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, 2019

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**	**D04 C5Y6**
(Address of principal executive offices)	**(Zip code)**

+353-1-772-8000

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, $0.01 par value	ALKS	Nasdaq Global Select Market

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

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

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

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

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

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

Large Accelerated Filer ☒	Accelerated Filer ☐
Non-Accelerated Filer ☐	Smaller Reporting Company ☐
	Emerging Growth Company ☐

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

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

The aggregate market value of the registrant's ordinary shares held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the ordinary shares were last sold as of the last business day of the registrant's most recently completed second fiscal quarter was $3,507,584,798.

As of February 4, 2020, 157,787,433 ordinary shares were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2020 Annual General Meeting of Shareholders are incorporated by reference into Part III of this report.

ALKERMES PLC AND SUBSIDIARIES
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2019
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CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This document contains and incorporates by reference "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In some cases, these statements can be identified by the use of forward-looking terminology such as "may," "will," "could," "should," "would," "expect," "anticipate," "continue," "believe," "plan," "estimate," "intend," or other similar words. These statements discuss future expectations and contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward-looking information. Forward-looking statements in this Annual Report on Form 10-K (this "Annual Report") include, without limitation, statements regarding:

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

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

This Annual Report includes data that we obtained from industry publications and third-party research, surveys and studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. This Annual Report also includes data based on our own internal estimates and research. Our internal estimates and research have not been verified by any independent source, and, while we believe the industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Such third-party data and our internal estimates and research are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Item 1A—Risk Factors" in this Annual Report. These and other factors could cause results to differ materially from those expressed in this Annual Report.

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

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

NOTE REGARDING TRADEMARKS

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

The following are trademarks of the respective companies listed: ABILIFY® and ABILIFY MAINTENA®—Otsuka Pharmaceutical Co., Ltd. (“Otsuka Pharm. Co.”); AMPYRA® and FAMPYRA®—Acorda Therapeutics, Inc. (“Acorda”); ANTABUSE®—Teva Women’s Health, Inc.; AUBAGIO® and LEMTRADA®—Sanofi Societe Anonyme France; AVONEX®, PLEGRIDY®, TECFIDERA®, TYSABRI® and VUMERITY®—Biogen MA Inc. (together with its affiliates, “Biogen”); BETASERON®—Bayer Pharma AG; BRIXADI®—Braeburn Inc.; BUNAVAIL™—BioDelivery Sciences; CAMPRAL®—Merck Sante; CAPLYTA®—Intra-Cellular Therapies, Inc.; COPAXONE®—Teva Pharmaceutical Industries Ltd.; EXTAVIA®, GILENYA®, and MAYZENT®—Novartis AG; INVEGA SUSTENNA®, INVEGA TRINZA®, TREVICTA®, XEPLION® and RISPERDAL CONSTA®—Johnson & Johnson (or its affiliates); LATUDA®— Sumitomo Dainippon Pharma Co., Ltd.; MAVENCLAD®—Merck KGaA, REBIF®—Ares Trading S.A.; OCREVUS®—Genentech, Inc. (“Genentech”); PROBUPHINE®—Titan Pharmaceuticals, Inc.; REXULTI®— H. Lundbeck A/S plc; PERSERIS®, SUBOXONE®, SUBUTEX® and SUBLOCADE®—Indivior plc (or its affiliates); ZUBSOLV®—Orexo US, Inc.; ZYPREXA® and ZYPREXA RELPREVV®—Eli Lilly and Company (“Lilly”); and VRAYLAR®— Forest Laboratories, LLC. Other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PART I

Item 1. *Business*

The following discussion contains forward-looking statements. Actual results may differ significantly from those expressed or implied in the forward-looking statements. See “Cautionary Note Concerning Forward-Looking Statements” on page 3 in 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 products focused on central nervous system disorders such as addiction and schizophrenia and a pipeline of product candidates in the fields of neuroscience and oncology. Headquartered in Dublin, Ireland, Alkermes has a research and development (“R&D”) center in Waltham, Massachusetts; an R&D and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio.

In November 2019, Alkermes acquired Rodin Therapeutics, Inc. (“Rodin”), a privately-held biopharmaceutical company focused on developing novel, small molecule therapeutics for synaptopathies. This acquisition expanded Alkermes’ R&D efforts to include small molecule therapeutics for synaptopathies.

Marketed Products

The key marketed products discussed below are expected to generate significant revenues for us. See “Patents and Proprietary Rights” in “Item 1—Business” in this Annual Report for information with respect to the IP protection for these marketed products.

The following provides summary information regarding our proprietary products that we commercialize:

Product	Indication(s)	Territory
	Initiation or re-initiation of ARISTADA for the treatment of Schizophrenia	U.S.
	Schizophrenia	U.S.
	Alcohol dependence and Opioid dependence	U.S.

The following provides summary information regarding our licensed products, and third-party products using our proprietary technologies under license, that are commercialized by our licensees:

Third-Party Products Using Our Proprietary Technologies

Product	Indication(s)	Licensee	Licensed 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 / XEPLION	*INVEGA SUSTENNA*: Schizophrenia and Schizoaffective disorder *XEPLION*: Schizophrenia	Janssen Pharmaceutica N.V. (together with Janssen, Inc., Janssen International and their affiliates "Janssen")	Worldwide
INVEGA TRINZA / TREVICTA	Schizophrenia	Janssen	Worldwide

Our Licensed Products

Product	Indication(s)	Licensee	Licensed Territory
VIVITROL	Alcohol dependence and Opioid dependence	Cilag GmbH International ("Cilag")	Russia and Commonwealth of Independent States ("CIS")
VUMERITY	Multiple sclerosis	Biogen	Worldwide

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 available in four dose strengths with once-monthly dosing options (441 mg, 662 mg and 882 mg), a six-week dosing option (882 mg) and a two-month dosing option (1064 mg). ARISTADA is packaged in a ready-to-use, pre-filled product format. We developed ARISTADA and exclusively manufacture and commercialize it in the U.S.

ARISTADA INITIO

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

What is schizophrenia?

Schizophrenia is a serious brain disorder marked by positive symptoms (hallucinations and delusions, disorganized speech and thoughts, and agitated or repeated movements) and negative symptoms (depression, blunted emotions and social withdrawal). Approximately 3.5 million people are diagnosed with schizophrenia in the U.S., with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia. Studies have demonstrated that as many as 75% of patients with schizophrenia have difficulty taking their oral medication on a regular basis, which can lead to worsening of symptoms.

VIVITROL (U.S.)

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

For a discussion of legal proceedings related to VIVITROL, see Note 19, *Commitments and Contingent Liabilities* in the “Notes to Consolidated Financial Statements” in this Annual Report, and for information about risks relating to such legal proceedings, see “Item 1A—Risk Factors” in this Annual Report and specifically the sections entitled “—Patent protection for our products is important and uncertain,” “—Uncertainty over intellectual property in the biopharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable, could significantly delay or prevent approval or commercialization of our products, and could adversely affect our business” and “—Litigation, arbitration or regulatory action (such as citizens petitions) filed against regulatory agencies related to our product or Alkermes, including securities litigation, may result in financial losses, harm our reputation, divert management resources, negatively impact the approval of our products, or otherwise negatively impact our business.”

What are opioid dependence and alcohol dependence?

Opioid dependence is a serious and chronic brain disease characterized by compulsive, prolonged self-administration of opioid substances that are not used for a medical purpose. According to the 2018 U.S. National Survey on Drug Use and Health, an estimated 1.9 million people aged 18 or older in the U.S. had an opioid use disorder in the past year. 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 2018 U.S. National Survey on Drug Use and Health, an estimated 14.4 million people aged 18 or older in the U.S. had an alcohol use disorder in the past year. Adherence to medication is particularly challenging with these patient populations.

In 2013, with the publication of the Diagnostic Statistical Manual (“DSM”) 5, the DSM IV diagnoses of substance use disorders as either dependence or abuse (i.e., opioid dependence or alcohol dependence), which reflects the approved indication of VIVITROL,

were combined into one diagnostic category of “substance use disorders” (i.e., opioid use disorder or alcohol use disorder) with three categories of disorder severity—mild, moderate or severe.

Licensed Products and Products Using Our Proprietary Technologies

We have licensed products to third parties for commercialization and have licensed our proprietary technologies to third parties to enable them to develop, commercialize and/or manufacture products. We receive royalties and/or manufacturing and other revenues from the commercialization of these products. Such arrangements include the following:

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

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

INVEGA SUSTENNA is approved in the U.S. for the treatment of schizophrenia and for the treatment of schizoaffective disorder as either a monotherapy or adjunctive therapy. Paliperidone palmitate extended-release injectable suspension is approved in the European Union (“EU”) and other countries outside of the U.S. for the treatment of schizophrenia and is marketed and sold under the trade name XEPLION. INVEGA SUSTENNA/XEPLION uses our nanoparticle injectable extended-release technology to increase the rate of dissolution and enable the formulation of an aqueous suspension for once-monthly intramuscular administration. INVEGA SUSTENNA/XEPLION is manufactured by Janssen. For a discussion of legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 19, *Commitments and Contingent Liabilities* in the “Notes to Consolidated Financial Statements” in this Annual Report and for information about risks relating to such legal proceedings, see “Item 1A—Risk Factors” in this Annual Report and specifically the section entitled “—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers.”

INVEGA TRINZA is approved in the U.S. for the treatment of schizophrenia in patients who have been adequately treated with INVEGA SUSTENNA for at least four months. TREVICTA is approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION. INVEGA TRINZA/TREVICTA is the first schizophrenia treatment to be taken once every three months. INVEGA TRINZA/TREVICTA uses our proprietary technology and is manufactured by Janssen.

RISPERDAL CONSTA is approved in the U.S. for the treatment of schizophrenia and as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA is approved in numerous countries outside of the U.S. for the treatment of schizophrenia and the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one intramuscular injection every two weeks. RISPERDAL CONSTA microspheres are exclusively manufactured by us. For a discussion of legal proceedings related to certain of the patents covering RISPERDAL CONSTA, see Note 19, *Commitments and Contingent Liabilities* in the “Notes to Consolidated Financial Statements” in this Annual Report and for information about risks relating to such legal proceedings, see “Item 1A—Risk Factors” in this Annual Report and specifically the section entitled “—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers.”

Revenues from Janssen accounted for approximately 28%, 29% and 33% of our consolidated revenues for the years ended December 31, 2019, 2018 and 2017, respectively. See “Collaborative Arrangements” in “Item 1—Business” in this Annual Report for additional 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. Patients with this brain disorder may experience debilitating mood swings, from extreme highs (mania) to extreme lows (depression). Bipolar I disorder is characterized based on the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode and affects approximately one percent of the American adult population in any given year. The median age of onset for bipolar I disorder is 25 years.

What is schizoaffective disorder?

Schizoaffective disorder is a condition in which a person experiences a combination of schizophrenia symptoms, such as delusions, hallucinations or other symptoms characteristic of schizophrenia, and mood disorder symptoms, such as mania or depression. Schizoaffective disorder is a serious mental illness that affects about one in 300 people.

VIVITROL (Russia and CIS)

VIVITROL is described more fully above under the heading “Proprietary Products” in “Item 1—Business” in this Annual Report. We developed and exclusively manufacture VIVITROL for Cilag. Cilag exclusively commercializes VIVITROL in Russia and certain countries of the CIS.

VUMERITY (Diroximel Fumarate)

VUMERITY (diroximel fumarate), formerly referred to as BIIB098, is a novel, oral fumarate with a distinct chemical structure that was approved in the U.S. in October 2019 for the treatment of relapsing forms of multiple sclerosis in adults, including clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.

Under our license and collaboration agreement with Biogen, Biogen holds the exclusive, worldwide license to develop and commercialize VUMERITY. For more information about the license and collaboration agreement with Biogen, see “Collaborative Arrangements—Biogen” in “Item 1—Business” in this Annual Report.

Revenues from Biogen related to this license and collaboration agreement accounted for approximately 17%, 10% and less than 10% of our consolidated revenues for the years ended December 31, 2019, 2018 and 2017, respectively.

What is multiple sclerosis?

Multiple sclerosis, or MS, is an unpredictable, often disabling disease of the CNS, which interrupts the flow of information within the brain, and between the brain and body. MS symptoms can vary over time and from person to person. Symptoms may include extreme fatigue, impaired vision, problems with balance and walking, numbness or pain and other sensory changes, bladder and bowel symptoms, tremors, problems with memory and concentration and mood changes, among others. Approximately 400,000 individuals in the U.S. and 2.5 million people worldwide have MS, and most are diagnosed between the ages of 15 and 50.

Key Development Programs

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

ALKS 3831

ALKS 3831 is an investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of adults with schizophrenia and for the treatment of adults with bipolar I disorder. ALKS 3831 is composed of samidorphan, a novel, new molecular entity, co-formulated with the established antipsychotic agent, olanzapine, in a single bilayer tablet.

ALKS 3831 is designed to provide the robust antipsychotic efficacy of olanzapine while mitigating olanzapine-associated weight gain. The ENLIGHTEN clinical development program for ALKS 3831 includes two key phase 3 studies in patients with schizophrenia: ENLIGHTEN-1, a four-week study which evaluated the antipsychotic efficacy of ALKS 3831 compared to placebo, and ENLIGHTEN-2, a six-month study which assessed weight gain with ALKS 3831 compared to ZYPREXA® (olanzapine). The program also includes supportive studies to evaluate the pharmacokinetic (“PK”) and metabolic profile and long-term safety of ALKS 3831, and pharmacokinetic bridging studies comparing ALKS 3831 and ZYPREXA.

In May 2019, we conducted a pre-NDA meeting with the U.S. Food and Drug Administration (“FDA”) to discuss the FDA’s key requirements for the new drug application (“NDA”) for ALKS 3831, including those related to efficacy, safety, weight and metabolic profile, and the expansion of the planned NDA for ALKS 3831 to encompass the treatment of bipolar I disorder in addition to the treatment of schizophrenia. In November 2019, we submitted our NDA to the FDA,seeking approval for ALKS 3831 for the treatment of schizophrenia and for the treatment of manic and mixed episodes associated with bipolar I disorder as a monotherapy or adjunct to lithium or valproate and for maintenance treatment of bipolar I disorder. In January 2020, the FDA accepted the ALKS 3831 NDA and assigned a Prescription Drug User Fee Act (“PDUFA”) target action date of November 15, 2020. The ALKS 3831 NDA includes data from the ENLIGHTEN clinical development program in patients with schizophrenia, as well as PK bridging data comparing ALKS 3831 and ZYPREXA. We are seeking approval of fixed dosage strengths of ALKS 3831 composed of 10 mg of samidorphan co-formulated with 5 mg, 10 mg, 15 mg or 20 mg of olanzapine.

ALKS 4230

ALKS 4230 is a novel, engineered fusion protein designed to selectively expand tumor-killing immune cells while avoiding the activation of immunosuppressive cells by preferentially binding to the intermediate-affinity interleukin-2 ("IL-2") receptor complex. The selectivity of ALKS 4230 is designed to leverage the proven anti-tumor effects of existing IL-2 therapy while mitigating certain limitations.

ARTISTRY is our clinical development program that evaluates ALKS 4230 in patients with advanced solid tumors. ARTISTRY-1, an ongoing phase 1/2 study of ALKS 4230 administered via intravenous infusion as a monotherapy and in combination with the anti-PD-1 therapy, pembrolizumab, is designed to evaluate the safety profile and anti-tumor activity of ALKS 4230 in patients with select advanced solid tumors. ARTISTRY-1 has three distinct stages: an ongoing monotherapy dose-escalation stage, an ongoing monotherapy expansion stage, and an ongoing combination therapy stage with the PD-1 inhibitor pembrolizumab in patients with select advanced solid tumors. ARTISTRY-2, an ongoing phase 1/2 study of ALKS 4230 administered subcutaneously as monotherapy and in combination with pembrolizumab in patients with advanced solid tumors, is designed to explore the safety, tolerability and efficacy of ALKS 4230 and assess once-weekly and once-every-three-week subcutaneous dosing schedules. ARTISTRY-2, which we initiated in February 2019, is being conducted in two stages: an ongoing dose-escalation stage, to be followed by a dose-expansion stage.

In November 2019, we presented data from the ARTISTRY clinical development program at the 2019 Society for Immunotherapy of Cancer Meeting.

Collaborative Arrangements

We have entered into several collaborative arrangements to develop and commercialize products and, in connection with such arrangements, to access technological, financial, marketing, manufacturing and other resources. See "Patents and Proprietary Rights" in "Item 1—Business" in this Annual Report for information with respect to the IP protection for these products.

Janssen

INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA

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

Under this license agreement, we received milestone payments upon the achievement of certain development goals from Janssen; there are no further milestones to be earned under this agreement. We receive tiered royalty payments between 3.5% and 9% of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA end-market net sales in each country where the license is in effect, with the exact royalty percentage determined based on aggregate worldwide net sales. The tiered royalty payments consist of a patent royalty and a know-how royalty, both of which are determined on a country-by-country basis. The patent royalty, which equals 1.5% of net sales, is payable in each country until the expiration of the last of the patents with valid claims applicable to the product in such country. The know-how royalty is a tiered royalty of 3.5% on calendar year net sales up to $250 million, 5.5% on calendar year net sales of between $250 million and $500 million and 7.5% on calendar year net sales exceeding $500 million. The know-how royalty rate resets to 3.5% at the beginning of each calendar year and is payable until 15 years from the first commercial sale of a product in each individual country, subject 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 expiration of the last of the patents subject to the agreement. After expiration, Janssen retains a non-exclusive, royalty-free license to develop, manufacture and commercialize the products.

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

RISPERDAL CONSTA

Under a product development agreement, we collaborated with Janssen on the development of RISPERDAL CONSTA. Under the development agreement, Janssen provided funding to us for the development of RISPERDAL CONSTA, and Janssen is responsible for securing all necessary regulatory approvals for the product.

Under two license agreements, we granted Janssen and an affiliate of Janssen exclusive worldwide licenses to use and sell RISPERDAL CONSTA. Under our license agreements with Janssen, we receive royalty payments equal to 2.5% of Janssen's end-market net sales of RISPERDAL CONSTA in each country where the license is in effect based on the quarter when the product is sold

by Janssen. This royalty may be reduced in any country based on lack of patent coverage and significant competition from generic versions of the product. Janssen can terminate the license agreements upon 30 days' prior written notice to us. Either party may terminate the license agreements by written notice following a breach which continues for 90 days after the delivery of written notice thereof or upon the other party's insolvency. The licenses granted to Janssen expire on a country-by-country basis upon the later of (i) the expiration of the last patent claiming the product in such country or (ii) 15 years after the date of the first commercial sale of the product in such country, provided that in no event will the license granted to Janssen expire later than the twentieth anniversary of the first commercial sale of the product in each such country, with the exception of Canada, France, Germany, Italy, Japan, Spain and the United Kingdom, in each case, where the fifteen-year minimum shall pertain regardless. After expiration, Janssen retains a non-exclusive, royalty-free license to manufacture, use and sell RISPERDAL CONSTA.

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

Acorda

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

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

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

Under our commercial manufacturing supply agreement with Acorda, we manufacture and supply AMPYRA/FAMPYRA for Acorda (and its sub-licensee, Biogen). Under the terms of the agreement, Acorda may obtain up to 25% of its total annual requirements of product from a second-source manufacturer. We receive manufacturing royalties equal to 8% of net selling price (or higher under certain circumstances) 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: (i) $1.0 million upon initiation of a phase 3 clinical trial; (ii) $1.0 million upon acceptance of an NDA by the FDA; (iii) $1.5 million upon approval of the NDA by the FDA; and (iv) $1.5 million upon the first commercial sale.

Biogen

Under a license and collaboration agreement with Biogen, which we entered into in November 2017 and amended in October 2018, January 2019 and October 2019, we granted Biogen a worldwide, exclusive, sublicensable license to develop, manufacture and commercialize VUMERITY and other products covered by patents licensed to Biogen under the agreement.

Under this license and collaboration agreement, we received an upfront cash payment of $28.0 million in November 2017, and milestone payments of $50.0 million, $150.0 million and $5.0 million in June 2018, November 2019 and December 2019, respectively, upon the achievement of certain developmental milestones, including FDA approval of the NDA for VUMERITY in October 2019, and amendment of the license and collaboration agreement in October 2019. We are also eligible to receive additional payments upon achievement of milestones with respect to the first two products, other than VUMERITY, covered by patents licensed to Biogen under the license and collaboration agreement.

In addition, we receive a 15% royalty on worldwide net sales of VUMERITY, subject to, under certain circumstances, minimum annual payments for the first five years following FDA approval of VUMERITY. We are also entitled to receive royalties on net sales of products other than VUMERITY covered by patents licensed to Biogen under the license and collaboration agreement, at tiered royalty rates calculated as percentages of net sales ranging from high-single digits to sub-teen double digits. All royalties are payable on a product-by-product and country-by-country basis until the later of (i) the last-to-expire patent right covering the applicable product in the applicable country and (ii) a specified period of time from the first commercial sale of the applicable product in the applicable country. Royalties for all products and the minimum annual payments for VUMERITY are subject to customary reductions, as set forth in the license and collaboration agreement.

Except in limited circumstances, we were responsible for the development of VUMERITY until it was approved by the FDA. Following FDA approval of VUMERITY in October 2019 and except for the manufacturing responsibilities discussed below, Biogen is now responsible for all development and commercialization activities for VUMERITY and all other products covered by patents licensed to Biogen.

