw materials and active pharmaceutical agents from third parties. Issues with our third-party providers, including our inability to coordinate these efforts, lack of capacity available at such third-party providers or any other problems with the operations of these third-party providers, could require us to delay shipment of saleable products, recall products previously shipped or could impair our ability to supply products at all. This could increase our costs, cause us to lose revenue or market share and damage our reputation and have a material adverse effect on our business, financial condition, cash flows and results of operations.

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

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

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

We and our third-party providers are generally required to comply with cGMP regulations and other applicable foreign standards in the manufacture of our products. In addition, in the U.S., the DEA and state-level agencies heavily regulate the manufacturing, holding, processing, security, recordkeeping and distribution of substances, including

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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 suppliers 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 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, including the existence of barriers to coverage of our products (such as prior authorization, criteria for use or other requirements), limitations by healthcare providers on how much, or under what circumstances, they will prescribe or administer our products or unwillingness by patients to pay any required co-payments, or deductible amounts, could reduce the use of, and revenues generated from, our products and could have a material adverse effect on our business, financial condition, cash flows and results of operations. In addition, when a new product is approved, the availability of government and private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement for our products.

In the U.S., federal and state legislatures, health agencies and third-party payers continue to focus on containing the cost of healthcare, including by comparing the effectiveness, benefits and costs of similar treatments. Any adverse findings for our products from such comparisons may reduce the extent of reimbursement for our products. Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs, including but not limited to price control initiatives, discounts and other

pricing-related actions. For example, in 2016, the State of California proposed a ballot initiative that, if passed, would have prohibited state agencies from entering into purchasing agreements with drug manufacturers unless the net cost of the drug was equal to less than that paid by the Veterans Administration. We expect similar state drug pricing initiatives in 2017. 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 2017, we may face uncertainties as a result of likely federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the Patient Protection and Affordable Care Act (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.

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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 licenses with our licensees;
- 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. Our pending patent applications, together with those we may file in the future, or those we may license 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 other parties, we cannot ascertain the existence of all potentially conflicting claims. Therefore, there is a risk that third parties may make claims of infringement against our products or technologies. We know of several patents issued in the U.S. to third parties that may relate to our products. We also know of patent applications filed by other parties in the U.S. and various countries outside the U.S. that may relate to

some of our products if such patents are issued in their present form. If patents 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 revenue and earnings could be adversely impacted.

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, 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. Thus, 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.

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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 pharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable.

There is considerable uncertainty within the pharmaceutical 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 face claims against our intellectual property rights 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.

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.

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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 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 new 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).

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 partners 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 collaborative 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, including those by 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

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around the world, including in Eastern Europe and Asia. We depend on independent clinical investigators, CROs and other third-party service providers and our collaborators in the conduct of clinical trials for our products and in the accurate reporting of results from such clinical trials. We rely heavily on these parties for successful execution of our clinical trials but do not control many aspects of their activities. For example, while the investigators are not our employees, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols.

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

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

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

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

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

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

- a product may not demonstrate safety and efficacy for each target indication in accordance with regulatory agency 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 partners interpret it;
- the FDA or other regulatory agencies might not approve our or our partners' manufacturing processes or facilities;
- the FDA or other regulatory agencies may not approve accelerated development timelines for our product;
- 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;
- 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; and
- the FDA or other regulatory agencies may not agree with our or our partners' regulatory approval strategies or components of our or our partners' filings, such as clinical trial designs.

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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.

The FDA or other regulatory agencies may impose limitations on any product approval.

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

Further, even if the FDA provides regulatory approval, controlled substances 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 change after its initial designation. We currently expect ALKS 5461 and ALKS 3831 to require such DEA final schedule designation prior to commercialization. Restrictive designation could adversely affect our ability to commercialize such products and could adversely affect our business and share price.

Citizen Petitions and other actions filed with, or litigation against, the FDA or other regulatory agencies or litigation against Alkermes may negatively impact the approval of our products and our business.

As described under "Item 3—Legal Proceedings" in this Annual Report, on July 13, 2015, Otsuka Pharmaceutical Development & Commercialization, Inc. ("Otsuka PD&C") filed a Citizen Petition with the FDA which requested that the FDA refuse to approve the NDA for ARISTADA or delay approval of such NDA until the exclusivity rights covering long-acting aripiprazole expire in December 2017. The FDA approved ARISTADA on October 5, 2015 and, concurrent with such approval, denied Otsuka PD&C's Citizen Petition. On October 15, 2015, Otsuka Pharm. Co., Otsuka PD&C, and Otsuka America Pharmaceutical, Inc. (collectively, "Otsuka") filed an action for declaratory and injunctive relief with the United States District Court for the District of Columbia (the "DC Court") against the FDA requesting, among other things, that the DC Court vacate FDA's approval of the ARISTADA NDA. We successfully intervened in, and received the DC Court's approval to become a party to, this action.

On July 28, 2016, the DC Court issued an opinion in favor of us and the FDA, affirming in all respects FDA's decision to approve ARISTADA for the treatment of schizophrenia, and denying the action filed by Otsuka for declaratory and injunctive relief. Otsuka has filed an appeal of the DC Court's decision with the U.S. Court of Appeals for the District of Columbia Circuit ("DC Circuit") asking the DC Circuit to reverse the DC Court's decision, vacate FDA's approval of the ARISTADA NDA and remand the case to the DC Court for consideration of any appropriate equitable remedy for Otsuka's lost exclusivity. The DC Circuit's appellate hearing for this matter occurred on December 12, 2016.

If Otsuka's action is successful, the DC Circuit could remand the case to the DC Court and the DC Court could remand the ARISTADA NDA to the FDA for further action, vacate the FDA's approval of the ARISTADA NDA, declare that Otsuka's exclusivity rights preclude FDA from granting approval of the NDA for ARISTADA until December 2017, grant injunctive relief and require that we remove ARISTADA from the market, and/or require that the FDA impose limitations on the approval of the ARISTADA NDA. These outcomes and others could adversely affect our ability to generate revenues from the commercialization and sale of ARISTADA, and our share price.

In addition, in the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against companies. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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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 the approval 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 their production and sale, and other civil or criminal sanctions, including fines and penalties. Pharmaceutical and biotechnology 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 potentially applicable U.S. federal and state regulations and/or laws or all potentially 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 and/or laws, a range of actions could result, including the termination of clinical trials, the failure to approve a product, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation.

Changes in laws affecting the healthcare industry could also adversely affect our revenues and profitability, 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. The enactment in the U.S. of healthcare reform, 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.

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, pharmaceutical and biotechnology companies, including other companies with similar technologies, and manufacturers of generic drugs (see “—We face claims against our intellectual property rights 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 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 pharmaceutical and biotechnology industries are 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 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

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technology to use with their drugs instead of one of our product platforms and could develop products that compete with our products.

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products, including, but not limited to, Luye Pharma, which is developing risperidone formulated as extended release microspheres for intramuscular injection for the treatment of schizophrenia and/or schizoaffective disorders. In the treatment of schizophrenia, ARISTADA, RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION, and INVEGA TRINZA/TREVICTA currently 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, 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 methadone, oral naltrexone, SUBOXONE (buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE (buprenorphine/naloxone) Sublingual Film, and SUBUTEX (buprenorphine HCl sublingual tablets), each of which is marketed and sold by Indivior plc, and BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences, PROBUPHINE (buprenorphine), marketed and sold by Braeburn Pharmaceuticals and ZUBSOLV (buprenorphine and naloxone) marketed by Orexo US, Inc. It also competes with 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 competes 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 also competes 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.

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; 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.