Under the license and collaboration agreement, Biogen appointed us as the toll manufacturer of clinical and commercial supplies of VUMERITY, subject to Biogen's right to manufacture or have manufactured commercial supplies as a back-up manufacturer and subject to good faith agreement by the parties on the terms of such manufacturing arrangements. In October 2019, we entered into a commercial supply agreement with Biogen for the commercial supply of VUMERITY, an amendment to such commercial supply agreement and an amendment to the November 2017 license and collaboration agreement with Biogen. Under these agreements, Biogen has an option to assume responsibility, subject to a transition period, for the manufacture (itself or through a designee) of clinical supplies of VUMERITY and up to 100% of commercial supplies of VUMERITY in exchange for an increase in the royalty rate to be paid by Biogen to us on net sales of product that is manufactured by Biogen or its designee.

If VUMERITY discontinuations due to gastrointestinal adverse events in VUMERITY's long-term safety clinical trial exceed a certain pre-defined threshold, then "GI Inferiority" shall be deemed to exist, and (i) Biogen shall have the right to recapture from us its $50.0 million option payment through certain temporary reductions in royalty rates, and (ii) the minimum annual payments Biogen owes to us shall terminate.

Unless earlier terminated, the license and collaboration agreement will remain in effect until the expiry of all royalty obligations. Biogen has the right to terminate the license and collaboration agreement at will, on a product-by-product basis or in its entirety upon 180 days' prior notice to us. Either party has the right to terminate the license and collaboration agreement following any governmental prohibition of the transactions effected by the agreement, or in connection with an insolvency event involving the other party. Upon termination of the license and collaboration agreement by either party, then, at our request, the VUMERITY program will revert to us.

Proprietary Technology Platforms

We have used our proprietary technology platforms, which include technologies owned and exclusively licensed to us, 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 with varied drug release profiles.

Manufacturing and Product Supply

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

Although some materials and services for our products are currently only 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. However, we cannot be certain that we will continue to be able to obtain long-term supplies of our manufacturing materials.

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

Marketed Products

We manufacture ARISTADA and ARISTADA INITIO, and microspheres for RISPERDAL CONSTA and VIVITROL, in our Wilmington, Ohio facility. We are currently operating one RISPERDAL CONSTA line, two VIVITROL lines, two ARISTADA lines and one ARISTADA INITIO line at commercial scale. We source our packaging operations for VIVITROL, ARISTADA and ARISTADA INITIO to third-party contractors. Janssen is responsible for packaging operations for RISPERDAL CONSTA and, in Russia and certain countries of the CIS, VIVITROL. Our Wilmington, Ohio facility has been inspected by U.S., European (including the UK 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, VUMERITY, and other products in our Athlone, Ireland facility. This facility has been inspected by U.S., Irish, Brazilian, Turkish, Saudi Arabian, Korean, Belarusian, Russian and Chinese regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing. In 2019, the FDA completed a pre-approval inspection and recommended the Athlone, Ireland facility for approval to manufacture commercial supplies of VUMERITY.

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

Clinical Products

We have established, and are operating, facilities with the capability to produce clinical supplies of injectable extended-release products, solid dosage form products and biologics products at our Wilmington, Ohio facility and solid dosage form 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 “Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Annual Report for additional information relating to our R&D expenditures.

Permits and Regulatory Approvals

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

We do not generally act as the marketing 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 marketing authorization from the FDA or other regulatory authority, and we would support this authorization by furnishing a copy of the product’s Drug Master File, or chemistry, manufacturing and controls data, to the relevant regulator. We generally update this information annually with the relevant regulator. In other cases where we have developed proprietary products, such as VIVITROL, ARISTADA and ARISTADA INITIO, we hold the marketing authorization and related regulatory documentation ourselves.

Marketing, Sales and Distribution

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

Our sales force for VIVITROL in the U.S. consists of approximately 100 individuals. VIVITROL is primarily sold to pharmaceutical wholesalers, pharmacies, specialty distributors and treatment providers. Product sales of VIVITROL during the year ended December 31, 2019 to Cardinal Health, McKesson Corporation and AmerisourceBergen Corporation (“AmerisourceBergen”) represented approximately 23%, 21% and 12%, respectively, of total VIVITROL gross sales.

Our sales force for ARISTADA and ARISTADA INITIO in the U.S. consists of approximately 250 individuals. ARISTADA and ARISTADA INITIO are primarily sold to pharmaceutical wholesalers. Product sales of ARISTADA and ARISTADA INITIO during the year ended December 31, 2019 to Cardinal Health, McKesson Corporation and AmerisourceBergen represented approximately 43%, 25% and 24%, respectively, of total ARISTADA and ARISTADA INITIO gross sales.

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

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

Competition

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

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

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

With respect to our products, we believe that our ability to successfully compete will depend on, among other things, the existence of competing or alternative products in the marketplace, including generic competition, and the relative price of those products; the efficacy, safety and reliability of our products compared to competing or alternative products; product acceptance by, and preferences of, 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 relating to our products; our ability to obtain reimbursement for our products in approved indications; our ability to complete clinical development and obtain regulatory approvals for our products, and the timing and scope of regulatory approvals; our ability to provide a reliable supply of commercial quantities of a product to the market; and our ability to recruit, retain and develop skilled employees.

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products, including, but not limited to Luye Pharma Group Ltd. (“Luye Pharma”), which is developing risperidone formulated as extended release microspheres for intramuscular injection for the treatment of schizophrenia and/or schizoaffective disorders. In the treatment of schizophrenia, ARISTADA, INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA compete with each other and a number of other injectable products including ZYPREXA RELPREVV ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly; ABILIFY MAINTENA (aripiprazole for extended release injectable suspension), a once-monthly injectable formulation of ABILIFY (aripiprazole) developed by Otsuka Pharm. Co.; PERSERIS (risperidone for extended release injectable suspension), a once-monthly formulation of risperidone marketed by Indivior plc; CAPLYTA (lumateperone), an oral, once-daily anti-psychotic developed by Intra-Cellular Therapies, Inc.; other 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, which is co-marketed by Otsuka Pharm Co. and H. Lundbeck A/S plc; LATUDA, which is marketed and sold by Sunovion Pharmaceuticals Inc.; VRAYLAR, which is marketed and sold by Allergan plc; ABILIFY MAINTENA; risperidone; quetiapine; olanzapine; ziprasidone and clozapine.

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

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

In the treatment of MS, VUMERITY competes with AVONEX, TYSABRI, TECFIDERA, and PLEGRIDY from Biogen; OCREVUS from Genentech; BETASERON from Bayer HealthCare Pharmaceuticals; COPAXONE from Teva Pharmaceutical Industries Ltd.; REBIF and MAVENCLAD from EMD Serono, Inc.; GILENYA, EXTAVIA and MAYZENT from Novartis AG; and AUBAGIO and LEMTRADA from Sanofi-Aventis.

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

Patents and Proprietary Rights

Our success will be dependent, in part, on our ability to obtain and maintain patent protection for our products, including those marketed and sold by our licensees, to maintain trade secret protection and to operate without infringing upon the proprietary rights of others. We have a proprietary portfolio of patent rights and exclusive licenses to patents and patent applications, which includes numerous patents in the U.S. and in other countries directed to compositions of matter, methods of treatment and formulations, as well as processes of preparation. In the future, we plan to file additional patent applications in the U.S. and in other countries directed to new or improved products and processes, and we intend to continue to vigorously defend our patent positions. In addition, our licensees may own additional patents that cover those products owned by such licensees that incorporate our proprietary technologies and for which we receive royalties.

ARISTADA and ARISTADA INITIO

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

U.S. Patent No.	Product(s) Covered	Expiration Date
8,431,576	ARISTADA; ARISTADA INITIO	2030
8,796,276	ARISTADA; ARISTADA INITIO	2030
10,112,903	ARISTADA; ARISTADA INITIO	2030
10,023,537	ARISTADA	2030
10,352,529	ARISTADA; ARISTADA INITIO	2030
9,034,867	ARISTADA	2032
10,226,458	ARISTADA	2032
9,193,685	ARISTADA	2033
9,861,699	ARISTADA	2033
10,342,877	ARISTADA	2033
9,452,131	ARISTADA	2035
9,526,726	ARISTADA	2035
10,064,859	ARISTADA	2035
10,238,651	ARISTADA	2035
10,478,434	ARISTADA	2035
10,016,415	ARISTADA INITIO	2035

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

VIVITROL and RISPERDAL CONSTA

We have a number of patents and pending patent applications covering our microsphere technology throughout the world, which, to some extent, cover VIVITROL and RISPERDAL CONSTA. The latest to expire of our patents covering RISPERDAL CONSTA expire in the U.S. in 2023 and in the EU in 2021. We own one unexpired Orange-Book listed U.S. patent covering RISPERDAL CONSTA, which expires in 2020. For a discussion of legal proceedings related to certain of the patents covering RISPERDAL CONSTA, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Annual Report.

We own seven unexpired Orange-Book listed U.S. patents covering VIVITROL. The latest to expire of our patents covering VIVITROL expire in the U.S. in 2029 and in the EU in 2021. Under the terms of a settlement and license agreement entered into in July 2019 with Amneal Pharmaceuticals LLC ("Amneal"), we granted Amneal a non-exclusive license under certain patents covering VIVITROL, including the latest to expire patent covering VIVITROL in the U.S., to market and sell a generic formulation of VIVITROL in the U.S. beginning sometime in 2028 or earlier under certain circumstances.

INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA

Our NanoCrystal technology patent portfolio, licensed to Janssen in relation to INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA, contains a number of granted patents and pending patent applications throughout the world, including in the U.S. and in countries outside of the U.S. The latest of the patents subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expires in 2030 in the U.S. and certain other countries and in 2022 in the EU. The latest to expire of the licensed patents covering INVEGA TRINZA/TREVICTA in the U.S. expired in 2017 and in the EU will expire in 2022. In addition, Janssen has other patents not subject to our license agreement, including one that covers INVEGA SUSTENNA in the U.S. and expires in 2031 and one that covers INVEGA TRINZA in the U.S. and expires in 2036. For a discussion of legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Annual Report.

VUMERITY

We have U.S. patents and patent applications, and a number of corresponding foreign counterparts, that cover VUMERITY. U.S. Patent Nos. 8,669,281, 9,090,558 and 10,080,733, each expiring in 2033, cover compositions of, or methods of treatment for, VUMERITY.

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

ALKS 3831

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

U.S. Patent No.	Product(s) Covered	Expiration Date
7,956,187	ALKS 3831	2021
8,252,929	ALKS 3831	2021
7,262,298	ALKS 3831	2025
8,680,112	ALKS 3831	2030
9,119,848	ALKS 3831	2031
10,005,790	ALKS 3831	2031
8,778,960	ALKS 3831	2031
9,126,977	ALKS 3831	2031
9,517,235	ALKS 3831	2031
9,943,514	ALKS 3831	2031
10,300,054	ALKS 3831	2031

ALKS 4230

We have U.S. patents and patent applications, and a number of corresponding foreign counterparts, that cover ALKS 4230. U.S. Patent Nos. 9,359,415 and 10,407,481, each expiring in 2033, cover compositions of ALKS 4230.

Protection of Proprietary Rights and Competitive Position

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

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

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

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

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

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

Regulatory

Regulation of Pharmaceutical Products

United States

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

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 Investigational New Drug ("IND") Application, and are reviewed by the FDA prior to the commencement of human clinical trials. The pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial clinical studies in human volunteers.

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

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

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

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

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

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

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

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

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

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

Outside the United States

Certain of our products are commercialized by our licensees in numerous jurisdictions outside the U.S. Most of these jurisdictions have product approval and post-approval regulatory processes that are similar in principle to those in the U.S. In Europe, there are several tracks for marketing approval, depending on the type of product for which approval is sought. Under the centralized procedure, a company submits a single application to the European Medicines Agency ("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 approval 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 and other regulatory agencies both in the manufacture of clinical product and following product approval. The FDA, the EMA and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities and processes following the initial approval of a product. If, as a result of these inspections, it is determined that our equipment, facilities or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations.

Good Clinical Practices

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

Hatch-Waxman Act

Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Congress created an abbreviated FDA review process for generic versions of pioneer, or brand-name, drug products. The law also provides incentives by awarding, in certain circumstances, non-patent related marketing exclusivities to pioneer drug manufacturers. Newly approved drug products and changes to the conditions of use of approved products may benefit from periods of non-patent-related marketing exclusivity in addition to any patent protection the drug product may have. The Hatch-Waxman Act provides five years of new chemical entity ("NCE") marketing exclusivity to the first applicant to gain approval of an NDA for a product that contains an active ingredient, known as the active drug moiety, not found in any other approved product. The FDA is prohibited from accepting any abbreviated NDA ("ANDA") for a generic drug or 505(b)(2) application referencing the NCE for five years from the date of approval of the NCE, or four years in the case of an ANDA or 505(b)(2) application containing a patent challenge, and in both cases may not approve such generic drug or 505(b)(2) application until expiration of NCE marketing exclusivity. 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 the applicant 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" in this Annual Report and specifically those sections entitled "—If we fail to comply with the extensive legal and regulatory requirements affecting the healthcare industry, we could face increased costs, penalties and a loss of business," "—Revenues generated by sales of our products depend on the availability of reimbursement from third-party payers, and a reduction in payment rate or reimbursement or an increase in our financial obligation to governmental payers could result in decreased sales of our products and decreased revenues" and "—The commercial use of our products may cause unintended side effects or adverse reactions, or incidents of misuse may occur, which could adversely affect our business and share price."

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

Pricing and Reimbursement

United States

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

Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Under the Medicaid rebate program, we are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate for each product is set by law as the greater of 23.1% of average manufacturer price ("AMP") or the difference between AMP and the best price available from us to any commercial or non-federal governmental customer. The rebate amount must be adjusted upward where the AMP for a product's first full quarter of sales, when adjusted for increases in the Consumer Price Index—Urban, is less than the AMP for the current quarter, with this difference being the amount by which the rebate is adjusted upwards. The rebate amount is required to be recomputed each quarter based on our report of current AMP and best price for each of our products to the Centers for Medicare & Medicaid Services ("CMS"). The terms of our participation in the rebate program imposes a requirement for us to report revisions to AMP or best price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. In addition, if we were found to have knowingly submitted false information to the government, the statute provides for civil monetary penalties per item of false information in addition to other penalties available to the government. Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part B pays physicians who administer our products under a payment methodology using average sales price ("ASP") information. Manufacturers, including us, are required to provide ASP information to the CMS on a quarterly basis. This information is used to compute Medicare payment rates, with rates for Medicare Part B drugs outside the hospital outpatient setting and in the hospital outpatient setting consisting of ASP plus a specified percentage. These rates are adjusted periodically. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, the statute provides for civil monetary penalties for each misrepresentation and for each day in which the misrepresentation was applied.

Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e. drugs that do not need to be injected or otherwise administered by a physician) and certain physician-administered drugs reimbursed under a pharmacy benefit. Medicare Part D also covers the prescription drug benefit for dual eligible beneficiaries. Medicare Part D is administered by private prescription drug plans approved by the U.S. government and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time. The prescription drug plans negotiate pricing with manufacturers and may condition formulary placement on the availability of manufacturer discounts. Except for dual eligible Medicare Part D beneficiaries who qualify for low income subsidies, manufacturers, including us, are required to provide a seventy percent (70%) 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 Patient Protection and Affordable Care Act (the "PPACA") to the Medicaid drug rebate statute in 2010 and addresses a number of other issues with respect to the Medicaid program, including, but not limited to, the eligibility and calculation methodologies for AMP and best price, and the expansion of Medicaid rebate liability to include Medicaid managed care organizations. The final Medicaid covered outpatient drug regulation established two calculation methodologies for AMP: one for drugs generally dispensed through retail community pharmacies ("RCP") and one for so-called "5i drugs" (inhaled, infused, instilled, implanted or injectable drugs) "not generally dispensed" through RCPs. The regulation further made clear that 5i drugs would qualify as "not generally dispensed" and, therefore, able to use the alternative AMP calculation, if not more than thirty percent (30%) of their sales were to RCPs or to wholesalers for RCPs. The primary difference between the two AMP calculations is the requirement to exclude from AMP, for those qualifying 5i drugs not generally dispensed through RCPs, certain payments, rebates and discounts related to sales to non-RCPs; such exclusion often leads to a lower AMP. The decision of which AMP calculation a product is eligible to use must be made and applied on a monthly basis based on the percentage of sales of such product to RCPs or to wholesalers for RCPs.

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

Outside the United States

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

Other Regulations

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

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

The General Data Protection Regulation ("GDPR"): The GDPR came into force on May 25, 2018 and replaced the previous EU Data Protection Directive (95/46). The GDPR, which governs the processing of personal data (including personal health data), applies to the Company and any of its subsidiaries that are established in the EU as well as any of its subsidiaries that are established outside the EU to the extent that they process personal data relating to clinical trial participants in the EU. The GDPR imposes significant obligations on controllers and processors of personal data, including, as compared to the prior directive, higher standards for obtaining consent from individuals to process their personal data, more robust notification requirements to individuals about the processing of their personal data, a strengthened individual data rights regime, mandatory data breach notifications, limitations on the retention of personal data, increased requirements pertaining to health data, and strict rules and restrictions on the transfer of personal data outside of the EU, including to the U.S. The GDPR also imposes additional obligations on, and required contractual provisions to be included in, contracts between companies subject to the GDPR and their third-party processors that relate to the processing of personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data.

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

Employees

As of February 4, 2020, we had approximately 2,235 full-time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biopharmaceutical or medical product companies. We believe that we have been successful in attracting skilled and experienced scientific and senior management personnel; however, competition for such personnel is intense. None of our employees is covered by a collective bargaining agreement. We consider our relations with our employees to be good.

Available Information and Website Disclosure

Our principal executive offices are located at Connaught House, 1 Burlington Road, Dublin 4, Ireland D04 C5Y6. Our telephone number is +353-1-772-8000 and our website address is www.alkermes.com. Information found on, or accessible through, our website is not incorporated into, and does not form a part of, this Annual Report. We make available free of charge through the Investors section of our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. We also make available on our website (i) the charters for the standing committees of our board of directors, including the Audit and Risk Committee, Compensation Committee, and Nominating and Corporate Governance Committee, and (ii) our Code of Business Conduct and Ethics governing our directors, officers and employees. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the SEC.

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

Item 1A. Risk Factors

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

We receive substantial revenue from our key products and our success depends on our ability to maintain or increase sales of such products.

Sales of our proprietary products, VIVITROL and ARISTADA, comprise an increasingly significant portion of our revenues, and we continue to depend upon the substantial revenue generated from the sales of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA by Janssen and upon sales of FAMPYRA by Biogen. Any significant negative developments relating to these products, or to our licensee relationships, could have a material adverse effect on our business, financial condition, cash flows and results of operations.

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

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

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

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

In addition, most of our licensees can terminate their agreements with us without cause, and we cannot guarantee that any of these relationships will continue. Failure to make or maintain these arrangements or a delay in, or failure of, a licensee's performance,

or factors that may affect a licensee's sales, may materially adversely affect our business, financial condition, cash flows and results of operations.

We face competition in the biopharmaceutical industry.

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

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

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

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products, including, but not limited to Luye Pharma, which is developing risperidone formulated as extended release microspheres for intramuscular injection for the treatment of schizophrenia and/or schizoaffective disorders. In the treatment of schizophrenia, ARISTADA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA compete with each other and a number of other injectable products including ZYPREXA RELPREVV ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly; ABILIFY MAINTENA, (aripiprazole for extended release injectable suspension), a once-monthly injectable formulation of ABILIFY (aripiprazole) developed by Otsuka Pharm. Co.; PERSERIS (risperidone for extended release injectable suspension), a once-monthly formulation of risperidone marketed by Indivior plc; CAPLYTA (lumateperone), an oral, once-daily anti-psychotic developed by Intra-Cellular Therapies, Inc.; other 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, which is co-marketed by Otsuka Pharm Co. and H. Lundbeck A/S plc; LATUDA, which is marketed and sold by Sunovion Pharmaceuticals Inc.; VRYLAR, which is marketed and sold by Allergan plc; ABILIFY MAINTENA, risperidone, quetiapine, olanzapine, ziprasidone and clozapine.

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

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

In the treatment of MS, VUMERITY competes with AVONEX, TYSABRI, TECFIDERA, and PLEGRIDY from Biogen; OCREVUS from Genentech; BETASERON from Bayer HealthCare Pharmaceuticals; COPAXONE from Teva Pharmaceutical Industries Ltd.; REBIF and MAVENCLAD from EMD Serono, Inc.; GILENYA, EXTAVIA and MAYZENT from Novartis AG; and AUBAGIO and LEMTRADA from Sanofi-Aventis.

With respect to our NanoCrystal technology, we are aware that other technology approaches similarly address poorly water-soluble drugs. These approaches include nanoparticles, cyclodextrins, lipid-based self-emulsifying drug delivery systems, dendrimers and micelles, among others, any of which could limit the potential success and growth prospects of products incorporating our

NanoCrystal technology. In addition, there are many competing technologies to our OCR technology, some of which are owned by large pharmaceutical companies with drug delivery divisions and other, smaller drug delivery-specific companies.