Our inability to compete successfully in the pharmaceutical and biotechnology industries could materially adversely affect our business, results of operations, cash flows and financial condition.

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We face claims against our intellectual property rights and competition from generic drug manufacturers.

In the U.S., generic manufacturers of innovator drug products may file ANDAs and, in doing so, 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 as “Paragraph IV” litigation in the U.S.

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 “Item 3—Legal Proceedings.”

Although we intend to vigorously enforce our intellectual property rights, there can be no assurance that we will prevail in our defense of our patent rights. Our existing patents could be invalidated, found unenforceable or found not to cover generic forms of our products. If an ANDA filer were to receive FDA approval to sell a generic version of our products and/or prevail in any patent litigation, our products would become subject to increased competition and our revenue could be 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), all of which could have a material adverse effect on our business, financial condition, cash flows and results of operations. 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.

Our business involves environmental, health and safety risks.

Our business involves the controlled 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 those 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, 2016, our accumulated deficit was $947.9 million, which was primarily the result of net losses incurred from 1987, the year Alkermes, Inc., was founded, through December 31, 2016, partially offset by net income over certain of our recent 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 partners' ability to manufacture economically, our marketed products. Our ability to achieve sustained profitability in the future depends, in part, on our or our licensees', as applicable, ability to:

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successfully commercialize VIVITROL and ARISTADA in the U.S.;

obtain and maintain regulatory approval for products both in the U.S. and in other countries;

efficiently manufacture our products;

support the commercialization of products by our licensees;

enter into agreements to develop and commercialize our products;

develop, have manufactured or expand our capacity to manufacture and market our products;

obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third-party payers;

obtain additional research and development funding for our proprietary products; and

achieve certain product development milestones.

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

the progress of our research and development programs for our products, including clinical trials;

the time and expense that will be required to pursue FDA and/or non-U.S. 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.

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

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

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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 partners 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 Disclosure about Market Risk” for additional information relating to our foreign currency exchange rate risk.

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

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

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

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

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

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

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

- uncertainties in assessing the value, strengths and potential profitability of, and identifying the extent of all weaknesses, risks, contingent and other liabilities of, the respective parties;
- the potential loss of key customers, management and employees of an acquired business;

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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, 2016, we have $318.2 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, results of operations and growth prospects.

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 business 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

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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 million of U.S. Federal net operating loss ("NOL") and $38 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 pharmaceutical and biotechnology industries over the last few years. If faced with a proxy contest, we may not be able to respond successfully to the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest involving us because:

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

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

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

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

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

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

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

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

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

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

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

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 and includes a tenant option to terminate in 2017. 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 65,000 square feet of office space. This lease expires in 2020 and includes a tenant option to extend the term for up to two one-year periods.

We own a R&D and manufacturing facility in Athlone, Ireland (approximately 400,000 square feet) and a manufacturing facility in Wilmington, Ohio (approximately 300,000 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

ARISTADA

On July 13, 2015, Otsuka PD&C filed a Citizen Petition with the FDA which requested that the FDA refuse to approve the NDA for ARISTADA or delay approval of such NDA until the exclusivity rights covering long-acting aripiprazole expire in December 2017. The FDA approved ARISTADA on October 5, 2015 and, concurrent with such approval, denied Otsuka PD&C's Citizen Petition.

On October 15, 2015, Otsuka filed an action for declaratory and injunctive relief with the DC Court against Sylvia Mathews Burwell, Secretary, U.S. Department of Health and Human Services; Dr. Stephen Ostroff, Acting Commissioner, FDA; and the FDA, requesting that the DC Court (a) expedite the legal proceedings; (b) declare that the FDA's denial of Otsuka's claimed exclusivity rights and approval of the ARISTADA NDA were arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law; (c) vacate FDA's approval of the ARISTADA NDA and vacate any FDA decisions or actions underlying or supporting or predicated upon that approval; (d) declare that Otsuka's claimed exclusivity rights preclude FDA from granting approval of the Alkermes

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NDA until the expiration of such exclusivity rights in December 2017; and (e) grant any and all other, further, and additional relief, including all necessary and appropriate protective preliminary, interim, or permanent relief, as the nature of the cause may require, including all necessary and appropriate declarations of rights and injunctive relief. We successfully intervened in, and received the DC Court's approval to become a party to, this action.

On July 28, 2016, the DC Court issued an opinion in favor of us and the FDA, affirming in all respects FDA's decision to approve ARISTADA for the treatment of schizophrenia, and denying the action filed by Otsuka for declaratory and injunctive relief. Otsuka has filed an appeal of the DC Court's decision with the DC Circuit asking the DC Circuit to reverse the DC Court's decision, vacate FDA's approval of the ARISTADA NDA and remand the case to the DC Court for consideration of any appropriate equitable remedy for Otsuka's lost exclusivity. The DC Circuit's appellate hearing for this matter occurred on December 12, 2016. We believe Otsuka's action is without merit and will continue to vigorously defend ARISTADA against such action. For information about risks relating to this action, see "Item 1A—Risk Factors" of this Annual Report and specifically the section entitled "Citizen Petitions and other actions filed with, or litigation against, the FDA or other regulatory agencies or litigation against Alkermes may negatively impact the approval of our products and our business."

AMPYRA

AMPYRA ANDA Litigation

Ten separate Paragraph IV Certification Notices have been submitted to us and/or our partner Acorda from Accord Healthcare, Inc. ("Accord"); Actavis Laboratories FL, Inc. ("Actavis"); Alkem Laboratories Ltd. ("Alkem"); Apotex Corporation and Apotex, Inc. (collectively, "Apotex"); Aurobindo Pharma Ltd. ("Aurobindo"); Mylan Pharmaceuticals, Inc. ("Mylan"); Par Pharmaceutical, Inc. ("Par"); Roxane Laboratories, Inc.; Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. (collectively, "Sun"); and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an ANDA to the FDA seeking marketing approval for generic versions of AMPYRA (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of the Orange Book-listed patents for AMPYRA, and they have also asserted that their generic versions do not infringe certain claims of these patents. In response, we and/or Acorda filed lawsuits against the ANDA filers in the U.S. District Court for the District of Delaware (the "Delaware Court") asserting infringement of U.S. Patent Nos. 5,540,938 (which we own), 8,007,826, 8,354,437, 8,440,703, and 8,663,685 (which are owned by Acorda). Requested judicial remedies include recovery of litigation costs and injunctive relief. Lawsuits with eight of the ANDA filers have been consolidated into a single case. The Delaware Court held a bench trial that concluded on September 23, 2016. All lawsuits were filed within 45 days from the date of receipt of each of the Paragraph IV Certification Notices. As a result, a 30-month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30-month stay starts from January 22, 2015, which is the end of the new chemical entity exclusivity period for AMPYRA. This stay restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of the asserted Orange Book-listed patents prior to that date.

Mylan challenged the jurisdiction of the Delaware Court with respect to the Delaware action. In January 2015, the Delaware Court denied Mylan's motion to dismiss. Subsequently, in January 2015, the Delaware Court granted Mylan's request for an interlocutory appeal of its jurisdictional decision to the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit"). In March 2016, the Federal Circuit denied Mylan's appeal, and the case remains in the Delaware Court. Mylan requested the Federal Circuit to reconsider its decision. However, on June 20, 2016, the Federal Circuit denied Mylan's request. Mylan filed an appeal with the U.S. Supreme Court, which was denied. Due to Mylan's motion to dismiss, we, along with Acorda, also filed another patent infringement suit against Mylan in the U.S. District Court for the Northern District of West Virginia asserting the same U.S. Patents and requesting the same judicial relief as in the Delaware action. In December 2014, we, along with Acorda, filed a motion in the Northern District of West Virginia to stay that action in deference to the Delaware proceeding. In February 2014, the District Court for the Northern District of West Virginia granted our motion to stay the proceeding. The patent infringement case against Mylan, however, is still proceeding in Delaware along with the cases against the other ANDA filers.