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

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

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

- the perception of physicians and other members of the healthcare community as to our products' safety and efficacy relative to that of competing products and the willingness or ability of physicians and other members of the healthcare community to prescribe, dispense and/or administer, and patients to use, our products, including those that may be scheduled by the DEA (if and when approved);
- unfavorable publicity concerning us or our products, similar classes of drugs or the industry generally;
- the cost-effectiveness of our products;
- patient and physician satisfaction with our products;
- the successful manufacture of our products on a timely and cost-effective basis;
- the cost and availability of raw materials necessary for the manufacture of our products;
- the size of the markets for our products;
- reimbursement policies of government and third-party payers;
- the introduction, availability and acceptance of competing treatments, including treatments marketed and sold by our licensees;
- the reaction of companies that market competitive products;
- adverse event information relating to our products or to similar classes of drugs;
- changes to the product labels of our products, or of products within the same drug classes, to add significant warnings or restrictions on use;
- our continued ability to access third parties to vial, package and/or distribute our products on acceptable terms;
- the unfavorable outcome of investigations, litigation or other legal proceedings, including government investigations regarding VIVITROL, securities litigation relating to ALKS 5461, and litigation or other proceedings before the U.S. Patent and Trademark Office's (the "USPTO") Patent Trial and Appeal Board (the "PTAB"), including so-called "Paragraph IV" litigation relating to INVEGA SUSTENNA and RISPERDAL CONSTA, opposition proceedings in the EU relating to RISPERDAL CONSTA and any other litigation related to any of our products;
- regulatory developments related to the manufacture or continued use of our products, including the issuance of a REMS by the FDA;
- the extent and effectiveness of the sales and marketing and distribution support our products receive, including from our licensees;
- our licensees' decisions as to the timing and volume of product orders and product shipments, the timing of product launches, and product pricing and discounting;
- disputes with our licensees relating to the marketing and sale of products from which we receive revenue;
- exchange rate valuations and fluctuations;
- global political changes and/or instability, including the exit of the United Kingdom from the European Union (commonly referred to as "Brexit"), and any related changes in applicable laws and regulations, that may impact resources and markets for our products outside of the U.S.; and
- any other material adverse developments with respect to the commercialization of our products.

These and other factors, including other risks disclosed in this "Item 1A—Risk Factors" in this Annual Report, could materially adversely affect our revenues, financial condition, cash flows and results of operations.

Revenues generated by sales of our products depend on the availability from third-party payers of reimbursement for our products and the extent of cost-sharing arrangements for patients (e.g., patient co-payment, co-insurance, deductible obligations), cost-control measures imposed, reductions in payment rate or reimbursement or increases in our financial obligation to payers could result in decreased sales of our products and decreased revenues.

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

In the U.S., federal and state legislatures, health agencies and third-party payers continue to focus on containing the cost of healthcare, including by comparing the effectiveness, benefits and costs of similar treatments. Any adverse findings for our products from such comparisons may reduce the extent of reimbursement for our products. Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs, including but not limited to price control initiatives, discounts and other pricing-related actions. For example, in 2017, the State of California enacted as law SB-17, a drug pricing transparency bill that requires, among other things, that manufacturers notify the state and health insurers, and justify, any time such manufacturers plan to increase the price of a medication by sixteen percent (16%) or more over a two-year period. Similar state drug pricing initiatives were enacted in 2018 and 2019 (e.g., Oregon HB 4005 with reporting requirements commencing in 2019) and we expect additional state drug pricing initiatives to be proposed and enacted in 2020. 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 2020, we may face uncertainties as a result of likely continued federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA and potential reforms and changes to government negotiation or regulation of drug pricing. PPACA significantly expanded coverage of mental health and substance use disorders and provided federal parity protections to such coverage benefits. There is no assurance that such efforts and proposed legislation will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform and drug pricing will affect our business.

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

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.

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

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

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

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

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

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

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

For example, in November 2019, we submitted an NDA to the FDA, seeking approval for ALKS 3831 for the treatment of schizophrenia and for the treatment of bipolar I disorder. The FDA accepted the NDA for review in January 2020 and assigned a PDUFA target action date of Nov. 15, 2020. We cannot predict whether our NDA will be approved in a timely manner, or at all, and the review process involves risks and uncertainties, including whether the NDA and the preclinical and clinical results of the ALKS 3831 studies and the PK bridging data will meet FDA regulatory requirements, including those related to efficacy, safety, weight and metabolic profile for approval for the proposed indications.

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

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

Clinical trials for our products are expensive, may take several years to complete, and their outcomes are uncertain.

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

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

- the potential delay by a partner in beginning a clinical trial;
- issues with the opening of a new clinical trial site or with inspections of clinical trial sites;
- the failure of third-party CROs and other third-party service providers and independent clinical investigators to manage and conduct the trials, to perform oversight of the trials, including data audit and verification procedures, or to meet expected deadlines;
- the inability to recruit clinical trial participants at the expected rate;
- the inability to follow patients adequately after treatment;
- unforeseen safety issues;
- the inability to manufacture or obtain sufficient quantities of materials used for clinical trials; and
- unforeseen governmental or regulatory issues or concerns, including those of the FDA, DEA and other regulatory agencies; and
- unforeseen global instability, including political instability or instability from an outbreak of pandemic or contagious disease, such as the novel coronavirus, in or around the countries in which we conduct our clinical trials.

In addition, we are currently conducting and enrolling patients in clinical studies in a number of countries where our experience is more limited. We depend on independent clinical investigators, CROs and other third-party service providers and our collaborators in the conduct of clinical trials for our products and in the auditing, verification and 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. In oncology, since we may report preliminary or interim data from one or more patients in a clinical study of our product as of a point in time, there is also the added risk that this preliminary or interim data may not be predictive of future data from this same study, including future data from these same patients. As such, these data may change as patient clinical study enrollment continues and as more patient data becomes available. 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.

Preliminary, topline or interim data from our clinical trials that we may announce, publish or report from time to time may change as more patient data become available, are subject to audit and verification procedures that could result in material changes in the final data, and may not be indicative of final data or results of future clinical trials.

From time to time, we may announce, publish or report preliminary, topline or interim data from our clinical trials. Preliminary, topline or interim data from our clinical trials, including those in oncology, are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and/or more patient data become available and may not be indicative of final data from such trials or results of future clinical trials. Preliminary, topline or interim data also remain subject to audit confirmation and verification procedures that may result in the final data being materially different from the preliminary, topline or interim data we previously announce, published or reported. For example, preliminary data from our ongoing clinical trials of ALKS 4230 may change as more patient data become available and are not necessarily predictive of final data from such trials. As a result, preliminary, topline and interim data should be viewed with caution until the final data are available. Material adverse differences between preliminary, topline or interim data and final data or results of future clinical trials could significantly harm our business, financial condition, cash flows and results of operations.

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

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

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

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

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

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

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

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, manufacturing failures or products not being manufactured to specifications, which could require us to delay shipment of products or recall products previously shipped, or could impair our ability to receive regulatory approval for a product, expand into new markets or supply products in existing markets. We may not be able to resolve any such problems in a timely fashion, if at all.

We rely solely on our manufacturing facility in Wilmington, Ohio for the manufacture of RISPERDAL CONSTA, VIVITROL, ARISTADA, ARISTADA INITIO and certain of our other products in development. We rely on our manufacturing facility in Athlone, Ireland for the manufacture of AMPYRA (including the authorized generic version of AMPYRA), FAMPYRA, VUMERITY and some of our other products using our NanoCrystal and OCR technologies.

Due to regulatory and technical requirements, we have limited ability to shift production among our facilities or to outsource any part of our manufacturing to third parties. Any such shift of production among our facilities or transition of our manufacturing processes to a third party could take a significant amount of time and money and may not be successful.

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

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

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

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

We endeavor to qualify and register new vendors and to develop contingency plans so that production is not impacted by issues associated with third-party providers. Nonetheless, our business could be materially and adversely affected by issues associated with third-party providers.

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

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

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

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

us or our third-party providers to gain or maintain regulatory compliance with the FDA or other regulatory agencies could materially adversely affect our business, financial condition, cash flows and results of operations.

Patent protection for our products is important and uncertain.

The following factors are important to our success:

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

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

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

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

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our licensees, licensors, contract manufacturers, potential business partners, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information, or our competitors might learn of the information in some other way. To the extent that our employees, consultants or contractors use IP 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 and adversely affect our business, financial condition, cash flows and results of operations.

In addition, in the case of certain of our licensed products or products incorporating our licensed technology, our licensees are responsible for prosecuting, maintaining, enforcing and defending the IP related to the product(s) from which we derive revenue. Their failure to secure, maintain, enforce and defend this IP could materially and adversely affect our business, financial condition, cash flows, and results of operations. See also “—We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers” for risks related to our licensed products or products incorporating our licensed technology.

Uncertainty over IP in the biopharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable, could significantly delay or prevent approval or commercialization of our products, and could adversely affect our business.

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

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

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

We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers.

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

For example, we and our partner Acorda received notices of numerous ANDA filings challenging the validity of one or more of the Orange Book-listed patents for AMPYRA and/or asserting that a generic form of AMPYRA would not infringe such patents, and we and Acorda engaged in Paragraph IV litigation with various ANDA filers disputing such claims. For further discussion of the legal proceedings related to the patents covering AMPYRA, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Annual Report.

Similarly, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated patent infringement lawsuits against Teva entities (Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd.) and Mylan entities (Mylan Laboratories Limited, Mylan Pharmaceuticals Inc., and Mylan Institutional LLC), each of whom filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA. For a discussion of this Paragraph IV litigation, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Annual Report.

Although we intend to vigorously enforce our IP rights, and we expect our licensees will do the same, there can be no assurance that we or our licensees will prevail in defense of such patent rights. Our and our licensees' existing patents could be invalidated, found unenforceable or found not to cover generic forms of our or our licensees' products. If an ANDA filer were to receive FDA approval to sell a generic version of our products and/or prevail in any patent litigation, our products would become subject to increased competition and our business, financial condition, cash flows and results of operations could be materially adversely affected.

Litigation, arbitration or regulatory action (such as citizens petitions) filed against regulatory agencies related to our product or Alkermes, including securities litigation, may result in financial losses, harm our reputation, divert management resources, negatively impact the approval of our products, or otherwise negatively impact our business.

We may be the subject of certain claims, including those asserting violations of securities and fraud and abuse laws and derivative actions. Following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against companies. For example, in December 2018 and January 2019, two purported stockholders of ours filed putative class actions against us and certain of our officers on behalf of a putative class of purchasers of our securities during the period of February 17, 2017 through November 1, 2018. In March 2019, the U.S. District Court for the Eastern District of New York consolidated the two cases and appointed a lead plaintiff. Such action alleges violations of Sections 10(b) and 20(a) of the Exchange Act based on allegedly false or misleading statements and omissions regarding our regulatory submission for ALKS 5461, our drug candidate for the adjunctive treatment of major depressive disorder, and the FDA's review and consideration of that submission, and

seeks to recover unspecified money damages, prejudgment and postjudgment interest, reasonable attorneys' fees, expert fees and other costs. For further discussion of this putative class action, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements in this Annual Report. This class action and any similar future litigation could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We may be the subject of certain government inquiries or requests for documentation. For example, in June 2017 we received a subpoena from an Office of the U.S. Attorney, and in January 2019 we received a civil investigative demand from an Office of the U.S. Attorney, in each case for documents related to VIVITROL. We are cooperating with the government. If, as a result of the government's requests, proceedings are initiated and we are found to have violated one or more applicable laws, we may be subject to significant liability, including without limitation, civil fines, criminal fines and penalties, civil damages and exclusion from federal funded healthcare programs such as Medicare and Medicaid, as well as potential liability under the federal anti-kickback statute and False Claims Act and state False Claims Acts, and may be required to enter into a corporate integrity or other settlement with the government, any of which could materially affect our reputation, business, financial condition, cash flows and results of operations. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers or other persons allegedly harmed by such conduct. In addition, if some of our existing business practices are challenged as unlawful, we may have to change those practices, including changes and impacts on the practices of our sales force, which could also have a material adverse effect on our business, financial condition, cash flows and results of operations.

We may not be successful in defending ourselves in litigation or arbitration which may result in large judgments or settlements against us, which could have a negative effect on our business, financial condition, cash flows and results of operations. Further, our liability insurance coverage may not be sufficient to satisfy, or may not cover, any expenses or liabilities that may arise. Additionally, regardless of whether or not there is merit to the claims underlying any lawsuits or government inquiries of which we are subject, or whether or not we are found as a result of such lawsuits or inquiries to have violated any applicable laws, such lawsuits and inquiries can be expensive to defend or respond to, may divert the attention of our management and other resources that would otherwise be engaged in managing our business, and may further cause significant and potentially irreparable harm to our public reputation.

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

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

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

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

Changes affecting the healthcare industry, including new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to patent protection and enforcement, healthcare availability, and product pricing and marketing, could also adversely affect our revenues and our potential to be profitable. For example, the costs of prescription pharmaceuticals in the U.S. has been the subject of considerable discussion in the U.S. and the current administration has stated that it

will address such costs through new legislative and administrative measures. Such changes in law, regulation and the interpretation of existing laws and regulations could have a material adverse effect on our business, financial condition, cash flows and results of operations.

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

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

These events, among others, could result in product recalls, product liability actions or withdrawals or additional regulatory controls (including additional regulatory scrutiny, REMS programs, and requirements for additional labeling). As our development activities progress and we continue to have commercial sales, our product liability insurance coverage may be inadequate to satisfy liabilities that arise, we may be unable to obtain adequate coverage at an acceptable cost or at all, or our insurer may disclaim coverage as to a future claim. This could prevent or limit our commercialization of our products. In addition, the reporting of adverse safety events involving our products, including instances of product misuse, and public rumors about such events could cause our product sales or share price to decline or experience periods of volatility. These types of events could have a material adverse effect on our business, financial condition, cash flows and results of operations.

Our business involves environmental, health and safety risks.

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

We may not become profitable on a sustained basis.

At December 31, 2019, our accumulated deficit was $1.4 billion, which was primarily the result of net losses incurred from 1987, the year Alkermes, Inc., was founded, through December 31, 2019, partially offset by net income over certain fiscal periods. There can be no assurance we will achieve sustained profitability.

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

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

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

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

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

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

In March 2018, we amended and refinanced the term loan under our credit agreement (previously referred to as "Term Loan B-1", and as so amended and refinanced, the "2023 Term Loans"), in order to, among other things, extend the due date of the loan from September 25, 2021 to March 26, 2023, reduce the interest payable thereon from LIBOR plus 2.75% with a LIBOR floor of 0.75% to LIBOR plus 2.25% with a 0% LIBOR floor and increase covenant flexibility. As of December 31, 2019, our borrowings consisted of $279.3 million outstanding under the 2023 Term Loans.

The 2023 Term Loans are secured by a first priority lien on substantially all of the combined company assets and properties of Alkermes plc and most of its subsidiaries, which serve as guarantors. The agreements governing the 2023 Term Loans include a number of restrictive covenants that, among other things, and subject to certain exceptions and baskets, impose operating and financial restrictions on us. Our level of indebtedness and the terms of these financing arrangements could adversely affect our business by, among other things:

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

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

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

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

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

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

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

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

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

Currency exchange rates may affect revenues and expenses.

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

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

Our ability to compete and succeed in the highly competitive biopharmaceutical industry and in the disease states in which we market and sell products depends largely upon the continued service of our management and scientific and commercial teams and our ability to attract, retain and motivate highly skilled technical, scientific, manufacturing, management, regulatory, compliance and

selling and marketing personnel. Each of our executive officers and all of our employees are employed "at will," meaning we or each officer or employee may terminate the employment relationship at any time. The loss of key personnel or our inability to hire and retain personnel who have technical, scientific, manufacturing, management, regulatory, compliance or commercial backgrounds could materially adversely impact our business, including the achievement of our manufacturing, research and development, commercial and other business objectives.

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

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

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

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

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

Mergers, acquisitions and other strategic transactions involve various inherent risks, including:

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

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

The market price of our ordinary shares has been volatile and may continue to be volatile in the future, and the value of our ordinary shares could decline significantly.

The market price for our ordinary shares has fluctuated significantly from time to time. The market price of our ordinary shares is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market and industry factors, our results of operations, our ability to maintain and increase sales of our products, the success of our key development programs, and other factors, including the risk factors described in this Annual Report. The stock market in general, including the market for biopharmaceutical companies, has experienced extreme price and trading volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. In particular, negative publicity regarding pricing and price increases by pharmaceutical companies has negatively impacted, and may continue to negatively impact, the market for biopharmaceutical companies. These broad market and industry factors have harmed, and in the future may seriously harm, the market price of our ordinary shares, regardless of our operating performance.

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

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

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

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

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

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

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

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

At December 31, 2019, we had $150.6 million of amortizable intangible assets and $92.9 million of goodwill. Under accounting principles generally accepted in the U.S. ("GAAP"), we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite-lived intangible assets have been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

Our effective tax rate may increase.

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

Our deferred tax assets may not be realized.

As of December 31, 2019, we had $96.6 million in net deferred tax assets in the U.S. Included in this amount was approximately $2.9 million of U.S. federal net operating loss ("NOL") carryforwards and $42.8 million of research and development tax credit carryforwards that can be used to reduce U.S. taxable income or offset federal tax in future periods. These carryforwards will expire within the next twenty years. It is possible that some or all of the deferred tax assets will not be realized, especially if we incur losses in the U.S. in the future. Losses may arise from unforeseen operating events (see "—We may not become profitable on a sustained basis" for additional information relating to operating losses) or the occurrence of significant excess tax benefits arising from the

exercise of stock options and/or the vesting of restricted stock units. Unless we are able to generate sufficient taxable income in the future, a substantial valuation allowance to reduce the carrying value of our U.S. deferred tax assets may be required, which would materially increase our expenses in the period the allowance is recognized and materially adversely affect our business, financial condition and results of operations.

Furthermore, we have included within our U.S. net deferred tax assets of $96.6 million an amount of $41.5 million relating to employee share-based compensation expense. It is possible that a material portion of this deferred tax asset will not be realized, especially if the price of our ordinary shares remains at its current level (refer to "Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities" for details of the price of our ordinary shares). Unless the price of our ordinary shares increase we will incur a deferred tax expense as our employees exercise or forfeit their share options and the restricted stock units vest. This could materially increase our tax expense and may materially adversely affect our financial condition and results of operations.

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

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

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

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

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

We are subject to laws and regulations covering data privacy and the protection of personal information, including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., numerous federal and state laws and

regulations, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. The EU and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. In the EU, for example, effective May 25, 2018, the GDPR replaced the prior EU Data Protection Directive (95/46) that governed the processing of personal data in the European Union. The GDPR imposes significant obligations on controllers and processors of personal data, including, as compared to the prior directive, higher standards for obtaining consent from individuals to process their personal data, more robust notification requirements to individuals about the processing of their personal data, a strengthened individual data rights regime, mandatory data breach notifications, limitations on the retention of personal data and increased requirements pertaining to health data, and strict rules and restrictions on the transfer of personal data outside of the EU, including to the U.S. The GDPR also imposes additional obligations on, and required contractual provisions to be included in, contracts between companies subject to the GDPR and their third-party processors that relate to the processing of personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data.

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

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

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

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

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

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our products and the diseases our medicines are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve, as do the regulations relating to such use. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend the company or the public’s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

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

In March 2018, the Company entered into a lease agreement for approximately 220,000 square feet of office and laboratory space located in a building to be built at 900 Winter Street, Waltham, Massachusetts ("900 Winter Street"). The initial term of the lease commenced on January 20, 2020 (the "Commencement Date"). The initial lease term expires on January 31, 2035, with an option to extend for an additional ten years.

As a result of the acquisition of Rodin, we assumed a lease in Boston, Massachusetts. The facility has approximately 5,300 square feet of office space, expires in 2021 and includes an option to extend the term for one additional year.

We own an R&D and manufacturing facility in Athlone, Ireland (approximately 400,000 square feet) and a manufacturing facility in Wilmington, Ohio (approximately 370,000 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*

For information regarding legal proceedings, refer to the discussion under the heading "Litigation" in Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Annual Report, which discussion is incorporated into this Item 3 by reference.

Item 4. *Mine Safety Disclosures*

Not Applicable.

PART II

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

Market and shareholder information

Our ordinary shares are traded on the Nasdaq Global Select Market under the symbol "ALKS." There were 112 shareholders of record for our ordinary shares on February 4, 2020. In addition, the last reported sale price of our ordinary shares as reported on the Nasdaq Global Select Market on February 4, 2020 was $17.52.

Dividends

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

Repurchase of equity securities

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to $215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the year ended December 31, 2019. As of December 31, 2019, we had purchased a total of 8,866,342 shares at a cost of $114.0 million. The 2023 Term Loans include restrictive covenants that impose certain limitations on our ability to repurchase our ordinary shares.

During the three months ended December 31, 2019, we acquired 4,428 Alkermes ordinary shares, at an average price of $19.42 per share related to the vesting of employee equity awards to satisfy withholding tax obligations.

Irish taxes applicable to U.S. holders

The following is a general summary of the main Irish tax considerations applicable to the purchase, ownership and disposition of our ordinary shares by U.S. holders. It is based on existing Irish law and practices in effect on January 13, 2020, and on discussions and correspondence with the Irish Revenue Commissioners. Legislative, administrative or judicial changes may modify the tax consequences described below.

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

Withholding tax on dividends

While we have no current plans to pay dividends, dividends on our ordinary shares would generally be subject to Irish dividend withholding tax ("DWT") at 25%, 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

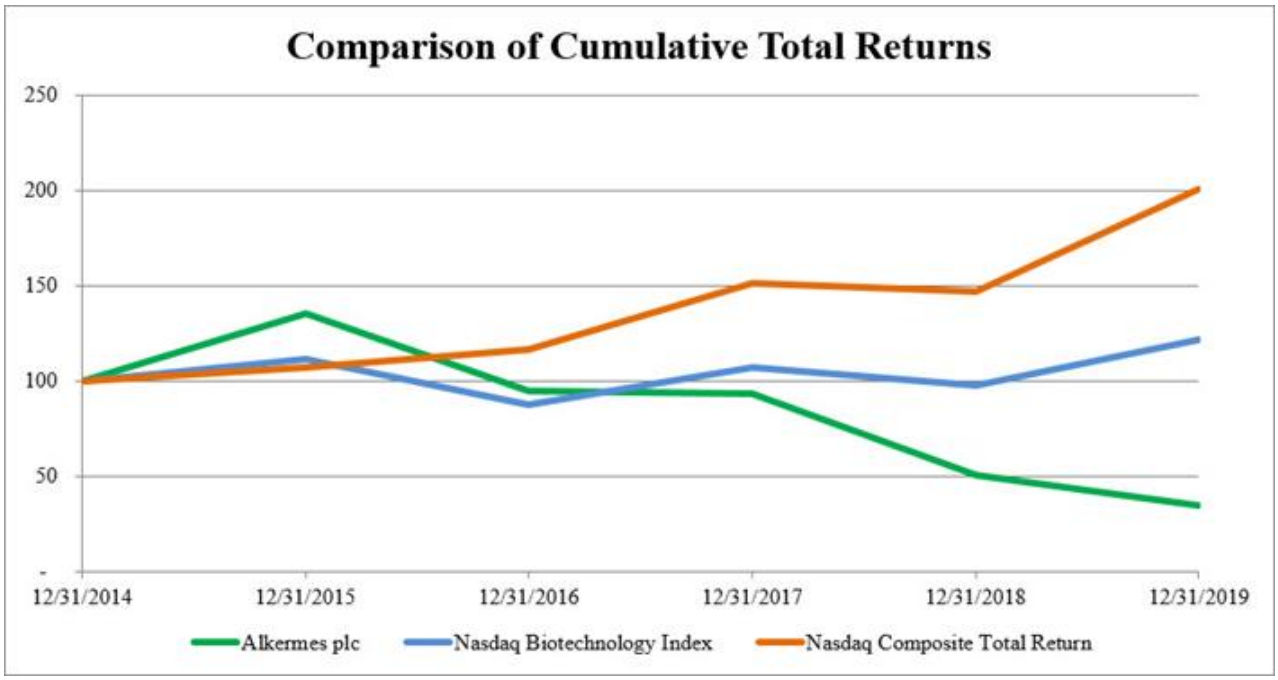
Irish stamp duty, if any, may become payable in respect of ordinary share transfers. However, a transfer of our ordinary shares from a seller who holds shares through DTC to a buyer who holds the acquired shares through DTC should not be subject to Irish stamp duty. A transfer of our ordinary shares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

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

Stock performance graph

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

The following graph compares the cumulative total shareholder return on our ordinary shares from December 31, 2014 through December 31, 2019 with the cumulative returns of the Nasdaq Composite Total Return Index and the Nasdaq Biotechnology Index. The comparison assumes $100 was invested on December 31, 2014 in our ordinary shares and in each of the foregoing indices and further assumes reinvestment of any dividends. We did not declare or pay any dividends on our ordinary shares during the comparison period.



	Year Ended December 31,					
	2014	2015	2016	2017	2018	2019
Alkermes	100	136	95	93	50	35
Nasdaq Composite Total Return	100	107	116	151	147	200
Nasdaq Biotechnology Index	100	112	88	107	97	122

Item 6. *Selected Financial Data*

The selected historical financial data set forth below at December 31, 2019 and 2018 and for the years ended December 31, 2019, 2018 and 2017 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, 2017 and for the years ended December 31, 2016 and 2015 are derived from audited consolidated financial statements, which are not included in this Annual Report.

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

	Year Ended December 31,				
(In thousands, except per share data)	**2019**	**2018**	**2017**	**2016**	**2015**
Consolidated Statements of Operations Data:					
REVENUES(1):					
Product sales, net	$ 524,499	$ 450,334	$ 362,834	$ 256,146	$ 149,028
Manufacturing and royalty revenues (2)	447,882	526,675	505,308	487,247	475,288
License revenue	145,750	48,370	28,000	—	—
Research and development revenue	52,816	68,895	7,232	2,301	4,019
Total revenues	1,170,947	1,094,274	903,374	745,694	628,335
EXPENSES:					
Cost of goods manufactured and sold	180,385	176,420	154,748	132,122	138,989
Research and development(3)	512,833	425,406	412,889	387,148	344,404
Selling, general and administrative	599,449	526,408	421,578	374,130	311,558
Amortization of acquired intangible assets	40,358	65,168	62,059	60,959	57,685
Restructuring(4)	13,401	—	—	—	—
Total expenses	1,346,426	1,193,402	1,051,274	954,359	852,636
OPERATING LOSS	(175,479)	(99,128)	(147,900)	(208,665)	(224,301)
OTHER (EXPENSE) INCOME, NET(5)	(21,577)	(27,839)	4,626	(5,722)	296
LOSS BEFORE INCOME TAXES	(197,056)	(126,967)	(143,274)	(214,387)	(224,005)
(BENEFIT) PROVISION FOR INCOME TAXES	(436)	12,344	14,671	(5,943)	3,158
NET LOSS	$ (196,620)	$ (139,311)	$ (157,945)	$ (208,444)	$ (227,163)
LOSS PER ORDINARY SHARE:					
BASIC AND DILUTED	$ (1.25)	$ (0.90)	$ (1.03)	$ (1.38)	$ (1.52)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:					
BASIC AND DILUTED	157,051	155,112	153,415	151,484	149,206
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 614,370	$ 620,039	$ 590,716	$ 619,165	$ 798,849
Total assets	1,805,403	1,825,007	1,797,227	1,726,423	1,855,744
Long-term debt	277,138	279,308	281,436	283,666	349,944
Shareholders' equity	1,085,442	1,171,285	1,202,808	1,209,481	1,314,275

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

(2) Included in manufacturing and royalty revenues in 2018 is $26.7 million of royalty revenue representing our proportional share of the proceeds Zealand Pharma A/S ("Zealand") sale to Royalty Pharma of certain royalty streams for products that utilize technology we had previously licensed to Zealand.

(3) In the fourth quarter of 2019, we acquired Rodin in a transaction accounted for as an asset acquisition and we expensed $86.6 million of in-process research and development ("IPR&D") acquired as part of the transaction, as it was determined to have no alternative future use.

(4) In the fourth quarter of 2019, our board of directors approved a restructuring plan following a review of our operations, cost structure and growth opportunities (the "Restructuring").

(5) 2015 includes a $9.6 million gain on the sale of our Gainesville, GA manufacturing facility, the related manufacturing and royalty revenue associated with certain products manufactured at the facility, and the rights to IV/IM and parenteral forms of Meloxicam (the "Gainesville Transaction"). 2014 includes a gain on the sale of property, plant and equipment of $41.9 million, a gain on the sale of an investment in Civitas Therapeutics, Inc. of $29.6 million and a gain on the sale of an investment in Acceleron Pharma Inc. of $15.3 million.

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

The following should be read in conjunction with our consolidated financial statements and related notes beginning on page F-1 of this Annual Report. The following discussion contains forward-looking statements. Actual results may differ significantly from those projected in the forward-looking statements. See "Cautionary Note Concerning Forward-Looking Statements" on page 3 of this Annual Report. Factors that might cause future results to differ materially from those projected in the forward-looking statements also include, but are not limited to, those discussed in "Item 1A—Risk Factors" and elsewhere in this Annual Report. A detailed discussion of our 2017 financial condition and results of operations, and of 2018 year-over-year changes as compared to 2017, can be found in "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the SEC on February 15, 2019.

Overview

We earn revenue on net sales of VIVITROL, ARISTADA and ARISTADA INITIO, which are proprietary products that we manufacture, market and sell in the U.S., and manufacturing and/or royalty revenues on net sales of products commercialized by our licensees. These key marketed products are expected to generate significant revenues for us in the near- and medium-term and we believe are singular or competitively advantaged products in their classes. In 2019, these key marketed products consisted of VIVITROL; ARISTADA and ARISTADA INITIO; INVEGA SUSTENNA/XEPLION; INVEGA TRINZA/TREVICTA; and RISPERDAL CONSTA.

In 2019, we incurred an operating loss of $175.5 million, as compared to $99.1 million in 2018. Revenues increased by 7% in 2019, as compared to 2018, which was primarily due to revenue earned under our license and collaboration agreement with Biogen for VUMERITY and increased sales of VIVITROL and ARISTADA. This was partially offset by a 13% increase in operating expenses, which were primarily due to the $86.6 million charge related to the IPR&D acquired as part of the acquisition of Rodin, support for the increase in sales of our proprietary products and a $13.4 million charge in the fourth quarter of 2019 related to the Restructuring. These items are discussed in further detail within the "Results of Operations" section below.

Results of Operations

Product Sales, Net

Our product sales, net consist of sales of VIVITROL, ARISTADA and ARISTADA INITIO in the U.S., primarily to wholesalers, specialty distributors and pharmacies. The following table presents the adjustments deducted from product sales, gross to arrive at product sales, net for sales of VIVITROL, ARISTADA and ARISTADA INITIO in the U.S. during the years ended December 31, 2019 and 2018:

	Year Ended December 31,			
(In millions, except for % of Sales)	**2019**	**% of Sales**	**2018**	**% of Sales**
Product sales, gross	$ 1,019.4	100.0 %	$ 846.5	100.0 %
Adjustments to product sales, gross:				
Medicaid rebates	(237.0)	(23.3) %	(197.0)	(23.3) %
Chargebacks	(84.4)	(8.3) %	(65.5)	(7.7) %
Product discounts	(78.9)	(7.7) %	(65.1)	(7.7) %
Medicare Part D	(45.2)	(4.4) %	(29.8)	(3.5) %
Other	(49.4)	(4.8) %	(38.8)	(4.6) %
Total adjustments	(494.9)	(48.5) %	(396.2)	(46.8) %
Product sales, net	$ 524.5	51.5 %	$ 450.3	53.2 %

Our product sales, net for VIVITROL and ARISTADA/ARISTADA INITIO in 2019 were $335.4 million and $189.1 million, respectively, as compared to $302.6 million and $147.7 million in 2018, respectively.

The increase in product sales, gross was due to a 12% increase in VIVITROL gross sales and a 40% increase in ARISTADA and ARISTADA INITIO gross sales. The increase in VIVITROL gross sales was due to a 12% increase in the number of units sold as there was no change to the selling price of VIVITROL in 2019. The increase in sales of ARISTADA and ARISTADA INITIO was primarily due to a 27% increase in the number of units sold and 4% and 6% price increases that went into effect in July 2018 and February 2019, respectively. The increase in the adjustments to product sales, gross were all primarily due to the increase in sales.

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 may lead to reduced unit sales of VIVITROL and increased pricing pressure. The latest to expire of our patents covering VIVITROL in the U.S. will expire in 2029 and in Europe will expire in 2021. We do not anticipate generic versions of this product to enter the market until 2028. Under the terms of a settlement and license agreement, we granted Amneal a license under certain patents covering VIVITROL, including

the latest to expire patent covering VIVITROL in the U.S., to market and sell a generic formulation of VIVITROL in the U.S. beginning sometime in 2028 or earlier under certain circumstances. A number of companies, including us, currently market and/or are developing products to treat schizophrenia that may compete with and negatively impact future sales of ARISTADA and ARISTADA INITIO. Increased competition may lead to reduced unit sales of ARISTADA and ARISTADA INITIO and increased pricing pressure. The latest to expire of our patents covering ARISTADA and ARISTADA INITIO in the U.S. will expire in 2035; and, as such, we do not anticipate any generic versions of this product to enter the market in the near term. We expect our product sales, net will continue to grow as VIVITROL continues to penetrate the opioid and alcohol dependence markets in the U.S., and as ARISTADA and ARISTADA INITIO continue to gain market share in the U.S.

Manufacturing and Royalty Revenues

Manufacturing revenues for third-party products using our proprietary technologies, except for those from Janssen related to RISPERDAL CONSTA, are recognized over time as products move through the manufacturing process, using an input method based on costs as a measure of progress. Manufacturing revenue from RISPERDAL CONSTA is recognized at the point in time the product has been fully manufactured. Royalties are generally earned on our licensees' net sales of third-party products using our proprietary technologies and are recognized in the period such products are sold by our licensees. The following table compares manufacturing and royalty revenues earned in the years ended December 31, 2019 and 2018:

(In millions)	Year Ended December 31, 2019	Year Ended December 31, 2018	Change Favorable/(Unfavorable) 2019–2018
Manufacturing and royalty revenues:			
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ 256.9	$ 241.4	$ 15.5
RISPERDAL CONSTA	66.4	71.1	(4.7)
AMPYRA/FAMPYRA	37.2	107.1	(69.9)
Other	87.4	107.1	(19.7)
Manufacturing and royalty revenues	$ 447.9	$ 526.7	$ (78.8)

Under our agreements with Janssen related to INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA, we earn tiered royalty payments which consist of a patent royalty and a know-how royalty, both of which are determined on a country-by-country basis. The patent royalty, which equals 1.5% of net sales, is payable in each country until the expiration of the last of the patents with valid claims applicable to the product in such country. The know-how royalty is a tiered royalty of 3.5% on calendar year net sales up to $250 million; 5.5% on calendar year net sales of between $250 million and $500 million; and 7.5% on calendar year net sales exceeding $500 million. The know-how royalty rate resets to 3.5% at the beginning of each calendar year and is payable until 15 years from the first commercial sale of a product in each individual country, subject to the expiry of the license agreement. The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues was due to an increase in Janssen's end-market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. Janssen's end-market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA were $3.3 billion and $2.9 billion during the years ended December 31, 2019 and 2018, respectively.

We recognize manufacturing revenue, equal to 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA, at the point in time when RISPERDAL CONSTA has been fully manufactured, which is deemed to have occurred when the product is approved for shipment by both us and Janssen. We record royalty revenue, equal to 2.5% of end-market net sales, when the end-market sale of RISPERDAL CONSTA occurs. The decrease in RISPERDAL CONSTA revenue was due to a 4% decrease in manufacturing revenue and a 13% decrease in royalty revenue. The decrease in manufacturing revenues was primarily due to a decrease in the number of units of RISPERDAL CONSTA manufactured for Janssen. The decrease in royalty revenue was due to a decline in Janssen's end-market net sales of RISPERDAL CONSTA. Janssen's end-market net sales of RISPERDAL CONSTA were $688.0 million and $737.0 million during the years ended December 31, 2019 and 2018, respectively. The latest to expire patent covering RISPERDAL CONSTA will expire in 2021 in the EU and 2023 in the U.S. For a discussion of legal proceedings related to patents covering RISPERDAL CONSTA, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Annual Report, and for risks relating to such legal proceedings, see "Item 1A—Risk Factors" in this Annual Report and specifically the section entitled "—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers."

We expect revenues from our long-acting, atypical antipsychotic franchise to continue to grow as INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA grow around the world. A number of companies, including us, are working to develop products to treat schizophrenia and/or bipolar disorder that may compete with INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA. Increased competition may lead to reduced unit sales of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA, and increasing pricing pressure. The latest of the patents subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expires in 2030 in the U.S. and certain other countries and in 2022 in the EU. The latest of the licensed patents covering INVEGA TRINZA/TREVICTA expired in

2017 in the U.S. and will expire in 2022 in the EU. In addition, Janssen has other patents not subject to our license agreement, including one that covers INVEGA SUSTENNA in the U.S. and expires in 2031 and one that covers INVEGA TRINZA in the U.S. and expires in 2036. In August 2019, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Mylan entities (Mylan Laboratories Limited ("Mylan Labs"), Mylan Pharmaceuticals Inc. ("Mylan"), and Mylan Institutional LLC), following filings by Mylan Labs of an abbreviated new drug application ("ANDA") seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of U.S. Patent No. 9,439,906. For further discussion of the legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Annual Report and for information about risks relating to the INVEGA SUSTENNA Paragraph IV litigation, see "Item 1A—Risk Factors" in this Annual Report, and specifically the section entitled "—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers."

We record manufacturing and royalty revenue for AMPYRA as the product is being manufactured, rather than when it is shipped to Acorda. For FAMPYRA, we record manufacturing revenue as the product is being manufactured and record royalty revenue when the end-market sale of FAMPYRA occurs.

The decrease in the amount of manufacturing and royalty revenue recognized for AMPYRA and FAMPYRA was primarily due to a 93% decrease in AMPYRA revenues due to the entry of generic forms of AMPYRA to the U.S. market in September 2018. This was partially offset by a 23% increase in FAMPYRA revenues, which was primarily due to a 40% increase in FAMPYRA manufacturing revenues due primarily to a 38% increase in FAMPYRA manufacturing activity. For further discussion of the legal proceedings related to the patents covering AMPYRA, see Note 19, *Commitments and Contingent Liabilities* in this Annual Report, and for information about risks relating to such legal proceedings see "Item 1A—Risk Factors" in this Annual Report and specifically the section entitled "—We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers." We expect revenues from AMPYRA to continue to decline due to the entry of generic forms of AMPYRA in the U.S. The legal proceedings related to the patents covering AMPYRA do not involve the patents covering FAMPYRA, and the latest of the patents covering FAMPYRA expires in 2025 in the EU.

Included in other manufacturing and royalty revenue in 2018 is $26.7 million of royalty revenue representing our proportional share of the proceeds Zealand's sale to Royalty Pharma of certain royalty streams for products that utilize technology that we had previously licensed to Zealand.

Certain of our manufacturing and royalty revenues are earned in countries outside of the U.S. and are denominated in currencies in which the product is sold. See "Item 7A—Quantitative and Qualitative Disclosures about Market Risk" in this Annual Report for information on currency exchange rate risk related to our revenues.

License Revenue

(In millions)	Year Ended December 31, 2019	Year Ended December 31, 2018	Change Favorable/(Unfavorable) 2019 - 2018
License revenue	$ 145.8	$ 48.4	$ 97.4

Amounts earned as license revenue in both periods presented primarily relate to our license and collaboration agreement with Biogen for VUMERITY. The increase in license revenue in 2019 was primarily due to the $150.0 million milestone payment we received upon approval of the NDA for VUMERITY by the FDA in 2019. The license revenue in 2018 was triggered by Biogen's decision to pay a $50.0 million option payment following its review of preliminary gastrointestinal tolerability data from the ongoing clinical development program for VUMERITY, including certain data from the long-term safety clinical trial and part A of the elective, randomized, head-to-head phase 3 gastrointestinal tolerability clinical trial comparing VUMERITY and dimethyl fumarate.

Research and Development Revenue

(In millions)	Year Ended December 31, 2019	Year Ended December 31, 2018	Change Favorable/(Unfavorable) 2019 - 2018
Research and development revenue	$ 52.8	$ 68.9	$ (16.1)

The decrease in R&D revenue was primarily due to a decrease in the revenue earned under our license and collaboration agreement with Biogen for VUMERITY, as discussed in further detail within the "Critical Accounting Estimates" section below. R&D revenues earned under our license and collaboration agreement with Biogen for VUMERITY were $50.0 million and $65.4 million in 2019 and 2018, respectively, and the decrease in revenue was due to a decrease in services performed as the NDA for VUMERITY was approved by the FDA in October 2019.

Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Year Ended December 31, 2019	2018	Change Favorable/(Unfavorable) 2019 - 2018
Cost of goods manufactured and sold	$ 180.4	$ 176.4	$ (4.0)

The increase in cost of goods manufactured and sold was primarily due to an 18% increase in cost of goods sold related to VIVITROL, driven by the increase in the sales of this product, partially offset by an 11% decrease in cost of goods manufactured for RISPERDAL CONSTA, which was primarily due to a decrease in the number of units manufactured.