We and/or Acorda have entered into a settlement agreement with each of Accord, Actavis, Apotex, Alkem, Aurobindo, Par and Sun (collectively, the "Settling ANDA Filers") to resolve the patent litigation that we and/or Acorda brought against the Settling ANDA Filers in the Delaware Court as described above. As a result of the settlement agreements, the Settling ANDA Filers will be permitted to market a generic version of AMPYRA in the

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U.S. at a specified date in 2025, or potentially earlier under certain circumstances. The parties have submitted their respective settlement agreements to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlements with the Settling ANDA Filers do not resolve pending patent litigation that we and Acorda brought against the other ANDA filers, as described in this Annual Report.

We intend to vigorously enforce our intellectual property rights. For information about risks relating to the AMPYRA Paragraph IV litigations and other proceedings see “Item 1A—Risk Factors” in this Annual Report and specifically the section entitled “We face claims against our intellectual property rights and competition from generic drug manufacturers.”

AMPYRA IPR Proceedings

A hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) has filed IPR petitions with the USPTO, challenging U.S. Patent Nos.8,663,685; 8,440,703; 8,354,437 and 8,007,826 (which are owned by Acorda). In March 2016, the USPTO’s PTAB instituted the IPR. Oral argument for the IPR was held on January 19, 2017, and a ruling on the IPR petitions is expected in March 2017. The challenged patents are four of the five AMPYRA Orange-Book listed patents. The 30-month statutory stay period based on patent infringement suits filed by us and Acorda against ANDA filers is not impacted by these filings, and remains in effect.

BYDUREON, RISPERDAL CONSTA AND VIVITROL IPR Proceedings

On June 3, 2016, Luye Pharma, Luye Pharma (USA) Ltd., Shandong Luye Pharmaceutical Co., Ltd., and Nanjing Luye Pharmaceutical Co., Ltd. (collectively, “Luye”) filed two separate IPR petitions challenging U.S. Patent Number 6,667,061 (the “061 Patent”), which is an Orange Book-listed patent for each of BYDUREON, RISPERDAL CONSTA and VIVITROL. We opposed the institution of these IPR petitions. On November 30, 2016, the USPTO’s PTAB instituted one of Luye’s IPR petitions and denied instituting Luye’s other IPR petition. Oral argument for the instituted IPR is currently scheduled for August 28, 2017. A decision on the instituted IPR would be expected, pursuant to the statutory time frame, by November 30, 2018.

We will vigorously defend the 061 Patent in the IPR proceedings. For information about risks relating to the 061 Patent IPR proceedings see “Item 1A—Risk Factors” in this Annual Report and specifically the sections entitled “Patent protection for our products is important and uncertain” and “Uncertainty over intellectual property in the pharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable.”

Item 4. Mine Safety Disclosures

Not Applicable.

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PART II

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

Market and shareholder information

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

	Year Ended December 31, 2016		Year Ended December 31, 2015	
	High	Low	High	Low
1st Quarter	$ 75.27	$ 29.05	$ 73.64	$ 58.24
2nd Quarter	47.00	35.67	67.00	55.37
3rd Quarter	51.78	43.77	72.79	55.08
4th Quarter	59.50	42.30	80.14	57.89

There were 145 shareholders of record for our ordinary shares on February 3, 2017. In addition, the last reported sale price of our ordinary shares as reported on the NASDAQ on February 3, 2017 was $54.95.

Dividends

No dividends have been paid on the ordinary shares to date, and we do not expect to pay cash dividends thereon in the foreseeable future. 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.

Securities authorized for issuance under equity compensation plans

For information regarding securities authorized for issuance under equity compensation plans, see "Item 12, Security Ownership of Certain Beneficial Owners and Management," which incorporates by reference to the Proxy Statement

relating to our 2017 Annual General Meeting of Shareholders.

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, 2016. As of December 31, 2016, 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, 2016, we acquired 108,423 Alkermes ordinary shares, at an average price of $46.45 per share related to the vesting of employee equity awards to satisfy withholding tax obligations. During the three months ended December 31, 2016, we acquired 6,073 Alkermes ordinary shares, at an average price of $57.26 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 24, 2017, 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

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in securities, trustees, insurance companies, collective investment schemes and shareholders who acquire, or who are deemed to acquire, their ordinary shares by virtue of an office or employment. This summary is not exhaustive and shareholders should consult their own tax advisers as to the tax consequences in Ireland, or other relevant jurisdictions where we operate, including the acquisition, ownership and disposition of ordinary shares.

Withholding tax on dividends

While we have no current plans to pay dividends, dividends on our ordinary shares would generally be subject to Irish dividend withholding tax ("DWT") at the standard rate of income tax, which is currently 20%, unless an exemption applies. Dividends on our ordinary shares that are owned by residents of the U.S. and held beneficially through the Depositary Trust Company ("DTC") will not be subject to DWT provided that the address of the beneficial owner of the ordinary shares in the records of the broker is in the U.S.

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

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

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 will 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.

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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.

Stock Performance Graph

The information contained in the performance graph 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 of 1933, as amended or the Securities Exchange Act of 1934, as amended (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 since March 31, 2012 through December 31, 2016 with the NASDAQ Composite Total Return Index and the NASDAQ Biotechnology Index. As a result of a change in the total return data made available to us through our vendor provider, our performance graphs going forward will use the NASDAQ Composite Total Return Index in lieu of the NASDAQ U.S. & Foreign Index. Please note that information for the NASDAQ U.S. & Foreign Index is provided only from March 31, 2012 through December 31, 2013, the last day this data was made available by our third party index provider. The NASDAQ Biotechnology Index was not affected by this change. The comparison assumes $100 was invested on March 31, 2012 in our common stock and in each of the foregoing indices and further assumes reinvestment of any dividends. We did not declare or pay any dividends on our common stock or ordinary shares during the comparison period.

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	Year Ended March 31,		Nine Months Ended December 31,	Year Ended December 31,		
	2012	2013	2013	2014	2015	2016
Alkermes	100	128	219	316	428	300
NASDAQ Composite Total Return	100	107	138	159	170	185
NASDAQ Biotechnology Index	100	130	185	248	276	216
NASDAQ Stock Market (U.S. and Foreign) Index	100	107	141	—	—	—

Item 6. Selected Financial Data

The selected historical financial data set forth below at December 31, 2016 and 2015 and for the years ended December 31, 2016, 2015 and 2014 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, 2014, 2013 and March 31, 2013 and as of the nine months ended December 31, 2013 and the year ended March 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 elsewhere in this Annual Report. The historical results are not necessarily indicative of the results to be expected for any future period.