Research and Development Expenses

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

The following table sets forth our external R&D expenses for the years ended December 31, 2019 and 2018 relating to our then-current key development programs and all other development programs, and our internal R&D expenses, listed by the nature of such expenses:

(In millions)	Year Ended December 31, 2019	2018	Change Favorable/(Unfavorable) 2019 - 2018
External R&D Expenses:			
Development programs:			
ALKS 4230	$ 45.2	$ 23.3	$ (21.9)
ALKS 3831	33.4	52.0	18.6
VUMERITY	27.7	43.1	15.4
ALKS 5461	21.3	30.3	9.0
ARISTADA and ARISTADA line extensions	7.2	20.1	12.9
IPR&D acquired from Rodin	86.6	—	(86.6)
Other external R&D expenses	65.5	49.7	(15.8)
Total external R&D expenses	286.9	218.5	(68.4)
Internal R&D expenses:			
Employee-related	175.8	163.9	(11.9)
Depreciation	14.0	11.9	(2.1)
Occupancy	12.3	11.0	(1.3)
Other	23.8	20.1	(3.7)
Total internal R&D expenses	225.9	206.9	(19.0)
Research and development expenses	$ 512.8	$ 425.4	$ (87.4)

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

The increase in expenses related to ALKS 4230 was primarily due to the advancement of the ARTISTRY development program for ALKS 4230. The decrease in expenses related to ALKS 3831 was primarily due to the decrease in activity within the ENLIGHTEN-1 and ENLIGHTEN-2 pivotal trials, which were initiated in December 2015 and February 2016, respectively, partially offset by an increase in activity within a phase 3 study of ALKS 3831 in young adults, which was initiated in June 2017. In the fourth quarter of 2019, we submitted our NDA for ALKS 3831 to the FDA. The decrease in expenses related to VUMERITY was primarily due to the completion of our elective, randomized, head-to-head phase 3 study, which compared the gastrointestinal tolerability of VUMERITY and TECFIDERA in patients with relapsing-remitting MS. The FDA approved the NDA for VUMERITY in the fourth quarter of 2019. The decrease in expenses related to ALKS 5461 was primarily due to a decrease in activity within the program as we completed submission of our NDA to the FDA seeking marketing approval of ALKS 5461 for the adjunctive treatment of MDD in January 2018. The decrease in expenses related to ARISTADA and ARISTADA line extensions was primarily due to the timing of ALPINE, our six-month study that evaluated the efficacy, safety and tolerability of ARISTADA and INVEGA SUSTENNA when used to initiate patients experiencing an acute exacerbation of schizophrenia in the hospital and to maintain treatment in an outpatient setting. For additional detail on the status of our key development programs, see “Key Development Programs” within “Item 1—Business” in this Annual Report.

Included in external R&D expenses is a charge of $86.6 million related to IPR&D acquired when we acquired Rodin in the fourth quarter of 2019. The acquisition of Rodin was treated as an asset acquisition and not a business combination for accounting purposes as substantially all of the fair value of the assets acquired in the acquisition of Rodin was tied to their IPR&D, which is largely in the preclinical stage. As the IPR&D was determined to have no alternative future use, the value ascribed to the IPR&D was charged to R&D expense upon its acquisition.

The increase in employee-related expenses was primarily due to an increase in R&D headcount of 5% prior to the Restructuring. The overall R&D-related headcount decreased by 2% from December 31, 2018 to December 31, 2019, due primarily to the Restructuring.

Selling, General and Administrative Expenses

(In millions)	Year Ended December 31, 2019	2018	Change Favorable/(Unfavorable) 2019 - 2018
Selling, general and administrative expense	$ 599.4	$ 526.4	$ (73.0)

The increase in selling, general and administrative (“SG&A”) expense was primarily due to increases in employee-related expenses and marketing and professional services fees. Employee-related expenses increased by 17%, primarily due to an increase in our SG&A-related headcount of 10% prior to the Restructuring. The overall SG&A related headcount increase was 5% at December 31, 2019, as compared to December 31, 2018. Marketing and professional services fees increased by 11% in 2019 and were primarily due to additional brand investments in VIVITROL, ARISTADA and ARISTADA INITIO, as well as an increased investment in patient access support services, such as reimbursement and transition assistance, for these products.

Amortization of Acquired Intangible Assets

(In millions)	Year Ended December 31, 2019	2018	Change Favorable/(Unfavorable) 2019 - 2018
Amortization of acquired intangible assets	$ 40.4	$ 65.2	$ 24.8

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

Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at December 31, 2019 is expected to be approximately $40.0 million, $40.0 million, $35.0 million, $35.0 million and $1.0 million in the years ending December 31, 2020 through 2024, respectively.

Restructuring

(In millions)	Year Ended December 31, 2019	2018	Change Favorable/(Unfavorable) 2019 - 2018
Restructuring expense	$ 13.4	$ —	$ (13.4)

In the fourth quarter of 2019, our board of directors approved a restructuring plan following a review of our operations, cost structure and growth opportunities. The Restructuring included a reduction in headcount of approximately 160 employees across the Company. We recorded a charge of $13.4 million in the fourth quarter of 2019 as a result of the Restructuring, which consisted of one-time termination benefits for employee severance, benefits and related costs, all of which are expected to result in cash expenditures and substantially all of which will be paid out by the end of 2020. We paid $4.2 million of the total $13.4 million accrued for the Restructuring during the year ended December 31, 2019.

Other (Expense) Income, Net

(In millions)	Year Ended December 31, 2019	2018	Change Favorable/(Unfavorable) 2019 - 2018
Interest income	$ 14.0	$ 9.2	$ 4.8
Interest expense	(13.6)	(15.4)	1.8
Change in the fair value of contingent consideration	(22.8)	(19.6)	(3.2)
Other income (expense), net	0.8	(2.0)	2.8
Total other (expense) income, net	$ (21.6)	$ (27.8)	$ 6.2

The increase in interest income was primarily due to a greater percentage of our cash and investments residing in investment accounts in 2019 as compared to 2018, and an increase in interest rates in 2019 as compared to 2018.

In April 2015, we completed the Gainesville Transaction with Recro Pharma, Inc. (“Recro”) and Recro Pharma LLC and received $54.0 million in cash, $2.1 million in warrants to acquire Recro common stock (which were exercised in the fourth quarter of 2019) 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 IP 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” in 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, 2019 and 2018, we determined that the fair value of the contingent consideration decreased by $22.8 million and $19.6 million, respectively. The decrease in 2019 was primarily due to a decrease in the probability of success used at December 31, 2019, as compared to December 31, 2018, due to Recro’s receipt of a second Complete Response Letter (“CRL”) in March 2019 regarding its NDA for IV Meloxicam. As a result of the receipt of the second CRL, we delayed the expectation of the anticipated date for the FDA’s approval of the IV Meloxicam NDA, resulting in a corresponding reduction in the amount of forecasted sales used in the valuation model. The decrease in 2018 was primarily due to the first CRL Recro received from the FDA in May 2018 regarding its NDA for IV Meloxicam. As a result of the receipt of that first CRL, we had delayed our expectation of the anticipated date for the FDA’s In addition, in December 2018, we amended our agreements with Recro and its affiliates relating to certain development milestone payments owed to us by Recro, such that the $45.0 million previously due to us upon approval by the FDA of the IV Meloxicam NDA was replaced with: $5.0 million which was paid in the first quarter of 2019, $5.0 million which was paid in the second quarter of 2019, $5.0 million to be paid within 180 days following FDA approval of the NDA for IV Meloxicam, and $45.0 million payable in seven equal annual installments of approximately $6.4 million beginning on the first anniversary of such NDA approval date. In November 2019, Recro spun out its acute care segment to Baudax Bio, Inc. (“Baudax”), a publicly-traded pharmaceutical company. As part of this transaction, Recro’s obligations to pay certain contingent consideration from the Gainesville Transaction were assigned and/or transferred to Baudax.

(Benefit) Provision for Income Taxes

(In millions)	Year Ended December 31, 2019	Year Ended December 31, 2018	Change Favorable/(Unfavorable) 2019 - 2018
Income tax (benefit) provision	$ (0.4)	$ 12.3	$ 12.7

The income tax benefit in 2019 and the income tax provision in 2018 was primarily due to U.S. federal and state taxes. The favorable change in income taxes in 2019, as compared to 2018, was primarily due to the foreign derived intangible income (“FDII”) proposed regulations issued by the U.S. Department of the Treasury and the U.S. Internal Revenue Service in March 2019.

No provision for income tax has been provided on undistributed earnings of the Company's foreign subsidiaries because such earnings are indefinitely reinvested in the foreign operations or may be repatriated to Ireland without incurring any tax liability. Cumulative unremitted earnings of overseas subsidiaries totaled approximately $418.1 million at December 31, 2019. In the event of a repatriation of those earnings in the form of dividends or otherwise, the Company may be liable for income taxes, subject to adjustment, if any, for foreign tax credits and foreign withholding taxes payable to foreign tax authorities. The Company estimates that approximately $12.9 million of income taxes would be payable on the repatriation of the unremitted earnings to Ireland.

As of December 31, 2019, the Company had $1.5 billion of Irish NOL carryforwards, $49.6 million of U.S. federal NOL carryforwards, $44.5 million of state NOL carryforwards, $49.6 million of federal R&D credits and $18 million of state tax credits which will either expire on various dates through 2039 or can be carried forward indefinitely. These loss and credit carryforwards are available to reduce certain future Irish and foreign taxable income and tax. These loss and credit carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. These loss and credit carryforwards, which may be utilized in a future period, may be subject to limitations based upon changes in the ownership of the Company's ordinary shares.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	December 31, 2019 U.S.	Ireland	Total	December 31, 2018 U.S.	Ireland	Total
Cash and cash equivalents	$ 63.3	$ 140.5	$ 203.8	$ 139.3	$ 127.5	$ 266.8
Investments—short-term	285.3	45.9	331.2	203.3	69.2	272.5
Investments—long-term	40.3	39.1	79.4	51.5	29.2	80.7
Total cash and investments	$ 388.9	$ 225.5	$ 614.4	$ 394.1	$ 225.9	$ 620.0
Outstanding borrowings—short and long-term	$ 277.1	$ —	$ 277.1	$ 279.3	$ —	$ 279.3

At December 31, 2019, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Investments—short-term available-for-sale	$ 329.8	$ 1.4	$ —	$ 331.2
Investments—long-term available-for-sale	75.9	—	(0.1)	75.8
Investments—long-term held-to-maturity	3.5	0.1	—	3.6
Total	$ 409.2	$ 1.5	$ (0.1)	$ 410.6

Sources and Uses of Cash

We generated $72.0 million and $99.3 million of cash from operating activities during the years ended December 31, 2019 and 2018, respectively. We expect that our existing cash and investments will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments on our long-term debt, for at least the twelve months following the date from which our financial statements were issued. Subject to market conditions, interest rates and other factors, we may pursue opportunities to obtain additional financing in the future, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures. In addition, the 2023 Term Loans have an incremental facility capacity in an amount of $175.0 million, plus additional amounts as long as we meet certain conditions, including a specified leverage ratio.

Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to generate investment income. We mitigate credit risk in our cash reserves by maintaining a well-diversified portfolio that limits the amount of investment exposure as to institution, maturity and investment type. Our available-for-sale investments consist primarily of short- and long-term U.S. government and agency debt securities and corporate debt securities. We classify available-for-sale investments in an unrealized loss position, which do not mature within 12 months, as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more-likely-than-not that we would not be required to sell these securities before recovery of their amortized cost. At December 31, 2019, 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, 2019 and 2018:

(In millions)	Year Ended December 31, 2019	2018
Cash and cash equivalents, beginning of period	$ 266.8	$ 191.3
Cash flows provided by operating activities	72.0	99.3
Cash flows used in investing activities	(141.8)	(22.2)
Cash flows provided by (used in) financing activities	6.8	(1.6)
Cash and cash equivalents, end of period	$ 203.8	$ 266.8

Operating Activities

The increase in cash provided by operating activities was primarily due to a 17% increase in the amount of cash collected from our customers, partially offset by a 19% increase in employee-related cash payments and the expense related to the IPR&D acquired in the acquisition of Rodin. The increase in the amount of cash we collected from our customers is primarily due to the increase in revenues previously discussed. The increase in the amount of cash paid to our employees is primarily due to increases in headcount, particularly in the R&D and SG&A areas, as discussed in greater detail in the “Selling, General and Administrative Expenses” section above. The cash flows related to the acquisition of Rodin are described below in the “Investing Activities” section.

Investing Activities

The increase in cash used in investing activities was primarily due to the net purchase of investments of $52.9 million in 2019, as compared to the net sales of investments of $46.7 million in 2018. We also had an increase in property, plant and equipment additions of $21.5 million, primarily due to the construction of facilities and equipment at our Wilmington, Ohio location for the manufacture of clinical products and commercial products, and the acquisition of equipment for a new leased facility in Waltham, Massachusetts. Amounts included as construction in progress at December 31, 2019 primarily consist of capital expenditures at these two facilities.

We expect to spend approximately $50.0 million during the year ended December 31, 2020 for capital expenditures. We continue to evaluate our manufacturing capacity based on expectations of demand for our products and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service, or we determine we have sufficient existing capacity and the assets are no longer required, at which time we would recognize an impairment charge. We continue to periodically evaluate whether facts and circumstances indicate that the carrying value of these long-lived assets to be held and used may not be recoverable.

In the fourth quarter of 2019, we acquired Rodin for an upfront cash payment of approximately $100.0 million and potential future milestone payments of up to $850.0 million. We accounted for the transaction as an asset acquisition, as substantially all of the fair value of the assets acquired in the acquisition of Rodin were tied to their IPR&D, which is largely in the preclinical stage. As the IPR&D was determined to have no alternative future use, the value ascribed to the IPR&D, $86.6 million, was charged to R&D expense upon its acquisition and was included in our net loss in 2019. The remaining $8.9 million of net assets acquired, net of cash transferred as part of the acquisition of $2.7 million, has been included as an investing activity in the 2019 cash flow statement.

The increase in investment cash outflows was partially offset by $10.0 million received from Recro in the form of two $5.0 million milestone payments in connection with the December 2018 amendments to our agreements with Baudax (as successor in interest to Recro), as discussed in the “Other (Expense) Income, Net” section above.

Financing Activities

The increase in cash flows from financing activities was primarily due to an $8.4 million increase in the net cash provided from stock option exercises by our employees.

Borrowings

At December 31, 2019, our borrowings consisted of $279.3 million outstanding under the 2023 Term Loans. Please refer to Note 11, *Long-Term Debt*, in the “Notes to Consolidated Financial Statements” in this Annual Report 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, 2019:

Contractual Obligations (In thousands)	Total	Less Than One Year (2020)	One to Three Years (2021 - 2022)	Three to Five Years (2023 - 2024)	More than Five Years (After 2024)
2023 Term Loans—Principal	$ 279,276	$ 2,843	$ 5,686	$ 270,747	$ —
2023 Term Loans—Interest	35,662	11,101	21,861	2,700	—
Operating lease obligations	15,888	9,053	3,227	1,029	2,579
Purchase obligations	428,745	428,745	—	—	—
Total contractual cash obligations	$ 759,571	$ 451,742	$ 30,774	$ 274,476	$ 2,579

As interest on the 2023 Term Loans is based on a one, three or six-month LIBOR rate of our choosing, for the purposes of this disclosure, we are using the one-month LIBOR rate, which was 1.74% at December 31, 2019 as this exceeds the LIBOR rate floor under the terms of the 2023 Term Loans and is the rate we were using at December 31, 2019 for interest payments under the 2023 Term Loans.

This table excludes up to $850.0 million in milestone payments that we would be obligated to make upon achievement by the platform of development candidates acquired in the acquisition of Rodin of certain specified clinical and regulatory milestones, and attainment of certain sales thresholds, as we cannot make a reliable estimate of the period of payment. At December 31, 2019, we have not recorded a liability related to these milestone payments, as none of the future events which would trigger a milestone payment are considered probable of occurring.

This table also 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, 2019, we had $6.9 million of net liabilities associated with

uncertain tax positions. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months.

Off-Balance Sheet Arrangements

At December 31, 2019, 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" in this Annual Report. We believe that the following accounting estimates are the most critical to aid in fully understanding and evaluating our reported financial results, and they require our most difficult, subjective or complex judgments, resulting from the need to make estimates about the effects of matters that are inherently uncertain. We have reviewed these critical accounting estimates and related disclosures with the Audit and Risk Committee of our board of directors.

Revenue from Contracts with Customers

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

We recognize revenue when or as we satisfy a performance obligation by transferring an asset or providing a service to a customer. Management judgment is required in determining the consideration to be earned under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement. Steering committee services that are not inconsequential or perfunctory and that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which we expect to complete our aggregate performance obligations.

Manufacturing Revenue

We recognize manufacturing revenues from the sale of products we manufacture for resale by our licensees. Manufacturing revenues for our partnered products, with the exception of those from Janssen related to RISPERDAL CONSTA, are recognized over time as products move through the manufacturing process, using a standard cost-based model as a measure of progress, which represents a faithful depiction of the transfer of control of the goods. We recognize manufacturing revenue from these products over time as we determined, in each instance, that we would have a right to payment for performance completed to date if our customer were to terminate the manufacturing agreement for reasons other than our non-performance and the products have no alternative use. We invoice our licensees upon shipment with payment terms between 30 to 90 days.

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

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

Royalty Revenue

We recognize royalty revenues related to the sale by our licensees of products that incorporate our technology. Royalties, with the exception of those earned on sales of AMPYRA as set forth below, qualify for the sales-and-usage exemption under Topic 606 as

(i) royalties are based strictly on the sales-and-usage by the licensee; and (ii) a license of IP is the sole or predominant item to which such royalties relate. Based on this exemption, these royalties are earned in the period the products are sold by our partner and we have a present right to payment. Royalties on AMPYRA manufactured under our license and supply agreements with Acorda are incorporated into the standard cost-based model described in the manufacturing revenues section, above, as the terms of such agreements entitle us to royalty revenue as the product is being manufactured, which represents a faithful depiction of the transfer of goods, and not based on the actual end-market sales of the licensee.

Certain of our royalty revenues are recognized based on information supplied to us by our licensees and require estimates to be made. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period in which they become known, which is generally within the same quarter. The difference between our actual and estimated royalty revenues has not been material to date.

Research and Development Revenue and License Revenue

Under a license and collaboration agreement with Biogen, which we entered into in November 2017 and amended in October 2018, January 2019 and October 2019, we granted Biogen a worldwide, exclusive, sublicensable license to develop, manufacture and commercialize VUMERITY and other products covered by patents licensed to Biogen under the agreement. Upon entering into the November 2017 license and collaboration agreement, we received an up-front cash payment of $28.0 million and were also eligible to receive additional payments upon achievement of developmental milestones with respect to VUMERITY. In June 2018, we received an additional cash payment of $50.0 million following Biogen's review of preliminary gastrointestinal tolerability data from the clinical development program for VUMERITY. In November 2019, we also received an additional payment of $150.0 million following FDA approval of the NDA for VUMERITY and transfer of such NDA to Biogen. We are also eligible to receive additional payments upon achievement of developmental milestones with respect to the first two products other than VUMERITY covered by patents licensed to Biogen under the November 2017 license and collaboration agreement. Biogen paid a portion of the VUMERITY development costs we incurred in 2017 and, since January 1, 2018, Biogen has been responsible for all VUMERITY development costs we incur, subject to annual budget limitations. Following FDA approval of the NDA for VUMERITY in October 2019, the NDA and any further development responsibilities with respect to VUMERITY were transferred to Biogen.

We evaluated the license and collaboration agreement under Topic 606 and determined that it had four deliverables: (i) the grant of a distinct, right-to-use license of IP to Biogen; (ii) future development services; (iii) clinical supply; and (iv) participation on a joint steering committee with Biogen. Our participation on the joint steering committee was considered to be perfunctory and thus not recognized as a performance obligation. The deliverables, aside from the participation in the joint steering committee which was considered to be perfunctory, were determined to be separate performance obligations as the license is separately identifiable from the development services and clinical supply, and the development services are not expected to significantly modify or customize the IP.

We allocated the arrangement consideration to each performance obligation using the standalone selling prices based on our estimate of selling price for the license and other deliverables. We used a discounted cash flow model to estimate the standalone selling price of the license in order to allocate the consideration to the performance obligations. To estimate the standalone selling price of the license, we assessed the likelihood of the FDA's approval of VUMERITY and estimated the expected future cash flows assuming FDA approval and maintenance of the IP protecting VUMERITY. We then discounted these cash flows using a discount rate of 8.0%, which we believe captures a market participant's view of the risk associated with the expected cash flows. The estimate of selling price of the development services and clinical supply were determined through third-party evidence. We believe that a change in the assumptions used to determine our estimate of selling price for the license most likely would not have a significant effect on the allocation of consideration transferred.

Under Topic 606, we allocated the $28.0 million up-front payment and the $50.0 million June 2018 payments as follows: $27.0 million and $48.3 million to the delivery of the license; $0.9 million and $1.5 million to future development services; and $0.1 million and $0.2 million to clinical supply, respectively.

In November 2019, following FDA approval of the NDA for VUMERITY and transfer of such NDA to Biogen, we received a $150.0 million milestone payment, $144.8 million of which was allocated to the delivery of the license; and $5.2 million of which was allocated to future development services and clinical supply. The amounts allocated to the license were recognized upon receipt of the payments as delivery of the license occurred upon entry into the agreement in 2017. The amounts allocated to the development services and clinical supply will be recognized over the course of the development work and as clinical supply is delivered to Biogen, which is expected to continue into 2020. We expect to earn an additional $0.3 million in research and development revenue under this agreement with Biogen through 2020.

In addition, we will receive a 15% royalty on worldwide net sales of VUMERITY, subject to, under certain circumstances, minimum annual payments for the first five years following FDA approval of VUMERITY. We are also entitled to receive royalties on net sales of products other than VUMERITY covered by patents licensed to Biogen under the license and collaboration agreement, at tiered royalty rates calculated as percentages of net sales ranging from high-single digits to sub-teen double digits. All royalties are payable on a product-by-product and country-by-country basis until the later of (i) the last-to-expire patent right covering the

applicable product in the applicable country and (ii) a specified period of time from the first commercial sale of the applicable product in the applicable country. Royalties for all products and the minimum annual payments for VUMERITY are subject to customary reductions, as set forth in the license and collaboration agreement.

We determined that the future development milestones and sales-based royalties that we may be entitled to receive are variable consideration. We are using the most likely amount method for estimating the variable consideration to be received related to the milestones under this arrangement. The royalties are subject to the sales-based exception and will be recorded when the corresponding sale occurs.