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	Year Ended December 31,			Nine Months Ended December 31,	Year Ended March 31,
	2016	2015	2014	2013	2013
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
REVENUES:					
Manufacturing and royalty revenues	$ 487,247	$ 475,288	$ 516,876	$ 371,039	$ 510,900
Product sales, net	256,146	149,028	94,160	57,215	58,107
Research and development revenue	2,301	4,019	7,753	4,657	6,541
Total revenues	745,694	628,335	618,789	432,911	575,548
EXPENSES:					
Cost of goods manufactured and sold	132,122	138,989	175,832	134,306	170,466
Research and development	387,148	344,404	272,043	128,125	140,013
Selling, general and administrative	374,130	311,558	199,905	116,558	125,758
Amortization of acquired intangible assets	60,959	57,685	58,153	38,428	41,852
Restructuring(1)	—	—	—	—	12,300
Impairment of long-lived assets(2)	—	—	—	—	3,346
Total expenses	954,359	852,636	705,933	417,417	493,735
OPERATING (LOSS) INCOME	(208,665)	(224,301)	(87,144)	15,494	81,813
OTHER (EXPENSE) INCOME, NET(3)	(5,722)	296	73,115	(10,097)	(46,372)
(LOSS) INCOME BEFORE INCOME TAXES	(214,387)	(224,005)	(14,029)	5,397	35,441
(BENEFIT) PROVISION FOR INCOME TAXES	(5,943)	3,158	16,032	(12,252)	10,458
NET (LOSS) INCOME	$ (208,444)	$ (227,163)	$ (30,061)	$ 17,649	$ 24,983
(LOSS) EARNINGS PER COMMON SHARE:					
BASIC	$ (1.38)	$ (1.52)	$ (0.21)	$ 0.13	$ 0.19
DILUTED	$ (1.38)	$ (1.52)	$ (0.21)	$ 0.12	$ 0.18
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:					
BASIC	151,484	149,206	145,274	135,960	131,713
DILUTED	151,484	149,206	145,274	144,961	137,100
Consolidated Balance Sheet Data:					
	$ 619,165	$ 798,849	$ 801,646	$ 449,995	$ 304,179

Cash, cash equivalents and investments					
Total assets(4)	1,726,423	1,855,744	1,919,058	1,574,848	1,467,121
Long-term debt(4)	283,666	349,944	355,756	361,553	365,837
Shareholders' equity	1,209,481	1,314,275	1,396,837	1,065,186	952,374

(1)Represents a one time charge in connection with the restructuring plan related to our Athlone, Ireland manufacturing facility recorded in the year ended March 31, 2013. The charge consists of severance payments and other employee related expenses.

(2)Includes an impairment charge of $3.3 million related to the impairment of certain of our equipment located at our Wilmington, Ohio manufacturing facility in the year ended March 31, 2013.

(3)Includes $9.6 million Gain on the Gainesville Transaction in the year ended December 31, 2015.

(4)In 2015, the Company retrospectively adopted the Financial Accounting Standards Board's guidance, simplifying the presentation of debt issuance costs. As a result, deferred financing costs of $2.2 million, $2.7 million and $3.2 million that were classified within "Other long-term assets" at December 31, 2014, December 31, 2013 and March 31, 2013, respectively, were reclassified to "Long-term debt" to conform to the current period presentation.

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

The following should be read in conjunction with our consolidated financial statements and related notes beginning on page F 1 of this Annual Report. The following discussion contains forward looking statements. Actual results may differ significantly from those projected in the forward looking statements. See "Cautionary Note Concerning Forward Looking Statements" on pages 3 and 4 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 INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA; AMPYRA/FAMPYRA; BYDUREON; VIVITROL; and ARISTADA. Revenues from these products accounted for 92% of our total revenues during the year ended December 31, 2016, as compared to 88% and 74% during the years ended December 31, 2015 and 2014, respectively.

During the year ended December 31, 2016 we incurred an operating loss of $208.7 million, which was primarily due to the continued significant investment in our R&D pipeline and commercial organization. During 2016, within R&D we:

- filed a sNDA for Aripiprazole Lauroxil Two-Month Dose;
- announced results from three phase 3 studies for ALKS 5461, met with the Division of Psychiatric Products at a Type C meeting and will request a pre-NDA meeting with the FDA and plan to submit the NDA for ALKS 5461 in the second half of 2017;
- continued the ENLIGHTEN phase 3 pivotal program for ALKS 3831, initiated in December 2015. We also announced the initiation of a phase 1 study of ALKS 3831 in October 2016;
- continued the two-year, multicenter, open-label phase 3 study designed to assess the safety of ALKS 8700, initiated in December 2015. We also announced our plan to initiate a randomized, head-to-head phase 3 study of the gastrointestinal tolerability of ALKS 8700 compared to TECFIDERA in the first half of 2017;
- completed, as of October 2016, enrollment of the phase 3 study evaluating the safety, tolerability and efficacy of ALKS 6428 in patients with opioid dependence, which was initiated in September 2015; and
- filed an IND with the FDA and initiated a phase 1 study of ALKS 4230 in May 2016.

In 2016, we had increases in net sales of VIVITROL of 45% when compared to 2015, and we had a full year of ARISTADA sales as ARISTADA was launched in October 2015. As a result of the approval of ARISTADA, and our continued investment in VIVITROL, selling, general and administrative expenses increased by 20% in 2016, when compared to 2015, most of which was driven by increases in headcount and increased marketing activity related to these two products.

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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, 2016, 2015 and 2014:

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2016	2015	2014	2016–2015	2015–2014
Manufacturing and royalty revenues:					
Continuing products:					
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ 184.2	$ 149.7	$ 127.8	$ 34.5	$ 21.9
AMPYRA/FAMPYRA	114.2	104.7	80.9	9.5	23.8
RISPERDAL CONSTA	87.2	100.7	120.6	(13.5)	(19.9)
BYDUREON	45.6	46.1	36.6	(0.5)	9.5
Other	56.0	55.3	80.6	0.7	(25.3)
	487.2	456.5	446.5	30.7	10.0
Divested products:					
RITALIN LA & FOCALIN XR	—	9.3	40.7	(9.3)	(31.4)
Other	—	9.5	29.7	(9.5)	(20.2)
	—	18.8	70.4	(18.8)	(51.6)
Manufacturing and royalty revenues	$ 487.2	$ 475.3	$ 516.9	$ 11.9	$ (41.6)

Under our INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA agreement with Janssen, we earn royalties on end market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA of 5% up to the first $250 million in calendar year sales, 7% on calendar year sales of between $250 million and $500 million, and 9% on calendar year sales exceeding $500 million. The royalty rate resets at the beginning of each calendar year to 5%. Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earn manufacturing revenues of 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA and royalty revenues of 2.5% of end market 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 sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. Janssen's end market sales of INVEGA SUSTENNA/XEPLION and INVEGA

TRINZA/TREVICTA were $2.2 billion, $1.8 billion and $1.6 billion, during the years ended December 31, 2016, 2015 and 2014, respectively. Partially offsetting the increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA end-market sales by Janssen in 2015, as compared to 2014, was an 8% decrease in revenue due to the strengthening of the U.S. dollar in relation to the currencies in which XEPLION/TREVICTA were sold.

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 $893.0 million, $970.0 million and $1,190.0 million, during the years ended December 31, 2016, 2015 and 2014, respectively. The decline in Janssen's end-market net sales led to a decrease in our royalty revenues of 8% in 2016, as compared to 2015, and 18% in 2015, as compared to 2014. Contributing to the decrease in RISPERDAL CONSTA end-market net sales by Janssen in 2015, as compared to 2014, was a 9% decrease in revenue due to the strengthening of the U.S. dollar in relation to the currencies in which RISPERDAL CONSTA was sold.

The manufacturing revenue we earned on shipments of RISPERDAL CONSTA to Janssen also declined by 15% in 2016, as compared to 2015, and by 16% in 2015, as compared to 2014. The decrease in manufacturing revenue in 2016, as compared to 2015, was primarily due to a 13% decrease in the number of units shipped to Janssen and the decrease in manufacturing revenue in 2015, as compared to 2014, was primarily due to a 17% decrease in the number of units shipped to Janssen.

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

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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, such as Australia and South Korea, in 2023. The latest of the patents covering INVEGA TRINZA/TREVICTA expire in November 2017 in the U.S. and 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. RISPERDAL CONSTA is covered by a patent until 2021 in the EU and 2023 in the U.S. As such, we do not anticipate generic versions in the near term for any of these products.

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 with Biogen, 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 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 were $573.9 million, $520.7 million and $446.4 million in the years ended December 31, 2016, 2015 and 2014, respectively.

The increase in AMPYRA/FAMPYRA revenues in 2015, as compared to 2014, was due to a 31% increase in manufacturing revenue and a 28% increase in royalty revenue. The increase in manufacturing revenue was primarily due to a 20% increase in product shipped to Acorda and Biogen and an 8% increase in price.

We expect AMPYRA/FAMPYRA sales to continue to grow as Acorda continues to penetrate the U.S. market with AMPYRA and Biogen continues to launch FAMPYRA in the rest of the world. AMPYRA is covered by a patent until 2027 in the U.S. and FAMPYRA is covered by a patent until 2025 in the EU. AMPYRA is subject to an IPR proceeding and Paragraph IV litigation. For a discussion of legal proceedings related to the patents covering AMPYRA, see “Item 3—Legal Proceedings.” A number of companies, including us, are working to develop products to treat multiple sclerosis that may compete with AMPYRA/FAMPYRA, which may negatively impact future sales of the products.

Under our BYDUREON license agreement with AstraZeneca, we earned royalties on end-market net sales of BYDUREON of 8% in the years ended December 31, 2016, 2015 and 2014. The change in BYDUREON royalty revenues in each period presented was due to the amount of end market net sales of BYDUREON. AstraZeneca’s end-market net sales of BYDUREON were $576.3 million, $580.0 million and $457.3 million in 2016, 2015 and 2014, respectively. BYDUREON is covered by a patent until 2026 in the U.S. and until 2024 in the EU, and as such, we do not anticipate any generic versions of this product in the near term.

Included in other manufacturing and royalty revenues in 2015 and 2014 was $9.5 million and $29.7 million, respectively, of revenue associated with certain products manufactured at our divested manufacturing facility in Gainesville, GA, including VERELAN, ZOHYDRO ER, and BIDIL, which were sold in April 2015. RITALIN LA and FOCALIN XR were also manufactured at our Gainesville facility.

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 “Item 7A. Quantitative and Qualitative Disclosures about Market Risk” for information on currency exchange rate risk related to our revenues.

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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 specialty 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, 2016, 2015 and 2014:

	Year Ended December 31,								
(In millions)	2016	% of Sales		2015	% of Sales		2014	% of Sales	
Product sales, gross	$ 444.6	100.0	%	$ 227.0	100.0	%	$ 137.1	100.0	%
Adjustments to product sales, gross:									
Medicaid rebates	(94.2)	(21.2)	%	(32.2)	(14.2)	%	(11.1)	(8.1)	%
Product discounts	(35.1)	(7.9)	%	(13.2)	(5.8)	%	(7.2)	(5.3)	%
Chargebacks	(31.5)	(7.1)	%	(17.8)	(7.8)	%	(9.3)	(6.8)	%
Co-pay assistance	(8.5)	(1.9)	%	(6.5)	(2.9)	%	(6.1)	(4.4)	%
Other	(19.2)	(4.3)	%	(8.3)	(3.7)	%	(9.2)	(6.7)	%
Total adjustments	(188.5)	(42.4)	%	(78.0)	(34.4)	%	(42.9)	(31.3)	%
Product sales, net	$ 256.1	57.6	%	$ 149.0	65.6	%	$ 94.2	68.7	%

The increase in product sales, gross in 2016, as compared to 2015, was primarily due to a 70% increase in VIVITROL gross sales, and a full year of ARISTADA sales. The increase in VIVITROL gross sales was primarily due to a 66% increase in the number of VIVITROL units sold and a 3% increase in the price of VIVITROL. The 66% increase in product sales, gross in 2015, as compared to 2014, was due to a 61% increase in VIVITROL gross sales and the launch of ARISTADA in October 2015. The 61% increase in VIVITROL gross sales was primarily due to a 46% increase in the number of VIVITROL units sold and an 11% increase in the price of VIVITROL.

The increase in Medicaid rebates as a percentage of sales in 2016, as compared to 2015, and in 2015, as compared to 2014, was primarily due to an increase in the amount of VIVITROL sold under the Medicaid Drug Rebate Program.

Our product sales, net for VIVITROL and ARISTADA in 2016 were $209.0 million and $47.1 million, respectively, as compared to $144.4 million and $4.6 million in 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 increase following its approval by the FDA in October 2015.

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.

Costs and Expenses

Cost of Goods Manufactured and Sold

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2016	2015	2014	2016 - 2015	2015 - 2014
Cost of goods manufactured and sold	$ 132.1	$ 139.0	$ 175.8	$ 6.9	$ 36.8

The decrease in cost of goods manufactured and sold in 2016, as compared to 2015, was primarily due to the Gainesville Transaction. During the years ended December 31, 2015 and 2014, the Gainesville facility had cost of goods manufactured of $10.2 million and $37.1 million, respectively. 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.

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The decrease in cost of goods manufactured and sold in 2015, as compared to 2014, was primarily due to the Gainesville Transaction. Also, in connection with the restructuring plan related to our Athlone, Ireland manufacturing facility initiated in April 2013, our cost of goods manufactured at our Athlone facility decreased by $14.3 million, with the most significant savings being occupancy and depreciation expense of $9.2 million and employee-related expenses of $4.1 million. These decreases were partially offset by an increase in cost of goods manufactured and sold related to our Ohio manufacturing facility of $4.4 million, which was primarily due to the increase in sales of VIVITROL and the launch of ARISTADA in October 2015, partially offset by a decrease in cost of goods manufactured for RISPERDAL CONSTA due to a decrease in the number of units shipped to Janssen.

Research and Development Expenses

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

The following table sets forth our external R&D expenses relating to our individual Key Development Programs and all other development programs, and our internal R&D expenses by the nature of such expenses:

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2016	2015	2014	2016 - 2015	2015 - 2014
External R&D Expenses:					
Key development programs:					
ALKS 3831	$ 71.0	$ 26.1	$ 28.8	$ (44.9)	$ 2.7
ALKS 5461	46.2	108.4	77.1	62.2	(31.3)
ARISTADA and ARISTADA line extensions	36.3	38.1	30.9	1.8	(7.2)
ALKS 8700	26.9	17.9	10.1	(9.0)	(7.8)
ALKS 6428	16.3	7.0	—	(9.3)	(7.0)
Other external R&D expenses	47.2	19.5	25.0	(27.7)	5.5
Total external R&D expenses	243.9	217.0	171.9	(26.9)	(45.1)
Internal R&D expenses:					
Employee-related	110.1	97.5	75.7	(12.6)	(21.8)
Occupancy	9.0	8.1	6.9	(0.9)	(1.2)
Depreciation	7.9	6.2	8.2	(1.7)	2.0

Other	16.2	15.6	9.3	(0.6)	(6.3)
Total internal R&D expenses	143.2	127.4	100.1	(15.8)	(27.3)
Research and development expenses	$ 387.1	$ 344.4	$ 272.0	$ (42.7)	$ (72.4)

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 the expenses related to ALKS 3831 in 2016, as compared to 2015, was primarily due to the ENLIGHTEN-1 and ENLIGHTEN-2 pivotal trials, which were initiated in December 2015 and February 2016, respectively. The decrease in expenses related to ALKS 5461 in 2016, as compared to 2015, and the increase in expenses in 2015, as compared to 2014, were primarily due to the timing of the three core phase 3 studies related to the program. We announced the results of the FORWARD-3 and FORWARD-4 studies in January 2016 and topline results from FORWARD-5 were announced in October 2016. The ALKS 5461 pivotal clinical development program was initiated in March 2014. The decrease in expenses related to ARISTADA and ARISTADA line extensions in 2016, as compared to 2015, and the increase in 2015, as compared to 2014, were 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 following an NDA filing in August 2014, based on the positive phase 3 results announced in April 2014. Also, in December 2014, we initiated a phase 1 clinical study of extended dosing intervals of ARISTADA in patients with schizophrenia. Based on the results of this study, we submitted a sNDA to the FDA in August 2016. The increase in expenses related to ALKS 6428 was primarily due to the initiation of the

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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 ALKS 8700 in each of the three years presented 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 ALKS 8700 in December 2015, following the completion of a phase 1 study of ALKS 8700 initiated in 2014.