Under the license and collaboration agreement, Biogen appointed us as the toll manufacturer of clinical and commercial supplies of VUMERITY, subject to Biogen's right to manufacture or have manufactured commercial supplies as a back-up manufacturer and subject to good faith agreement by the parties on the terms of such manufacturing arrangements. In October 2019, we entered into a commercial supply agreement with Biogen for the commercial supply of VUMERITY, an amendment to such commercial supply agreement and an amendment to the November 2017 license and collaboration agreement with Biogen. Under these agreements, Biogen has an option to assume responsibility, subject to a transition period, for the manufacture (itself or through a designee) of clinical supplies of VUMERITY and up to 100% of commercial supplies of VUMERITY in exchange for an increase in the royalty rate to be paid by Biogen to us on net sales of product that is manufactured by Biogen or its designee. We evaluated the commercial supply agreement and the related amendments under Topic 606 and determined that these agreements should be combined and accounted for as a separate contract since the commercial supply agreement and amendment to the November 2017 license and collaboration agreement were negotiated together to achieve a common economic objective and the additional performance obligations under the commercial supply agreement are considered distinct obligations priced at their standalone selling prices. We determined that we had two separate performance obligations, the commercial supply of VUMERITY and, upon an election by Biogen to commence a transfer of technology relating to the manufacture of VUMERITY (a "Tech Transfer"), services to be performed by us in connection with such Tech Transfer. There are other deliverables under the agreements that were determined to be perfunctory or immaterial.

In connection with the entry into the commercial supply agreement and the related amendments, we received payments in the aggregate amount of $5.8 million in the fourth quarter of 2019 and, if Biogen opts to assume responsibility for the manufacture of VUMERITY, we will be eligible to receive an additional $5.0 million payment upon the earlier of successful completion of the Tech Transfer or a date in the fourth quarter of 2022. The $5.8 million received in the fourth quarter of 2019 plus amounts received in connection with the Tech Transfer, if any, will be allocated to each of the performance obligations using the standalone selling prices based on the Company's estimate of selling price for the commercial supply of VUMERITY and the services related to the Tech Transfer, and this additional arrangement consideration will be recognized as we deliver commercial supply of VUMERITY and/or provide services relating to the Tech Transfer. We expect to begin performing under this commercial supply agreement in the first quarter of 2020.

Product Sales, Net

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

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

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

historical experience and our estimates of future participation in these programs. To date, actual chargebacks have not differed materially from our estimates;

- *Product Discounts*—cash consideration, including sales incentives, given by us under agreements with a number of wholesaler, distributor, pharmacy, and treatment provider customers that provide them with a discount on the purchase price of products. The reserve is made using the expected value and to date, actual product discounts have not differed materially from our estimates;
- *Product Returns*—we record an estimate for product returns at the time our customers take control of our product. We estimate this liability using the expected value based on our historical return levels and specifically identified anticipated returns due to known business conditions and product expiry dates. Return amounts are recorded as a deduction to arrive at product sales, net. Once product is returned, it is destroyed; and
- *Medicare Part D*—We record accruals for Medicare Part D liabilities under the Medicare Coverage Gap Discount Program ("CGDP") as a reduction of sales. Under the CGDP, patients reaching the annual coverage gap threshold are eligible for reimbursement coverage for out-of-pocket costs for covered prescription drugs. Under an agreement with the Center for Medicare and Medicaid, manufacturers are responsible to reimburse prescription plan sponsors for the portion of out-of-pocket expenses not covered under their Medicare plans.

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

(In millions)	Medicaid Rebates	Chargebacks	Product Discounts	Product Returns	Medicare Part D	Other	Total
Balance, December 31, 2017	$ 89.9	$ 1.9	$ 8.6	$ 18.8	$ 3.9	$ 4.6	$ 127.7
Provision:							
Current year	203.1	65.5	65.2	6.6	29.8	32.1	402.3
Prior year	(6.1)	—	(0.1)	—	—	—	(6.2)
Total	197.0	65.5	65.1	6.6	29.8	32.1	396.1
Actual:							
Current year	(80.5)	(63.7)	(51.1)	—	(17.8)	(27.5)	(240.6)
Prior year	(83.0)	(1.4)	(10.4)	(3.5)	(4.8)	(3.7)	(106.8)
Total	(163.5)	(65.1)	(61.5)	(3.5)	(22.6)	(31.2)	(347.4)
Balance, December 31, 2018	$ 123.4	$ 2.3	$ 12.2	$ 21.9	$ 11.1	$ 5.5	$ 176.4
Provision:							
Current year	243.0	84.4	78.9	10.7	45.2	40.8	503.0
Prior year	(5.9)	—	—	(2.2)	—	—	(8.1)
Total	237.1	84.4	78.9	8.5	45.2	40.8	494.9
Actual:							
Current year	(128.6)	(81.6)	(66.3)	—	(33.9)	(32.0)	(342.4)
Prior year	(105.9)	(1.6)	(13.2)	(5.8)	(13.2)	(5.8)	(145.5)
Total	(234.5)	(83.2)	(79.5)	(5.8)	(47.1)	(37.8)	(487.9)
Balance, December 31, 2019	$ 126.0	$ 3.5	$ 11.6	$ 24.6	$ 9.2	$ 8.5	$ 183.4

Amortization and Impairment of Long-Lived Assets

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

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

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

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

Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at December 31, 2019, is expected to be approximately $40.0 million, $40.0 million, $35.0 million, $35.0 million and $1.0 million in the years ending December 31, 2020 through 2024, 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, 2019, we have one operating segment and two reporting units. Our goodwill, which solely relates to the Business Combination, has been assigned to one reporting unit which consists of the former EDT business.

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

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

On October 31, 2019, we elected to perform a qualitative assessment to determine whether it was necessary to perform a quantitative impairment test. Based on the weight of all available evidence, we determined that the fair value of the reporting unit more-likely-than-not exceeded its carrying value.

Contingent Consideration

We record contingent consideration we receive at fair value on the acquisition date. We estimate the fair value of contingent consideration through valuation models that incorporate probability-adjusted assumptions related to the achievement of milestones and thus likelihood of receiving related payments. We revalue our contingent consideration each reporting period, with changes in the fair value of contingent consideration recognized within the consolidated statements of operations and comprehensive loss. Changes in the fair value of contingent consideration can result from changes to one or multiple assumptions, including adjustments to the discount rates, changes in the amount and timing of cash flows, changes in the assumed achievement and timing of any development and 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, 2019, our contingent consideration related to consideration to be received as part of the Gainesville Transaction. We received one $5.0 million payment in the first quarter of 2019 and another $5.0 million payment in the second quarter of 2019; we are eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and any other Meloxicam Product(s); and we are eligible to receive up to $130.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products.

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

- We received $5.0 million in the first quarter of 2019 and another $5.0 million in the second quarter of 2019; we are entitled to receive $5.0 million upon regulatory approval of an NDA for the first Meloxicam Product; and $45.0 million in seven equal, annual installments beginning on the first anniversary of such approval. The fair value of the regulatory milestone was estimated based on applying the likelihood of achieving the regulatory milestone and applying a discount rate from the expected time the milestone occurs to the balance sheet date. We expect the regulatory milestone event to occur in the first quarter of 2020 and used a discount rate of 16.0%;
- We are entitled to receive future royalties on net sales of Meloxicam Products. To estimate the fair value of the future royalties, we assessed the likelihood of a Meloxicam Product being approved for sale and estimated the expected future sales given approval and IP protection. We then discounted these expected payments using a discount rate of 16.0%, which we believe captures a market participant’s view of the risk associated with the expected payments; and
- We are entitled to receive payments of up to $80.0 million upon achieving certain sales milestones on future sales of the Meloxicam Product. The sales milestones were determined through the use of a real options approach, where net sales are simulated in a risk-neutral world. To employ this methodology, we used a risk-adjusted expected growth rate based on our assessments of expected growth in net sales of the approved Meloxicam Product, adjusted by an appropriate factor capturing their respective correlation with the market. A resulting expected (probability-weighted) milestone payment was then discounted at a cost of debt of 16.0%.

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

Valuation of Deferred Tax Assets

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

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

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

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

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

The evaluation of deferred tax assets requires judgment in assessing the likely future tax consequences of events that have been recognized in our financial statements or tax returns and future profitability. Our accounting for deferred tax consequences represents our best estimate of those future events. Changes in our current estimates, due to unanticipated events or otherwise, could have a material effect on our financial condition and results of operations. For information related to risks surrounding our deferred tax assets, see "Item 1A—Risk Factors" in this Annual Report and specifically the section entitled "—Our deferred tax assets may not be realized."

Recent Accounting Pronouncements

Please refer to Note 2, *Summary of Significant Accounting Policies*, "New Accounting Pronouncements" in our "Notes to Consolidated Financial Statements" in this Annual Report for a discussion of new accounting standards.

Item 7A. *Quantitative and Qualitative Disclosures about Market Risk*

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

We do not believe that inflation and changing prices have had a material impact on our results of operations, and as approximately 48% and 29% of our investments at December 31, 2019 are in corporate debt securities with a minimum rating of Aa2 (Moody's)/AA (Standard and Poor's) and debt securities issued by the U.S. government or its agencies, respectively, our exposure to liquidity and credit risk is not believed to be significant.

At December 31, 2019, our borrowings consisted of $279.3 million outstanding under the 2023 Term Loans. The 2023 Term Loans bear interest at a LIBOR rate of our choosing (one, three or six months), plus 2.25% with a 0% LIBOR floor. We are currently using the one-month LIBOR rate, which was 1.74% at December 31, 2019. A 10% increase in the one-month LIBOR rate would have increased the amount of interest we owe under this agreement during the year ended December 31, 2019 by approximately $0.5 million. At December 31, 2018, a 10% increase in the one-month LIBOR rate, which was the LIBOR rate in use at the time, would have increased the amount of interest we owed by approximately $0.8 million. For a discussion about risks relating to LIBOR, see "Item 1A—Risk Factors" in this Annual Report and specifically the section entitled "—Discontinuation, reform or replacement of LIBOR, or uncertainty related to the potential for any of the foregoing, may adversely affect us."

Currency Exchange Rate Risk

Manufacturing and royalty revenues we receive on certain of our products and services are a percentage of the net sales made by our licensees, and a portion of these sales are made in countries outside the U.S. and are denominated in currencies in which the product is sold, which is predominantly the Euro. The manufacturing and royalty payments on these non-U.S. sales are calculated initially in the currency in which the sale is made and are then converted into USD to determine the amount that our licensees pay us for manufacturing and royalty revenues. Fluctuations in the exchange ratio of the USD and these non-U.S. currencies will have the effect of increasing or decreasing our revenues even if there is a constant amount of sales in non-U.S. currencies. For example, if the USD weakens against a non-U.S. currency, then our revenues will increase given a constant amount of sales in such non-U.S. currency. For the year ended December 31, 2019, an average 10% strengthening of the USD relative to the currencies in which these products are sold would have resulted in revenues being reduced by approximately $26.5 million, as compared to a reduction in revenues of approximately $36.1 million for the year ended December 31, 2018.

We incur significant operating costs in Ireland and face exposure to changes in the exchange ratio of the USD and the Euro arising from expenses and payables at our Irish operations that are settled in Euro. The impact of changes in the exchange ratio of the USD and the Euro on our USD denominated revenues earned in countries other than the U.S. is partially offset by the opposite impact of changes in the exchange ratio of the USD and the Euro on operating expenses and payables incurred at our Irish operations that are settled in Euro. For the year ended December 31, 2019, an average 10% weakening in the USD relative to the Euro would have resulted in an increase to our expenses denominated in Euro of approximately $7.1 million, as compared to an increase in our expenses of approximately $9.3 million in the year ended December 31, 2018.

Item 8. *Financial Statements and Supplementary Data*

Selected Quarterly Financial Data (unaudited)

(In thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Year Ended December 31, 2019					
REVENUES:					
Product sales, net	$ 99,481	$ 136,635	$ 138,774	$ 149,609	$ 524,499
Manufacturing and royalty revenues	108,915	127,897	103,783	107,287	447,882
License revenue	—	1,000	—	144,750	145,750
Research and development revenue	14,706	14,340	12,686	11,084	52,816
Total revenues	223,102	279,872	255,243	412,730	1,170,947
EXPENSES:					
Cost of goods manufactured and sold	45,361	46,223	42,319	46,482	180,385
Research and development(1)	102,570	104,435	107,671	198,157	512,833
Selling, general and administrative	141,220	155,075	148,701	154,453	599,449
Amortization of acquired intangible assets	9,952	10,062	10,173	10,171	40,358
Restructuring expense	—	—	—	13,401	13,401
Total expenses	299,103	315,795	308,864	422,664	1,346,426
OPERATING LOSS	(76,001)	(35,923)	(53,621)	(9,934)	(175,479)
OTHER (EXPENSE) INCOME, NET	(24,251)	(4,463)	(240)	7,377	(21,577)
LOSS BEFORE INCOME TAXES	(100,252)	(40,386)	(53,861)	(2,557)	(197,056)
INCOME TAX (BENEFIT) PROVISION	(3,854)	1,604	(983)	2,797	(436)
NET LOSS	$ (96,398)	$ (41,990)	$ (52,878)	$ (5,354)	$ (196,620)
LOSS PER SHARE—BASIC AND DILUTED	$ (0.62)	$ (0.27)	$ (0.34)	$ (0.03)	$ (1.25)

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

(1) Included in research and development expenses in the fourth quarter of 2019 is $86.6 million of expense related to the IPR&D acquired as part of the acquisition of Rodin, as it was determined that the IPR&D did not have an alternative future use.

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

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

Not applicable.

Item 9A. *Controls and Procedures*

Disclosure Controls and Procedures and Internal Control Over Financial Reporting

Controls and Procedures

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of December 31, 2019. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in its 2013 Internal Control—Integrated Framework.

Based on this assessment, our management has concluded that, as of December 31, 2019, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included in this Annual Report, beginning on page F-1.

Item 9B. *Other Information*

None.

PART III

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

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2020 Annual General Meeting of Shareholders.

Item 11. *Executive Compensation*

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2020 Annual General Meeting of Shareholders.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2020 Annual General Meeting of Shareholders.

Item 13. *Certain Relationships and Related Transactions, and Director Independence*

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2020 Annual General Meeting of Shareholders.

Item 14. *Principal Accounting Fees and Services*

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2020 Annual General Meeting of Shareholders.

PART IV

Item 15. *Exhibits and Financial Statement Schedules*

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

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

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

EXHIBIT INDEX

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
2.1 *	Purchase and Sale Agreement, dated March 7, 2015, by and among Alkermes Pharma Ireland Limited, Daravita Limited, Eagle Holdings USA, Inc., Recro Pharma, Inc., and Recro Pharma LLC (assigned by Recro to Baudax Bio, Inc. in November 2019).	Exhibit 2.1 to the Alkermes plc Current Report on Form 8-K/A (File No. 001-35299)	April 16, 2015
2.1.1	First Amendment to Purchase and Sale Agreement, dated December 8, 2016 by and among Alkermes Pharma Ireland Limited, Daravita Limited, Eagle Holdings USA, Inc., Recro Pharma, Inc., and Recro Gainesville LLC (assigned by Recro to Baudax Bio, Inc. in November 2019).	Exhibit 2.1.1 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 17, 2017
2.1.2	Second Amendment to Purchase and Sale Agreement, dated December 20, 2018, by and among Alkermes Pharma Ireland Limited, Daravita Limited, Alkermes US Holdings, Inc. (as successor in interest to Eagle Holdings USA, Inc.), Recro Pharma, Inc. and Recro Gainesville LLC (assigned by Recro to Baudax Bio, Inc. in November 2019).	Exhibit 2.1.2 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 15, 2019
2.2 **	Agreement and Plan of Merger, dated November 14, 2019 by and among Alkermes, Inc., Thinker Merger Sub, Inc., Alkermes plc, Rodin Therapeutics, Inc., and Shareholder Representative Services LLC, as Company Equityholder Representative.	Exhibit 2.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299)	November 25, 2019
3.1	Memorandum and Articles of Association of Alkermes plc.	Exhibit 3.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299)	May 26, 2016
4.1 #	Description of Securities.		
10.1	Lease between Alkermes, Inc. and PDM Unit 850, LLC, dated as of April 22, 2009.	Exhibit 10.5 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 28, 2009
10.1.1	First Amendment to Lease between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009.	Exhibit 10.2 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	August 6, 2009
10.1.2	Second Amendment to Lease between Alkermes, Inc. and PDM Unit 850, LLC, dated as of November 12, 2013.	Exhibit 10.74 to the Alkermes plc Transition Report on Form 10-KT (File No. 001-35299)	February 27, 2014
10.1.3	Third Amendment to Lease between Alkermes, Inc. and PDM 850 Unit, LLC, dated as of May 15, 2014.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 31, 2014
10.1.4	Fourth Amendment to Lease between Alkermes, Inc. and GI TC 850 Winter Street, LLC, dated as of December 30, 2014.	Exhibit 10.7 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 30, 2015

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.1.5	Fifth Amendment to Lease between Alkermes, Inc. and GI TC 850 Winter Street, LLC, dated as of October 31, 2018.	Exhibit 10.1.5 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 15, 2019
10.2	License Agreement, dated as of February 13, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica Inc. (United States) (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.2 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.2.1 *	Third Amendment to Development Agreement, Second Amendment to Manufacturing and Supply Agreement and First Amendment to License Agreements by and between Janssen Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated April 1, 2000 (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.5 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.2.2 *	Second Amendment, dated as of August 16, 2012, to the License Agreement, dated as of February 13, 1996, as amended, by and between Alkermes, Inc. and Janssen Pharmaceutica Inc. and the License Agreement, dated as of February 21, 1996, as amended, by and between Alkermes, Inc. and JPI Pharmaceutica International, and the Fifth Amendment, dated as of August 16, 2012, to the Manufacturing and Supply Agreement, dated as of August 6, 1997, as amended, by and between Alkermes, Inc., Janssen Pharmaceutica Inc. and JPI Pharmaceutica International.	Exhibit 10.3 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	November 1, 2012
10.3	License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except United States) (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.3 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.4	Manufacturing and Supply Agreement, dated August 6, 1997, by and among JPI Pharmaceutica International, Janssen Pharmaceutica, Inc. and Alkermes Controlled Therapeutics Inc. II (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.4 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.4.1 *	Fourth Amendment to Development Agreement and First Amendment to Manufacturing and Supply Agreement by and between Janssen Pharmaceutica International, Janssen Pharmaceutica Products, L.P. and Alkermes Controlled Therapeutics Inc. II, dated December 20, 2000 (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.4 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.4.2	Addendum to the Manufacturing and Supply Agreement by and among JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated August 1, 2001.	Exhibit 10.4.2 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.4.3	Letter Agreement and Exhibits to Manufacturing and Supply Agreement, dated February 1, 2002, by and among JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.4.3 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.4.4 *	Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 22, 2003 (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.6 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 30, 2015
10.4.5 *	Fourth Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated January 10, 2005 (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.9 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.4.6 *	Sixth Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II (assigned to Alkermes, Inc. in July 2006), effective as of July 1, 2018.	Exhibit 10.11 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	October 23, 2018
10.5 *	Development and License Agreement, dated as of May 15, 2000, by and between Alkermes Controlled Therapeutics Inc. II and Amylin Pharmaceuticals, Inc., as amended on October 24, 2005 and July 17, 2006 (assigned, as amended, to Alkermes, Inc. in July 2006).	Exhibit 10.28 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 21, 2010
10.5.1 *	Third Amendment to Development and License Agreement, dated March 20, 2018, by and between Amylin Pharmaceuticals, LLC and Alkermes Pharma Ireland Limited (as successor-in-interest to Alkermes Controlled Therapeutics Inc. II), amending that certain Development and License Agreement, by and between ACTII and Amylin, dated May 15, 2000, as amended on October 24, 2005 and July 17, 2006.	Exhibit 10.3 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	April 26, 2018
10.6 *	Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 21, 2002 (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.6 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.6.1 *	Amendment to Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 16, 2003 (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.7 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.7	Amended and Restated License Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc.	Exhibit 10.14 to the Acorda Therapeutics, Inc. Quarterly Report on Form 10-Q/A (File No.000-50513; film No. 11821367)	July 20, 2011
10.7.1 *	Supply Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc.	Exhibit 10.22 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.7.2	Amendment No. 1 Agreement, dated June 30, 2009, to the Amended and Restated License Agreement dated September 26, 2003 and the Supply Agreement dated September 26, 2003, and Consent to Sublicense, by and among Elan Pharma International Limited (as successor in interest to Elan Corporation, plc), Acorda Therapeutics, Inc. and Biogen Idec International GmbH.	Exhibit 10.56 to Acorda Therapeutics, Inc.'s Quarterly Report on Form 10-Q (File No.000-50513; film No. 09999376)	August 10, 2009
10.7.3	Amendment No. 2, dated March 29, 2012, to the Amended and Restated License Agreement, dated September 26, 2003, as amended, and the Supply Agreement, dated September 26, 2003, as amended, in each case by and between Acorda Therapeutics, Inc. and Alkermes Pharma Ireland Limited (as successor in interest to Elan Corporation, plc).	Exhibit 10.46 to the Acorda Therapeutics, Inc. Annual Report on Form 10-K (File No.000-50513; film no. 13653677)	February 28, 2013
10.7.4	Amendment No. 3, dated February 14, 2013, to the Amended and Restated License Agreement, dated September 26, 2003, as amended and the Supply Agreement, dated September 26, 2003, as amended, in each case by and between Acorda Therapeutics, Inc. and Alkermes Pharma Ireland Limited (as successor in interest to Elan Corporation, plc).	Exhibit 10.1 to the Acorda Therapeutics, Inc. Quarterly Report on Form 10-Q (File No. 000-50513; film No. 13831684)	May 10, 2013
10.8 *	License Agreement by and among Elan Pharmaceutical Research Corp., d/b/a Nanosystems and Elan Pharma International Limited and Janssen Pharmaceutica N.V. dated as of March 31, 1999.	Exhibit 10.23 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.8.1	First Amendment, dated as of July 31, 2003, to the License Agreement by and among Elan Drug Delivery, Inc. (formerly Elan Pharmaceutical Research Corp.) and Elan Pharma International Limited and Janssen Pharmaceutica NV dated March 31, 1999.	Exhibit 10.24 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.8.2 *	Agreement Amendment No. 2, dated as of July 31, 2009, to the License Agreement by and among Elan Pharmaceutical Research Corp., d/b/a Nanosystems and Elan Pharma International Limited and Janssen Pharmaceutica N.V. dated as of March 31, 1999, as amended by the First Amendment, dated as of July 31, 2003.	Exhibit 10.25 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.9	Amendment to First Lien Credit Agreement, dated September 25, 2012, among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto, Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the arrangers and agents party thereto.	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 25, 2012
10.9.1	Amendment No. 2, dated as of February 14, 2013, to Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012, among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto, Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the arrangers and agents party thereto.	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	February 19, 2013
10.9.2	Amendment No. 3 and Waiver to Amended and Restated Credit Agreement, dated as of May 22, 2013, among Alkermes, Inc., Alkermes plc, Alkermes Pharma Ireland Limited, Alkermes US Holdings, Inc., Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the lenders party thereto.	Exhibit 10.52 to the Alkermes plc Annual Report on Form 10-K (File No. 011-35299)	May 23, 2013
10.9.3	Amendment No. 4, dated as of October 12, 2016, to Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012, as further amended by Amendment No. 2 on February 14, 2013 and as amended by Amendment No. 3 and Waiver to Amended and Restated Credit Agreement dated as of May 22, 2013, among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto and Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	November 2, 2016
10.9.4	Amendment No. 5, dated as of March 26, 2018, to Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012, as further amended by Amendment No. 2 on February 14, 2013, as amended by Amendment No. 3 and Waiver to Amended and Restated Credit Agreement dated as of May 22, 2013, and as amended by Amendment No. 4, dated as of October 12, 2016, among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto and Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent.	Exhibit 10.5 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	April 26, 2018
10.10 *	License and Collaboration Agreement, dated November 27, 2017, by and between Alkermes Pharma Ireland Limited and Biogen Swiss Manufacturing GmbH.	Exhibit 10.10 of the Alkermes plc Annual Report on Form 10-K (File No. 011-35299)	February 16, 2018
10.10.1 *	First Amendment to License and Collaboration Agreement between Alkermes Pharma Ireland Limited and Biogen Swiss Manufacturing GmbH, effective as of October 3, 2018.	Exhibit 10.12 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	October 23, 2018
10.10.2	Second Amendment to License and Collaboration Agreement between Alkermes Pharma Ireland Limited and Biogen Swiss Manufacturing GmbH, effective as of January 31, 2019.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	April 25, 2019