The increase in other external R&D expenses was primarily due to a $10.0 million non-refundable, upfront payment made as partial consideration of a grant to us of rights and licenses pursuant to a collaboration and license option agreement with Reset Therapeutics, Inc., as well as an increase in external expenses 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 “Item 1—Business” in this Annual Report. Expenses incurred under the ALKS 7119 and ALKS 4230 development programs in 2016, 2015 and 2014 were not material.

The increase in employee-related expenses was primarily due to an increase in headcount. Our R&D-related headcount increased by 20% in 2016, as compared to 2015, and by 20% in 2015 as compared to 2014, respectively.

Selling, General and Administrative Expenses

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2016	2015	2014	2016 - 2015	2015 - 2014
Selling, general and administrative expense	$ 374.1	$ 311.6	$ 199.9	$ (62.5)	$ (111.7)

The increase in selling, general and administrative (“SG&A”) expense in 2016, as compared to 2015, was primarily due to a $28.9 million increase in employee-related expenses and a $27.1 million increase in marketing and professional services expenses. The increase in employee-related expenses was primarily due to a 15% increase in our SG&A-related headcount during 2016. The increase in marketing and professional services expenses was primarily due to additional brand investments in both VIVITROL and ARISTADA in 2016, as well as an increase in patient access support services, such as reimbursement and transition assistance, for both of these products.

The increase in SG&A expense in 2015, as compared to 2014, was primarily due to the preparation of the launch of ARISTADA in October 2015, which consisted of an $82.9 million increase in employee-related expenses and a $24.3

million increase in marketing and professional services expenses. The increase in employee-related expenses was primarily due to a 92% increase in SG&A-related headcount and a $26.4 million increase in share-based compensation expense, due to the increase in the amount of equity awards granted, the vesting of performance-based restricted stock units in October 2015 that were tied to the approval of ARISTADA, and recent equity grants were awarded with higher grant-date fair values than older grants due to the increase in our stock price. The increase in marketing and professional services expenses was primarily due to pre-launch activities for ARISTADA.

Amortization of Acquired Intangible Assets

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2016	2015	2014	2016 - 2015	2015 - 2014
Amortization of acquired intangible assets	$ 61.0	$ 57.7	$ 58.2	$ (3.3)	$ 0.5

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.

As part of the Gainesville Transaction, we sold certain of the intellectual property we acquired from EDT that had an original cost of $57.8 million. Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at December 31, 2016 is expected to be approximately $60.0 million, $60.0 million, $55.0 million, $50.0 million and $45.0 million in the years ending December 31, 2017 through 2021, respectively.

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Other (Expense) Income, Net

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2016	2015	2014	2016 - 2015	2015 - 2014
Interest income	$ 3.8	$ 3.3	$ 2.0	$ 0.5	$ 1.3
Interest expense	(14.9)	(13.2)	(13.4)	(1.7)	0.2
Change in the fair value of contingent consideration	7.9	(2.3)	—	10.2	(2.3)
Gain on Gainesville Transaction	—	9.6	—	(9.6)	9.6
Gain on sale of property, plant and equipment	—	2.9	41.9	(2.9)	(39.0)
Gain on sale of investment in Civitas Therapeutics, Inc.	—	—	29.6	—	(29.6)
Gain on sale of investment in Acceleron Pharma Inc.	—	—	15.3	—	(15.3)
Other (expense) income, net	(2.5)	—	(2.3)	(2.5)	2.3
Total other (expense) income, net	$ (5.7)	$ 0.3	$ 73.1	$ (6.0)	$ (72.8)

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, 2016 and 2015, we determined that the fair value of the contingent consideration increased by $7.9 million and decreased by $2.3 million, respectively. The increase in contingent

consideration in 2016 was 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 on the milestones and royalties included in the contingent consideration. The decrease in contingent consideration recorded in 2015 was primarily due to a delay in the timing of future clinical events.

Gain on the sale of property, plant and equipment in 2014 consisted of the following two transactions: in April 2014, we sold certain of our land, buildings and equipment at our Athlone, Ireland facility that had a carrying value of $2.2 million, in exchange for $17.5 million and recorded a gain of $12.3 million, as $3.0 million of the sale proceeds were placed in escrow pending the completion of certain additional services we were obligated to perform, which were completed in December 2015. In October 2014, we sold certain of our commercial scale pulmonary manufacturing equipment, which had a carrying value of $0.4 million, to Acorda in exchange for $30.0 million.

In October 2014, in connection with the acquisition of Civitas by Acorda, we received $27.2 million and $2.4 million was placed in escrow, for our approximate 6% equity interest in Civitas. We received the amounts held in escrow in October 2015. During the second quarter of 2014, we sold our investment in Acceleron Pharma Inc., which consisted of equity securities, for a gain of $15.3 million.

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(Benefit) Provision for Income Taxes

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2016	2015	2014	2016 - 2015	2015 - 2014
(Benefit) provision for income taxes	$ (5.9)	$ 3.2	$ 16.0	$ 9.1	$ 12.8

The income tax benefit for the year ended December 31, 2016 was primarily due to U.S. federal research credits. The favorable change in the income taxes in the year ended December 31, 2016, as compared to 2015, was due to a reduction in income earned in the U.S. The income tax provision for the years ended December 31, 2015 and 2014 was primarily due to U.S. federal and state taxes on income earned in the U.S.

No provision for income tax has been provided on undistributed earnings of our foreign subsidiaries because such earnings may be repatriated to Ireland without incurring any tax liability. Cumulative unremitted earnings of overseas subsidiaries totaled approximately $133.7 million at December 31, 2016.

At December 31, 2016, we maintained a valuation allowance of $4.8 million against certain U.S. state deferred tax assets and $137.1 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, 2016, we had $1.1 billion of Irish NOL carryforwards, $8.0 million of U.S. federal NOL carryforwards and $7.4 million of U.S. state NOL carryforwards, $53.1 million of federal R&D credits, $9.0 million of alternative minimum tax credits and $9.4 million of U.S. state tax credits which either expire on various dates through 2036 or can be carried forward indefinitely. These loss carryforwards and credits are available to reduce certain future Irish and U.S. taxable income and tax, respectively, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. These loss carryforwards, which may be utilized in any future period, may be subject to limitations based upon changes in the ownership of our ordinary shares. We have performed a review of ownership changes in accordance with the Code and have determined that it is more likely than not that, as a result of the Business Combination, we experienced a change of ownership. As a consequence, a portion of our U.S. federal NOL carryforwards and tax credit carryforwards are subject to an annual limitation of $127.0 million.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

	December 31, 2016			December 31, 2015		
(In millions)	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	$ 81.2	$ 105.2	$ 186.4	$ 70.8	$ 110.3	$ 181.1
Investments—short-term	184.4	126.5	310.9	202.4	151.2	353.6
Investments—long-term	60.1	61.8	121.9	129.1	135.0	264.1
Total cash and investments	$ 325.7	$ 293.5	$ 619.2	$ 402.3	$ 396.5	$ 798.8
Outstanding borrowings—current and long-term	$ 283.7	$ —	$ 283.7	$ 349.9	$ —	$ 349.9

At December 31, 2016, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized Gains	Losses	Estimated Fair Value
Investments—short-term	$ 310.9	$ 0.1	$ (0.1)	$ 310.9
Investments—long-term available-for-sale	119.0	—	(0.5)	118.5
Investments—long-term held-to-maturity	3.4	—	—	3.4
Total	$ 433.3	$ 0.1	$ (0.6)	$ 432.8

Sources and Uses of Cash

We used $63.8 million and $40.4 million and generated cash from operations of $11.1 million during the years ended December 31, 2016, 2015 and 2014, 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

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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.

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, 2016, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

Information about our cash flows, by category, is presented in the accompanying consolidated statements of cash flows. The following table summarizes our cash flows for the years ended December 31, 2016, 2015 and 2014:

	Year Ended December 31,		
(In millions)	2016	2015	2014
Cash and cash equivalents, beginning of period	$ 181.1	$ 224.1	$ 167.6
Cash (used in) provided by operating activities	(63.8)	(40.4)	11.1
Cash provided by (used in) investing activities	127.2	(43.5)	(263.4)
Cash (used in) provided by financing activities	(58.1)	40.9	308.8
Cash and cash equivalents, end of period	$ 186.4	$ 181.1	$ 224.1

Operating Activities

The $23.4 million increase in cash used in operating activities in 2016, as compared to 2015, was primarily due to a $57.8 million increase in the amount of cash paid to our employees and a $76.2 million increase in the amount of cash paid to our suppliers, partially offset by a $98.2 million 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.

The $51.5 million increase in cash used in operating activities in 2015, as compared to 2014, was primarily due to a $53.4 million increase in the amount of cash paid to our employees and a $18.5 million increase in the amount of cash

paid to our suppliers, partially offset by a $10.9 million 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

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. Cash used in investing activities decreased by $219.9 million in 2015, as compared to 2014, which was primarily due to a decrease in the net purchases of investments of $260.2 million. The net purchases of investments in 2014 was greater than that in 2015 due to certain significant transactions occurring in 2014 including: the receipt of $250.0 million in gross proceeds from the sale of 5.9 million of our ordinary shares to the Invesco Funds in January 2014; the receipt of $17.5 million from the sale of certain of our land, buildings and equipment located at our Athlone, Ireland facility in April 2014; and the receipt of $57.2 million from Civitas, $30.0 million of which was from the sale of certain commercial scale pulmonary manufacturing equipment and $27.2 million for our approximate 6% equity interest in Civitas when they were acquired by Acorda in October 2015. We used the majority of the proceeds from these transactions to purchase available-for-sale investments.

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In 2016, our capital spending decreased slightly when compared to 2015 and increased in 2015 when compared to 2014. These fluctuations were primarily due to the timing of our capital projects, primarily for 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, 2016 primarily include capital expenditures at our manufacturing facility in Wilmington, Ohio. We expect to spend approximately $75.0 million during the year ended December 31, 2017 for capital expenditures. We continue to evaluate our manufacturing capacity based on expectations of demand for our products and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service, or we determine we have sufficient existing capacity and the assets are no longer required, at which time we would recognize an impairment charge. We continue to periodically evaluate whether facts and circumstances indicate that the carrying value of these long lived assets to be held and used may not be recoverable.

Financing Activities

The increase in cash used in financing activities in 2016, as compared to 2015, 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 addition, there was a $12.2 million decrease in cash received from employee stock option exercises. The decrease in cash provided by financing activities in 2015, as compared to 2014, was primarily due to the Invesco transaction, as noted above. We also spent $13.1 million more in employee taxes related to the net share settlement of equity awards in 2015, as compared to 2014, but received $3.8 million less in proceeds from the exercise of stock options by our employees.

Borrowings

At December 31, 2016, our borrowings consisted of $287.3 million outstanding under Term Loan B-1. Please refer to Note 10, Long Term Debt, in the accompanying “Notes to Consolidated Financial Statements” for a discussion of our outstanding term loans.

Contractual Obligations

The following table summarizes our obligations to make future payments under our current contracts at December 31, 2016:

	Less Than	One to	Three to	More than

Contractual Obligations (In thousands)	Total	One Year (2017)	Three Years (2018 - 2019)	Five Years (2020 - 2021)	Five Years (After 2021)
Term Loan B-1—Principal	$ 287,250	$ 3,000	$ 6,000	$ 278,250	$ —
Term Loan B-1—Interest	56,333	10,014	19,714	26,605	—
Operating lease obligations	24,817	6,055	12,367	5,729	666
Purchase obligations	431,950	431,950	—	—	—
Total contractual cash obligations	$ 800,350	$ 451,019	$ 38,081	$ 310,584	$ 666

As interest on Term Loan B 1 is based on a one, three or six month LIBOR rate of our choosing, we assumed LIBOR to be 0.75%, which is the LIBOR rate floor under the terms of Term Loan B 1 as the one-month LIBOR rate at December 31, 2016 was 0.72%. 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, 2016, we had $4.7 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

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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, 2016, 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 effect of matters that are inherently uncertain. We have reviewed these critical accounting estimates and related disclosures with the Audit and Risk Committee of our Board of Directors.

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 collaborative partners. As the end market sale occurs after we have shipped our product and the risk of loss has passed to our collaborative partner, we estimate the sales price for our product based on information supplied to us by our collaborative partners, 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 actual and estimated manufacturing revenues has not been material.

Royalty revenues are related to the sale of products by our collaborative partners that incorporate our technologies. Royalties, with the exception of AMPYRA, are earned under the terms of a license agreement in the period the products are sold by our collaborative partner, and the royalty earned can be reliably measured and collectability is reasonably assured. Sales information is provided to us by our collaborative partners 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 actual and estimated royalty revenues has not been material. Royalties on AMPYRA are earned in the period product is shipped to Acorda. We also earn royalties on shipments of AMPYRA to Acorda manufactured by third party manufacturers.

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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 and specialty pharmacies.

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 pharmaceutical and biotechnology 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 Average Manufacturer Prices. 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—wholesaler and specialty pharmacy chargebacks are discounts that occur when contracted customers purchase directly from an intermediary wholesale purchaser. Contracted customers, which consist primarily of federal government agencies purchasing under the Federal Supply Schedule, generally purchase the product at its contracted price, plus a mark up from the wholesaler. The wholesaler, in turn, charges back to us the difference between the price initially paid by the wholesaler and the contracted price paid to the wholesaler by the customer. The allowance for wholesaler chargebacks is based on actual and expected utilization of these programs. Wholesaler chargebacks could exceed historical experience and our estimates of future participation in these programs. To date, actual wholesaler chargebacks have not differed materially from our estimates;

Product Discounts—cash consideration, including sales incentives, given by us under distribution service agreements with a number of wholesaler, distributor and specialty pharmacy customers that provide them with the opportunity to earn discounts in exchange for the performance of certain services. To date, actual product discounts have not differed materially from our estimates;

Co pay Assistance— the Company has a program whereby a patient can receive monetary assistance each month toward their product co-payment, co-insurance or deductible, provided the patient meets certain eligibility criteria. Reserves are recorded upon the product sale. To date, actual co-pay assistance has not differed materially from the Company's 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, 2016, our product return reserve was estimated to be approximately 1.6% of our VIVITROL product sales and 1.5% of our ARISTADA product sales.