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.10.3 #**	Third Amendment to License and Collaboration Agreement between Alkermes Pharma Ireland Limited and Biogen Swiss Manufacturing GmbH, effective as of October 30, 2019.		
10.11	Lease between Alkermes, Inc. and PDM 900 Unit, LLC, dated March 23, 2018.	Exhibit 10.4 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	April 26, 2018
10.11.1	First Amendment to Lease, dated June 21, 2018, by and between Alkermes, Inc. and PDM 900 Unit, LLC.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 26, 2018
10.11.2	Second Amendment to Lease, dated May 10, 2019, by and between Alkermes, Inc. and PDM 900 Unit, LLC.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 25, 2019
10.12 †	Employment agreement, dated as of December 12, 2007, by and between Richard F. Pops and Alkermes, Inc.	Exhibit 10.1 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 11, 2008
10.12.1 †	Amendment to Employment Agreement, dated as of October 7, 2008, by and between Alkermes, Inc. and Richard F. Pops.	Exhibit 10.5 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	October 7, 2008
10.12.2 †	Amendment No. 2 to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops, dated September 10, 2009.	Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	September 11, 2009
10.13 †	Form of Employment Agreement, dated as of December 12, 2007, entered into by and between Alkermes, Inc. and each of James M. Frates and Michael J. Landine.	Exhibit 10.3 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 11, 2008
10.13.1 †	Form of Amendment to Employment Agreement entered into by and between Alkermes, Inc. and each of James M. Frates and Michael J. Landine.	Exhibit 10.7 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	October 7, 2008
10.14 †	Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and James M. Frates.	Exhibit 10.15 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 30, 2008
10.15 †	Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and Michael J. Landine.	Exhibit 10.15(a) to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 30, 2008
10.17 †	Form of Employment Agreement entered into by and between Alkermes, Inc. and each of Iain M. Brown, David J. Gaffin, Craig C. Hopkinson, M.D. and James R. Robinson, Jr.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	November 2, 2016
10.17.1†	Offer Letter between Alkermes, Inc. and Craig C. Hopkinson M.D., effective as of April 24, 2017.	Exhibit 10.17.1 to the Alkermes plc Annual Report on Form 10-K (File No. 011-35299)	February 16, 2018
10.17.2 †	Offer Letter between Alkermes, Inc. and James R. Robinson, Jr., dated February 28, 2018.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	April 26, 2018
10.18 †	Form of Indemnification Agreement by and between Alkermes, Inc. and each of its directors and executive officers.	Exhibit 10.1 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	March 25, 2010
10.19 †	Form of Deed of Indemnification for Alkermes plc Officers.	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.20 †	Form of Deed of Indemnification for Alkermes plc Directors/Secretary.	Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.21 †	Form of Deed of Indemnification for Alkermes, Inc. and Subsidiaries Directors/Secretary.	Exhibit 10.3 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.22†	Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 (File No. 001-35299)	April 27, 2017
10.22.1 †	Form of Stock Option Award Certificate (Non-Employee Director) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.4 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016
10.22.2 †	Form of Restricted Stock Unit Award Certificate (Time Vesting Only – Irish) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.5 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016
10.22.3 †	Form of Restricted Stock Unit Award Certificate (Time Vesting Only – U.S.) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.6 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016
10.22.4 †	Form of Stock Option Award Certificate (Time Vesting Non-Qualified Option – Irish) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.7 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016
10.22.5 †	Form Stock Option Award Certificate (Time Vesting Non-Qualified Option – U.S.) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.8 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016
10.22.6 †	Form of Stock Option Award Certificate (Incentive Stock Option – U.S.) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.9 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016
10.22.7 †	Form of 2008 Restricted Stock Unit Award Certificate (Performance Vesting Only) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	May 22, 2009
10.23†	Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	May 24, 2017
10.23.1 †	Form of Incentive Stock Option Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.23.2 †	Form of Non-Qualified Stock Option (Employee) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.23.3 †	Form of Restricted Stock Unit (Time-Vesting) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.3 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.23.4 †	Form of Restricted Stock Unit (Performance-Vesting) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.4 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.23.5 †	Form of Non-Qualified Stock Option (Non-Employee Director) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.5 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.24 †	Alkermes plc 2018 Stock Option and Incentive Plan.	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	May 23, 2018
10.24.1 †	Form of Incentive Stock Option Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.	Exhibit 10.6 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.24.2 †	Form of Non-Qualified Stock Option (Employee) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.	Exhibit 10.7 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.24.3 †	Form of Restricted Stock Unit (Time-Vesting) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.	Exhibit 10.8 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23 ,2018
10.24.4 †	Form of Restricted Stock Unit (Performance-Vesting) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.	Exhibit 10.9 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.24.5 †	Form of Non-Qualified Stock Option (Non-Employee Director) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.	Exhibit 10.10 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
21.1 #	List of subsidiaries		
23.1 #	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm		
24.1 #	Power of Attorney (included on the signature pages hereto)		
31.1 #	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934		
31.2 #	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934		
32.1 ‡	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		
101.SCH #	Inline XBRL Taxonomy Extension Schema Document.		
101.CAL #	Inline XBRL Taxonomy Extension Calculation Linkbase Document.		
101.LAB #	Inline XBRL Taxonomy Extension Label Linkbase Document.		
101.PRE #	Inline XBRL Taxonomy Extension Presentation Linkbase Document.		
101.DEF #	Inline XBRL Taxonomy Extension Definition Linkbase Document.		
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)		

† Indicates a management contract or any compensatory plan, contract or arrangement.
# Filed herewith.
‡ Furnished herewith.
* Confidential treatment has been granted or requested for certain portions of this exhibit. Such portions have been filed separately with the SEC pursuant to a confidential treatment request.
** In accordance with Item 601(b)(2)(ii) of Regulation S-K, certain information (indicated by "[**]") has been excluded from this exhibit because it is both not material and would likely cause competitive harm to the Company if publicly disclosed.

Item 16. *Form 10-K Summary*

Not applicable.

SIGNATURES

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

ALKERMES PLC

By: /s/ Richard F. Pops
Richard F. Pops
Chairman and Chief Executive Officer

February 13, 2020

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Richard F. Pops Richard F. Pops	Chairman and Chief Executive Officer (Principal Executive Officer)	February 13, 2020
/s/ James M. Frates James M. Frates	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	February 13, 2020
/s/ Iain M. Brown Iain M. Brown	Senior Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 13, 2020
/s/ David W. Anstice David W. Anstice	Director	February 13, 2020
/s/ Robert A. Breyer Robert A. Breyer	Director	February 13, 2020
/s/ Shane Cooke Shane Cooke	Director	February 13, 2020
/s/ Richard Gaynor Richard Gaynor	Director	February 13, 2020
/s/ Wendy L. Dixon Wendy L. Dixon	Director	February 13, 2020
/s/ Paul J. Mitchell Paul J. Mitchell	Director	February 13, 2020
/s/ Nancy L. Snyderman Nancy L. Snyderman	Director	February 13, 2020
/s/ Frank Anders Wilson Frank Anders Wilson	Director	February 13, 2020
/s/ Nancy J. Wysenski Nancy J. Wysenski	Director	February 13, 2020

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Alkermes plc

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Alkermes plc and its subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, of shareholders' equity and of cash flows for each of the three years in the period ended December 31, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Changes in Accounting Principles

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019, the manner in which it accounts for revenue from contracts with customers in 2018, and the manner in which it accounts for share-based compensation in 2017.

Basis for Opinions

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

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

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Fair Value of Contingent Consideration

As described in Notes 2 and 5 to the consolidated financial statements, contingent consideration is recorded at fair value on the acquisition date and is revalued each reporting period, with changes in the fair value recognized within the consolidated statement of operations and comprehensive loss. As of and for the year ended December 31, 2019, management recorded a total contingent consideration asset of $32.4 million and expense of $22.8 million. Management estimated the fair value of contingent consideration through valuation models that incorporate probability-adjusted assumptions related to the achievement of milestones and thus the likelihood of receiving related payments. Changes in the fair value of contingent consideration can result from changes to one or multiple assumptions, including adjustments to discount rates, changes in the amount and timing of cash flows, changes in the assumed achievement and timing of any development and sales-based milestones and changes in the assumed probability associated with regulatory approval. These fair value measurements are based on significant inputs not observable in the market.

The principal considerations for our determination that performing procedures relating to the fair value of contingent consideration is a critical audit matter are there was significant judgment by management in developing the assumptions used in the fair value measurement, including the discount rate, the amount and timing of cash flows, the assumed achievement and timing of any development and sales-based milestones, and the assumed probability associated with regulatory approval. This in turn led to a high degree of auditor judgment, subjectivity and effort in performing procedures related to the fair value of contingent consideration and the audit effort involved the use of professionals with specialized skill and knowledge to assist in evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management’s estimation of the fair value of contingent consideration, including controls over the assumptions used to estimate the fair value. These procedures also included, among others, testing management’s process for developing the fair value of contingent consideration, evaluating the reasonableness of valuation models and assumptions used, including the discount rate, the amount and timing of cash flows, the assumed achievement and timing of any development and sales-based milestones, and the assumed probability associated with regulatory approval. Evaluating management’s assumptions related to cash flows, probability of success, and achievement and timing of milestone payments involved evaluating whether the assumptions used by management were reasonable considering the agreements associated with the transaction, the consistency with industry studies and the stage of product development. Professionals with specialized skill and knowledge were used to assist in evaluating the appropriateness of management’s valuation models and evaluating the reasonableness of the assumptions used in the models.

Rebate Accruals - Medicaid Drug Rebate Program

As described in Note 2 and Note 10 to the consolidated financial statements, the Company’s revenue from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with the Company’s customers, health care providers or payers. Accruals for rebates to states under the Medicaid Drug Rebate Program are recorded as a reduction of sales when the product is shipped into the distribution channel using the expected value method. As of December 31, 2019, total accrued sales discounts, allowances and reserves were $153.9 million, of which a significant amount related to Medicaid rebates. The Company rebates individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is based on the Company’s average manufacturer prices. Management estimated expected unit sales and rebates per unit under the Medicaid program and adjusted its rebate accrual based on actual unit sales and rebates per unit.

The principal considerations for our determination that performing procedures relating to rebate accruals for the Medicaid Drug Rebate Program is a critical audit matter are there was significant judgment by management in developing the rebate accruals,

including developing assumptions related to the estimates of units sold and rebates per unit under the Medicaid program. This in turn led to a high degree of auditor judgment, effort, and subjectivity in performing procedures related to rebate accruals for the Medicaid Drug Rebate Program.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to rebate accruals for the Medicaid drug rebate program, including controls over the assumptions used to estimate the rebate accruals. These procedures also included, among others, (i) obtaining an understanding of management's process and methodology for determining the Medicaid rebate accruals, (ii) assessing the appropriateness of management's methodology, (iii) comparing accrual balances and deduction to sales year over year, (iv) assessing the reasonableness of management's forecast of Medicaid units by comparing to historical results and considering the historical accuracy of the accrual for management bias, and (v) testing rebate claims processed by the Company.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
February 13, 2020

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

ALKERMES PLC AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2019 and 2018

	December 31, 2019	December 31, 2018
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 203,771	$ 266,762
Investments—short-term	331,208	272,533
Receivables, net	257,086	292,223
Contract assets	8,386	8,230
Inventory	101,803	90,196
Prepaid expenses and other current assets	59,716	53,308
Total current assets	961,970	983,252
PROPERTY, PLANT AND EQUIPMENT, NET	362,168	309,987
INTANGIBLE ASSETS, NET	150,643	191,001
GOODWILL	92,873	92,873
DEFERRED TAX ASSETS	96,558	85,807
INVESTMENTS—LONG-TERM	79,391	80,744
CONTINGENT CONSIDERATION	32,400	65,200
RIGHT-OF-USE ASSETS	12,379	—
OTHER ASSETS	17,021	16,143
TOTAL ASSETS	$ 1,805,403	$ 1,825,007
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 373,037	$ 333,762
Operating lease liabilities—short-term	8,466	—
Contract liabilities—short-term	6,766	3,169
Long-term debt—short-term	2,843	2,843
Total current liabilities	391,112	339,774
LONG-TERM DEBT	274,295	276,465
CONTRACT LIABILITIES—LONG-TERM	22,068	9,525
OPERATING LEASE LIABILITIES—LONG-TERM	5,342	—
OTHER LONG-TERM LIABILITIES	27,144	27,958
Total liabilities	719,961	653,722
COMMITMENTS AND CONTINGENT LIABILITIES (Note 19)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, $0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at December 31, 2019 and 2018, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 160,489,888 and 158,180,833 shares issued; 157,779,002 and 155,757,344 shares outstanding at December 31, 2019 and 2018, respectively	1,602	1,579
Treasury shares, at cost (2,710,886 and 2,423,489 shares at December 31, 2019 and 2018, respectively)	(118,386)	(108,969)
Additional paid-in capital	2,586,030	2,467,323
Accumulated other comprehensive loss	(1,816)	(3,280)
Accumulated deficit	(1,381,988)	(1,185,368)
Total shareholders' equity	1,085,442	1,171,285
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 1,805,403	$ 1,825,007

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

ALKERMES PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
Years Ended December 31, 2019, 2018 and 2017

	Year Ended December 31,		
	2019	2018	2017
	(In thousands, except per share amounts)		
REVENUES:			
Product sales, net	$ 524,499	$ 450,334	$ 362,834
Manufacturing and royalty revenues	447,882	526,675	505,308
License revenue	145,750	48,370	28,000
Research and development revenue	52,816	68,895	7,232
Total revenues	1,170,947	1,094,274	903,374
EXPENSES:			
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	180,385	176,420	154,748
Research and development	512,833	425,406	412,889
Selling, general and administrative	599,449	526,408	421,578
Amortization of acquired intangible assets	40,358	65,168	62,059
Restructuring expense	13,401	—	—
Total expenses	1,346,426	1,193,402	1,051,274
OPERATING LOSS	(175,479)	(99,128)	(147,900)
OTHER (EXPENSE) INCOME, NET:			
Interest income	13,976	9,238	4,649
Interest expense	(13,601)	(15,437)	(12,008)
Change in the fair value of contingent consideration	(22,800)	(19,600)	21,600
Other income (expense), net	848	(2,040)	(9,615)
Total other (expense) income, net	(21,577)	(27,839)	4,626
LOSS BEFORE INCOME TAXES	(197,056)	(126,967)	(143,274)
INCOME TAX (BENEFIT) PROVISION	(436)	12,344	14,671
NET LOSS	$ (196,620)	$ (139,311)	$ (157,945)
LOSS PER ORDINARY SHARE:			
Basic and diluted	$ (1.25)	$ (0.90)	$ (1.03)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:			
Basic and diluted	157,051	155,112	153,415
COMPREHENSIVE LOSS:			
Net loss	$ (196,620)	$ (139,311)	$ (157,945)
Holding gain (loss), net of a tax provision (benefit) of $426, $159, $(295), respectively	1,464	512	(518)
COMPREHENSIVE LOSS	$ (195,156)	$ (138,799)	$ (158,463)

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

ALKERMES PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
Years Ended December 31, 2019, 2018 and 2017

	Ordinary Shares		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Treasury Stock		
	Shares	Amount	Capital	Loss	Deficit	Shares	Amount	Total
	(In thousands, except share data)							
BALANCE — December 31, 2016	154,191,281	$ 1,539	$ 2,231,797	$ (3,274)	$ (947,942)	(1,760,767)	$ (72,639)	$ 1,209,481
Issuance of ordinary shares under employee stock plans	1,850,084	16	23,501	—	—	—	—	23,517
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	16,267	2	273	—	—	(287,409)	(16,708)	(16,433)
Share-based compensation expense	—	—	83,184	—	—	—	—	83,184
Unrealized loss on marketable securities, net of tax benefit of $(295)	—	—	—	(518)	—	—	—	(518)
Cumulative effect adjustment related to change in accounting for excess tax benefits	—	—	—	—	61,522	—	—	61,522
Net loss	—	—	—	—	(157,945)	—	—	(157,945)
BALANCE — December 31, 2017	156,057,632	$ 1,557	$ 2,338,755	$ (3,792)	$ (1,044,365)	(2,048,176)	$ (89,347)	$ 1,202,808
Issuance of ordinary shares under employee stock plans	1,087,815	11	20,866	—	—	—	—	20,877
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	1,035,386	11	(11)	—	—	(375,313)	(19,622)	(19,622)
Share-based compensation expense	—	—	107,713	—	—	—	—	107,713
Unrealized loss on marketable securities, net of tax provision of $159	—	—	—	512	—	—	—	512
Cumulative effect adjustment related to the adoption of new accounting standards	—	—	—	—	(1,692)	—	—	(1,692)
Net loss	—	—	—	—	(139,311)	—	—	(139,311)
BALANCE — December 31, 2018	158,180,833	$ 1,579	$ 2,467,323	$ (3,280)	$ (1,185,368)	(2,423,489)	$ (108,969)	$ 1,171,285
Issuance of ordinary shares under employee stock plans	1,510,177	15	18,910	—	—	—	—	18,925
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	798,878	8	92	—	—	(287,397)	(9,417)	(9,317)
Share-based compensation expense	—	—	99,705	—	—	—	—	99,705
Unrealized loss on marketable securities, net of tax provision of $426	—	—	—	1,464	—	—	—	1,464
Net loss	—	—	—	—	(196,620)	—	—	(196,620)
BALANCE — December 31, 2019	160,489,888	$ 1,602	$ 2,586,030	$ (1,816)	$ (1,381,988)	(2,710,886)	$ (118,386)	$ 1,085,442

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

ALKERMES PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2019, 2018 and 2017

	Year Ended December 31,		
	2019	2018	2017
	(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (196,620)	$ (139,311)	$ (157,945)
Adjustments to reconcile net loss to cash flows from operating activities:			
Depreciation and amortization	80,413	103,660	98,523
Share-based compensation expense	100,977	105,357	83,917
Deferred income taxes	(319)	10,623	7,234
Change in the fair value of contingent consideration	22,800	19,600	(21,600)
Loss on debt refinancing	—	2,298	—
Payment made for debt refinancing	—	(2,251)	—
Impairment of property, plant and equipment	—	5,746	—
Impairment of investment in Synchronicity Pharma, Inc.	—	—	10,471
Other non-cash charges	(580)	979	3,471
Changes in assets and liabilities, excluding the effect of acquisitions:			
Receivables	35,136	(58,632)	(42,489)
Contract assets	(5,156)	880	—
Inventory	(13,077)	(2,665)	(30,191)
Prepaid expenses and other assets	(1,784)	(5,990)	(9,506)
Right-of-use assets	8,399	—	—
Accounts payable and accrued expenses	34,847	46,739	72,658
Contract liabilities	16,140	3,252	(1,447)
Operating lease liabilities	(9,117)	—	—
Other long-term liabilities	18	8,996	6,094
Cash flows provided by operating activities	72,077	99,281	19,190
CASH FLOWS FROM INVESTING ACTIVITIES:			
Additions of property, plant and equipment	(90,942)	(69,431)	(51,300)
Proceeds from the sale of equipment	900	507	162
Proceeds from contingent consideration	10,000	—	—
Purchases of investments	(277,518)	(397,727)	(431,712)
Sales and maturities of investments	224,602	444,456	464,494
Acquisition of Rodin Therapeutics, Inc.'s net assets, net of cash acquired	(8,875)	—	—
Cash flows used in investing activities	(141,833)	(22,195)	(18,356)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	18,925	20,877	23,517
Employee taxes paid related to net share settlement of equity awards	(9,317)	(19,622)	(16,433)
Principal payments of long-term debt	(2,843)	(743)	—
Payment made for debt refinancing	—	(2,132)	(3,000)
Cash flows provided by (used in) financing activities	6,765	(1,620)	4,084
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(62,991)	75,466	4,918
CASH AND CASH EQUIVALENTS—Beginning of period	266,762	191,296	186,378
CASH AND CASH EQUIVALENTS—End of period	$ 203,771	$ 266,762	$ 191,296
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest	$ 13,254	$ 12,526	$ 11,143
Cash paid for taxes	$ 2,508	$ 754	$ 2,992
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	$ 13,789	$ 11,720	$ 11,151

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

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

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

Use of Estimates

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

Cash and Cash Equivalents

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

Investments

The Company has investments in various types of securities, consisting primarily of United States ("U.S.") government and agency obligations, corporate debt securities and debt securities issued by foreign agencies and backed by foreign governments. The Company generally holds its interest-bearing investments with major financial institutions and in accordance with documented investment policies. The Company limits the amount of credit exposure to any one financial institution or corporate issuer. At December 31, 2019, substantially all these investments were classified as available for sale and were recorded at fair value.