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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, 2014	$ 3.7	$ 0.1	$ 0.9	$ —	$ 5.5	$ 1.9	$ 12.1
Provision:							
Current period	31.4	17.8	13.2	7.2	3.3	6.1	79.0
Prior period	0.8	—	—	(0.7)	(1.1)	—	(1.0)
Total	32.2	17.8	13.2	6.5	2.2	6.1	78.0
Actual:							
Current period	(14.2)	(17.3)	(10.7)	(6.7)	(0.9)	(4.4)	(54.2)
Prior period	(4.5)	—	(0.5)	—	(0.1)	(0.2)	(5.3)
Total	(18.7)	(17.3)	(11.2)	(6.7)	(1.0)	(4.6)	(59.5)
Balance, December 31, 2015	$ 17.2	$ 0.6	$ 2.9	$ (0.2)	$ 6.7	$ 3.4	$ 30.6
Provision:							
Current period	92.1	31.5	35.3	9.2	7.1	12.1	187.3
Prior period	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 period	(48.7)	(30.6)	(30.6)	(8.9)	(1.0)	(10.8)	(130.6)
Prior period	(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

Investments

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

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

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

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

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Share Based Compensation

We have a share based compensation plan, which includes 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' 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 behavior 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, 2016, 2015 and 2014, the ranges in weighted average assumptions were as follows:

	Year Ended December 31,		
	2016	2015	2014
Expected option term	5 - 7 years	5 - 7 years	5 - 7 years
Expected stock volatility	39 % - 53 %	38 % - 46 %	39 % - 46 %
Risk-free interest rate	0.95 % - 2.14 %	1.29 % - 2.02 %	1.46 % - 2.24 %
Expected annual dividend yield	—	—	—

In addition to the above, we apply judgment in developing estimates of award forfeitures. For the year ended December 31, 2016, we used an estimated forfeiture rate of zero for our non employee directors, 2.25% for members of senior management and 6.0% for all other employees.

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

Amortization and Impairment of Long Lived Assets

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

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

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

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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 collaborative partners' 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, 2016, is expected to be approximately $60.0 million, $60.0 million, $55.0 million, $50.0 million and $45.0 million in the years ending December 31, 2017 through 2021, 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, 2016, we have one operating segment and two reporting units. Our goodwill, which solely relates to 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 two-step 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 our reporting unit is less than its carrying amount, the quantitative two step 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 immediately perform the quantitative two step impairment test.

The first step of the quantitative two-step goodwill impairment test requires us to compare the fair value of the reporting unit to its respective carrying value, which includes goodwill. If the fair value of the reporting unit exceeds its carrying value, the goodwill is not considered impaired. If the carrying value is higher than the fair value, there is an indication that an impairment may exist and the second step is required. In step two, the implied fair value of goodwill is calculated as the excess of the fair value of a reporting unit over the fair values assigned to its assets and liabilities. If the implied fair value of goodwill is less than the carrying value of the reporting unit’s goodwill, the difference is recognized as an impairment loss.

At October 31, 2016, we decided to perform the quantitative two-step goodwill impairment test primarily due to the length of time since we had last performed such a test. We worked with a third-party valuation firm and established

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fair value for the purpose of impairment testing by using an average of the income approach and the market approach. The income approach employs a discounted cash flow model that takes into account: (i) assumptions that market participants would use in their estimates of fair value; (ii) current period actual results; and (iii) budgeted results for future periods that have been vetted by senior management. The discounted cash flow model incorporates the same fundamental pricing concepts used to calculate fair value in an acquisition due diligence process and a discount rate that takes into consideration our estimated cost of capital adjusted for the uncertainty inherent in an acquisition. The market approach employs market multiples for comparable publicly traded companies in the pharmaceutical and biotechnology industries obtained from industry sources, taking into consideration the nature, scope and size of the acquired reporting unit. In the market approach, estimates of fair value are established using an average of both revenue and EBITDA multiples, adjusted for the reporting unit's performance relative to peer companies.

We determined that the fair value of the former EDT business reporting unit was substantially in excess of its respective carrying value and there was no impairment in the value of this asset as of October 31, 2016. A decline in the estimated fair value of a reporting unit could result in goodwill impairment, and a related non-cash impairment charge against earnings, if the estimated fair value for the reporting unit is less than the carrying value of the net assets of the reporting unit, including its goodwill. A large decline in estimated fair value of a reporting unit could result in an adverse effect on our financial condition and results of operations. In order to evaluate the sensitivity of the fair value calculations relating to our goodwill impairment assessment, we applied a hypothetical decrease to the estimated fair value of the former EDT business reporting unit and we determined that a decrease in fair value of approximately 87% would be required before this reporting unit would have a carrying value in excess of its fair value.

Contingent Consideration

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

The period over which we discount contingent consideration is based on the current development stage of the product candidates, the specific development plan for that product candidate adjusted for the probability of completing the development step, and the date on which contingent payments would be triggered. In estimating the probability of success, we utilize data regarding similar milestone events from several sources, including industry studies and our own experience. These fair value measurements are based on significant inputs not observable in the market. Significant judgment was employed in determining the appropriateness of these assumptions at the acquisition date and for each subsequent period. Accordingly, changes in assumptions described above could have a material impact on the increase or decrease in the fair value of contingent consideration recorded in any given period.

At December 31, 2016, our contingent consideration relates to consideration received as part of the Gainesville Transaction. The Company is eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and up to $125.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products, including, pursuant to the First Amendment to the Purchase Agreement, at Recro's election, either (i) $10.0 million upon the submission of an NDA filing for the first Meloxicam Product and $30.0 million upon regulatory approval of an NDA for the first Meloxicam Product or (ii) an aggregate of $45.0 million upon regulatory approval of an NDA for the first Meloxicam Product.

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 either (i) $10.0 million upon the submission of an NDA filing for the first Meloxicam Product and $30.0 million upon regulatory approval of an NDA for the first Meloxicam Product or (ii) an aggregate of $45.0 million upon regulatory approval of an NDA for the first Meloxicam Product. The fair value of the two regulatory milestones were estimated based on applying the likelihood of achieving the regulatory

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milestones and applying a discount rate from the expected time the milestones occur to the balance sheet date. We expect the regulatory milestone events to occur within the next year and two years, respectively, and used a discount rate of 2.8% and 3.6%, respectively, for each of these events. We then assessed the likelihood of Recro opting to pay us under either scenario (i) or scenario (ii) to arrive at a probability weighted present value for these regulatory milestones;

We are entitled to receive future royalties on net sales of Meloxicam Products. To estimate the fair value of the future royalties, we assessed the likelihood of a Meloxicam Product being approved for sale and estimated the expected future sales given approval and IP protection. We then discounted these expected payments using a discount rate of 16.0%, which we believe captures a market participant's view of the risk associated with the expected payments; and

We are entitled to receive payments upon achieving certain sales milestones on future sales of the Meloxicam Product. The sales milestones were determined through the use of a real options approach, where net sales are simulated in a risk-neutral world. To employ this methodology, we used a risk-adjusted expected growth rate based on its assessments of expected growth in net sales of the approved Meloxicam Product, adjusted by an appropriate factor capturing their respective correlation with the market. A resulting expected (probability-weighted) milestone payment was then discounted at a cost of debt plus a risk adjustment, which ranged from 10.6% to 12.3%.

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

Valuation of Deferred Tax Assets

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

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

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

- nature,