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

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

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

Fair Value of Financial Instruments

The Company's financial assets and liabilities are recorded at fair value and are classified as Level 1, 2 or 3 within the fair value hierarchy, as described in the accounting standards for fair value measurement. At December 31, 2019, the Company's financial assets consisted of cash equivalents, investments and contingent consideration and are classified within the fair value hierarchy as follows:

- *Level 1*–these valuations are based on a market approach using quoted prices in active markets for identical assets. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 1 inputs at December 31, 2019 included U.S. treasury securities, marketable securities classified as cash equivalents and a fixed term deposit account;
- *Level 2*–these valuations are based on a market approach using quoted prices obtained from brokers or dealers for similar securities or for securities for which the Company has limited visibility into their trading volumes. Valuations of these financial instruments do not require a significant degree of judgment. Assets utilizing Level 2 inputs at December 31, 2019 included U.S. government agency debt securities, debt securities issued by foreign agencies and backed by foreign governments and investments in corporate debt securities that are trading in the credit markets; and
- *Level 3*–these valuations are based on an income approach using certain inputs that are unobservable and are significant to the overall fair value measurement. Valuations of these products require a significant degree of judgment. At December 31, 2019, assets utilizing Level 3 inputs included contingent consideration and an investment in a corporate debt security.

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

Inventory

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

Property, Plant and Equipment

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

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

Contingent Consideration

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

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

Goodwill and Intangible Assets

Goodwill represents the excess cost of the Company's investment in the net assets of acquired companies over the fair value of the underlying identifiable net assets at the date of acquisition. The Company's goodwill consists solely of goodwill created as a result of the Company's acquisition of Elan Drug Technologies ("EDT") from Elan Corporation, plc (the "Business Combination") in September 2011 and has been assigned to one reporting unit. A reporting unit is an operating segment or one level below an operating segment or a component to which goodwill is assigned when initially recorded.

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

The Company's finite-lived intangible assets, consisting of core developed technology and collaboration agreements acquired as part of the acquisition of EDT, were recorded at fair value at the time of their acquisition and are stated within the Company's consolidated balance sheets net of accumulated amortization. The finite-lived intangible assets are amortized over their estimated useful lives using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. The useful lives of the Company's intangible assets are primarily based on the legal or contractual life of the underlying patent or contract, which does not include additional years for the potential extension or renewal of the contract or patent.

Impairment of Long-Lived Assets

The Company reviews long-lived assets to be held and used for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell them.

Revenue from Contracts with Customers

Effective January 1, 2018, the Company adopted the requirements of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("Topic 606") using the modified retrospective method. As part of the adoption, the Company reviewed all contracts that were not yet completed as of the date of initial application in determining the cumulative-effect impact related to the adoption of Topic 606. The cumulative-effect impact recorded to retained earnings resulted in an adjustment of approximately $0.8 million, which was primarily due to the acceleration of manufacturing revenue, offset by an adjustment to deferred revenue for license and milestone payments that will now be recognized over time. The following balance sheet accounts were impacted:

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

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

The Company recognizes revenue when or as it satisfies a performance obligation by transferring an asset or providing a service to a customer. Management judgment is required in determining the consideration to be earned under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement. Steering committee services that are not inconsequential or perfunctory and that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations.

Because the Company adopted Topic 606 using the modified retrospective method, the Company recognized the cumulative effect of initially applying Topic 606 as an adjustment to the opening balance of shareholders' equity at January 1, 2018. Therefore, the comparative information at December 31, 2017 has not been adjusted and continues to be reported under the old revenue recognition guidance ("Topic 605").

Product Sales, Net

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

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

- *Medicaid Rebates*—the Company records accruals for rebates to states under the Medicaid Drug Rebate Program as a reduction of sales when the product is shipped into the distribution channel using the expected value method. The Company rebates individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is based on the Company's average manufacturer prices. The Company estimates expected unit sales and rebates per unit under the Medicaid program and adjusts its rebate based on actual unit sales and rebates per unit. To date, actual Medicaid rebates have not differed materially from the Company's estimates;

- *Chargebacks*—discounts that occur when contracted indirect customers purchase directly from wholesalers and specialty distributors. Contracted customers generally purchase a product at its contracted price. The wholesaler or specialty distributor, in turn, then generally charges back to the Company the difference between the wholesale acquisition cost and the contracted price paid to the wholesaler or specialty distributor by the customer. The allowance for chargebacks is made using the expected value method and is based on actual and expected utilization of these programs. Chargebacks could exceed historical experience and the Company's estimates of future participation in these programs. To date, actual chargebacks have not differed materially from the Company's estimates;
- *Product Discounts*—cash consideration, including sales incentives, given by the Company under agreements with a number of wholesaler, distributor, pharmacy, and treatment provider customers that provide them with a discount on the purchase price of products. The reserve is made using the expected value method and to date, actual product discounts have not differed materially from the Company's estimates;
- *Product Returns*—the Company records an estimate for product returns at the time our customers take control of their product. The Company estimates this liability using the expected value based on historical return levels and specifically identified anticipated returns due to known business conditions and product expiry dates. Return amounts are recorded as a deduction to arrive at product sales, net. Once product is returned, it is destroyed; and
- *Medicare Part D*—the Company records accruals for Medicare Part D liabilities under the Medicare Coverage Gap Discount Program ("CGDP") as a reduction of sales. Under the CGDP, patients reaching the annual coverage gap threshold are eligible for reimbursement coverage for out-of-pocket costs for covered prescription drugs. Under an agreement with the Center for Medicare and Medicaid, manufacturers are responsible to reimburse prescription plan sponsors for the portion of out-of-pocket expenses not covered under their Medicare plans.

Collaborative Arrangements

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

Manufacturing Revenue

The Company recognizes manufacturing revenues from the sale of products it manufactures for resale by its licensees. Manufacturing revenues for the Company's partnered products, with the exception of those from Janssen related to RISPERDAL CONSTA, are recognized over time as products move through the manufacturing process, using a standard cost-based model as a measure of progress, which represents a faithful depiction of the transfer of control of the goods. The Company recognizes manufacturing revenue from these products over time as it determined, in each instance, that it would have a right to payment for performance completed to date if its customer were to terminate the manufacturing agreement for reasons other than the Company's non-performance and the products have no alternative use. The Company invoices its licensees upon shipment with payment terms between 30 to 90 days.

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

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

Royalty Revenue

The Company recognizes royalty revenues related to the sale by its licensees of products that incorporate the Company's technologies. Royalties, with the exception of those earned on sales of AMPYRA as set forth below, qualify for the sales-and-usage exemption under Topic 606 as (i) royalties are based strictly on the sales-and-usage by the licensee; and (ii) a license of intellectual property ("IP") is the sole or predominant item to which such royalties relate. Based on this exemption, these royalties are earned in the period the products are sold by the Company's partner and the Company has a present right to payment. Royalties on AMPYRA manufactured under our license and supply agreements with Acorda are incorporated into the standard cost-based model described in the manufacturing revenues section, above, as the terms of such agreements entitle the Company to royalty revenue as the product is being manufactured, which represents a faithful depiction of the transfer of goods, and not based on the actual end-market sales of the licensee. Certain of the Company's royalty revenues are recognized by the Company based on information supplied to the Company by its licensees and require estimates to be made. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period in which they become known, which is generally within the same quarter. The difference between the Company's actual and estimated royalty revenues has not been material to date.

Research and Development Revenue

R&D revenue consists of funding that compensates the Company for formulation, pre-clinical and clinical testing under R&D arrangements with its partners. The Company generally bills its partners under R&D arrangements using a full-time equivalent or hourly rate, plus direct external costs, if any. Revenue is recognized as the obligations under the R&D arrangements are performed.

License Revenue

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

Receivables, net

Receivables, net, include amounts billed and currently unconditionally due from customers. The amounts due are stated at their net estimated realizable value. The Company maintains an allowance for doubtful accounts to provide for the estimated amounts of receivables that will not be collected. The allowance is based upon an assessment of customer creditworthiness, historical payment experience, the age of outstanding receivables and collateral to the extent applicable. The Company's allowance for doubtful accounts was $0.2 million at each of December 31, 2019 and 2018.

Contract Assets

Contract assets include unbilled amounts resulting from sales under certain of the Company's manufacturing contracts where revenue is recognized over time, except for $5.0 million of consideration related to the Company's collaboration with Biogen related to Vumerity, which the Company expects to receive in approximately three years, and is included in "Other assets" in the accompanying consolidated balance sheets. The manufacturing related amounts included in the contract assets table below complete the manufacturing process in ten days to eight weeks and are classified as current assets.

Contract assets consisted of the following:

(In thousands)	Contract Assets
Contract assets at January 1, 2018	$ 9,110
Additions	57,617
Transferred to receivables, net	(58,497)
Contract assets at December 31, 2018	8,230
Additions	37,911
Transferred to receivables, net	(32,755)
Contract assets at December 31, 2019	$ 13,386

Contract Liabilities

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

Contract liabilities consisted of the following:

(In thousands)	Contract Liabilities
Contract liabilities at January 1, 2018	$ 9,442
Additions	6,381
Amounts recognized into revenue	(3,129)
Contract liabilities at December 31, 2018	12,694
Additions	18,677
Amounts recognized into revenue	(2,537)
Contract liabilities at December 31, 2019	$ 28,834

Foreign Currency

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within "Other (expense) income, net" in the accompanying consolidated statements of operations and comprehensive loss. During the years ended December 31, 2019, 2018 and 2017, the Company recorded a (loss) gain on foreign currency translation of $(0.9) million, $(2.3) million and $3.7 million, respectively.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk are receivables and marketable securities. Billings to large pharmaceutical companies and pharmaceutical wholesalers account for the majority of the Company's receivables, and collateral is generally not required from these customers. To mitigate credit risk, the Company monitors the financial performance and credit worthiness of its customers. The following represents revenue and receivables from the Company's customers exceeding 10% of the total in each category as of, and for the years ended, December 31, 2019, 2018 and 2017:

	Year Ended December 31,					
	2019		2018		2017	
Customer	Receivables	Revenue	Receivables	Revenue	Receivables	Revenue
Janssen	29%	28%	27%	29%	31%	33%
Biogen	*	17%	*	10%	*	*
Cardinal Health	12%	*	*	13%	*	*
AmerisourceBergen	10%	*	*	*	*	*
Acorda	*	*	15%	10%	14%	13%

* Indicates the revenues or receivables for the customer did not exceed 10% of the Company's total in each category as of or for the years ended December 31, 2019, 2018 and 2017, as noted.

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

Geographic Information

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

(In thousands)	Year Ended December 31, 2019	2018	2017
Revenue by region:			
U.S.	$ 966,929	$ 884,600	$ 700,090
Ireland	3,195	4,915	9,706
Rest of world	200,823	204,759	193,578
Assets by region:			
Current assets:			
U.S.	$ 551,799	$ 546,533	$ 402,481
Ireland	407,791	433,837	403,167
Rest of world	2,381	2,882	3,196
Long-term assets:			
U.S.:			
Other	$ 382,029	$ 312,243	$ 360,641
Ireland:			
Intangible assets	$ 150,643	$ 191,001	$ 256,168
Goodwill	92,873	92,873	92,873
Other	217,887	245,638	278,701

Research and Development Expenses

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

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses are primarily comprised of employee-related expenses associated with sales and marketing, finance, human resources, legal, information technology and other administrative personnel, outside marketing, advertising and legal expenses and other general and administrative costs.

Advertising costs are expensed as incurred. During the years ended December 31, 2019, 2018 and 2017, advertising costs totaled $31.1 million, $54.7 million and $34.4 million, respectively.

Share-Based Compensation

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

Time-Based Stock Options

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

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

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

	Year Ended December 31,		
	2019	2018	2017
Expected option term	5 - 7 years	5 - 8 years	5 - 8 years
Expected stock volatility	46 % - 50 %	44 % - 49 %	43 % - 47 %
Risk-free interest rate	1.34 % - 2.59 %	2.25 % - 3.10 %	1.69 % - 2.38 %
Expected annual dividend yield	—	—	—

Performance-Based Stock Options

Certain of the Company's granted stock options are subject to achievement of a specified market condition prior to vesting in addition to being subject to time-based vesting. The estimated fair value of these stock options that vest upon the achievement of a market condition was determined through the use of a Monte Carlo simulation model, which utilizes input variables that determine the probability of satisfying the market condition stipulated in the award and calculates the fair market value for the award. The Monte Carlo simulation model used the following assumptions:

Grant Date	Weighted-Average Expected Volatility	Cost of Equity	Risk-Free Interest Rate
February 21, 2019	45.0%	12.0%	2.69%

Compensation expense for the stock options that vest upon the achievement of a market condition is recognized over a derived service period as determined by the Monte Carlo simulation model. The vesting of these stock options is also subject to continued employment of the grantee.

Time-Based Restricted Stock Units

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

Performance-Based Restricted Stock Units

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

Income Taxes

The Company recognizes income taxes under the asset and liability method. Deferred income taxes are recognized for differences between the financial reporting and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. In evaluating the Company's ability to recover its deferred tax assets, the Company considers all available positive and negative evidence including its past operating results, the existence of cumulative income in the most recent fiscal years, changes in the business in which the Company operates and its forecast of future taxable income. In determining future taxable income, the Company is responsible for assumptions utilized including the amount of Irish, U.S. and other foreign pre-tax

operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that the Company is using to manage the underlying business.

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

Comprehensive Loss

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

Loss Per Share

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

Segment Information

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

Employee Benefit Plans

401(k) Plan

The Company maintains a 401(k) retirement savings plan (the "401(k) Plan"), which covers substantially all of its U.S.-based employees. Eligible employees may contribute up to 100% of their eligible compensation, subject to certain Internal Revenue Service ("IRS") limitations. The Company matches 100% of employee contributions up to the first 5% of employee pay, up to IRS limits. Employee and Company contributions are fully vested when made. During the years ended December 31, 2019, 2018 and 2017, the Company contributed $14.8 million, $12.1 million and $9.8 million, respectively, to match employee deferrals under the 401(k) Plan.

Defined Contribution Plan

The Company maintains a defined contribution plan for its Ireland-based employees (the "Defined Contribution Plan"). The Defined Contribution Plan provides for eligible employees to contribute up to a maximum of 40%, depending upon their age, of their total taxable earnings subject to an earnings cap of €115,000. The Company provides a match of up to 18% of taxable earnings depending upon an individual's contribution level. During the years ended December 31, 2019, 2018 and 2017, the Company contributed $4.1 million, $4.0 million and $3.7 million, respectively, in contributions to the Defined Contribution Plan.

New Accounting Pronouncements

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

Effective January 1, 2019, the Company adopted the requirements under Accounting Standards Update ("ASU") 2016-02, Leases ("Topic 842") using the optional modified retrospective transition method and recognized a cumulative-effect adjustment to the consolidated balance sheet on the date of adoption. Comparative periods have not been restated. Topic 842 was issued in order to increase transparency and comparability among organizations by recognizing right-of-use lease assets and operating lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The main difference between previous GAAP ("Topic 840") and Topic 842 is the recognition of right-of-use lease assets and lease liabilities by lessees for those leases classified as operating leases under Topic 840. At January 1, 2019, the Company recorded a right-of-use asset of $20.1 million and an operating lease liability of $22.1 million. For additional information regarding how the Company is accounting for leases under Topic 842, refer to Note 9, *Leases*, in the "Notes to Consolidated Financial Statements" in this Annual Report.

In April 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, as part of its simplification initiative that involves several aspects of the accounting for share-based payment transactions. The amendments in this

update established that: (i) all excess tax benefits and tax deficiencies be recognized as income tax expense or benefit in the income statement; (ii) excess tax benefits be classified as an operating activity in the statement of cash flows; (iii) the entity make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest, which is current GAAP, or account for forfeitures as they occur; (iv) the threshold to qualify for equity classification permits withholding up to the maximum statutory tax rates in the applicable jurisdictions; and (v) cash paid by an employer when directly withholding shares for tax withholding purposes be classified as a financing activity in the statement of cash flows. This ASU became effective for the Company on January 1, 2017. The amendments related to (i), (iii) and (iv) were adopted by the Company on a modified retrospective basis, which resulted in a cumulative-effect adjustment to reduce accumulated deficit by $61.5 million related to the timing of when excess tax benefits are recognized. The Company elected to continue to record expense only for those awards that are expected to vest. The amendments related to (ii) and (v) were adopted using the prospective transition method.

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*, to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. To achieve this objective, the amendments in this ASU replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. This ASU becomes effective for the Company in the year ending December 31, 2020. This standard primarily impacts how firms account for credit losses and requires an impairment model, known as the current expected credit loss model (“CECL”), that is based on expected losses rather than incurred losses. Companies are required to carry an allowance for expected credit losses for most debt instruments (except those carried at fair value), trade receivables, lease receivables, reinsurance receivables, financial guarantee contracts and loan commitments. Available-for-sale debt securities are scoped out of this guidance. The Company’s investment portfolio primarily consists of available-for-sale securities carried at fair value. Further, the Company’s trade receivables do not have abnormally long terms and the Company has rarely ever written off trade receivables. Accordingly, the Company has determined that the adoption of this standard will not have a material impact on the Company’s financial statements.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which addresses the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718, Compensation – Stock Compensation, to include share-based payment transactions for acquiring goods and services from nonemployees. This ASU became effective for and was adopted by the Company in the year ending December 31, 2019 and the adoption of this ASU did not have an impact on the Company’s consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which aims to improve the effectiveness of fair value measurement disclosures. The amendments in this ASU modify the disclosure requirements on fair value measurements based on the concepts in FASB Concepts Statement, Conceptual Framework for Financial Reporting - Chapter 8: Notes to Financial Statements, including the consideration of costs and benefits. This ASU becomes effective for the Company in the year ending December 31, 2020 and early adoption is permitted. Adoption of this standard only impacts the Company’s financial statement disclosures.

In August 2018, the FASB issued ASU 2018-15, *Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This ASU also requires the entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement, which includes reasonably certain renewals. This ASU becomes effective for the Company in the year ending December 31, 2020 and early adoption is permitted. The Company will adopt the standard as of January 1, 2020 using the prospective transition method, whereby it will apply the requirements to any eligible costs incurred after adoption. As such, there should be no impact to the Company’s consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Clarifying the Interaction Between Topic 808 and Topic 606*, which clarifies when transactions between participants in a collaborative arrangement are within the scope of the FASB’s revenue standard, Topic 606. This ASU becomes effective for the Company in the year ending December 31, 2020. The Company reviewed its collaborative arrangements and determined that there are no collaborative arrangements that are considered within the scope of this standard.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the general principles of ASC 740, *Income Taxes*. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. This ASU is effective for fiscal years beginning after December 15, 2020 and early adoption is permitted. Depending on the

amendment, adoption may be applied on a retrospective, modified retrospective or prospective basis. The Company is currently assessing the impact that this ASU will have on its consolidated financial statements.

3. REVENUE FROM CONTRACTS WITH CUSTOMERS

During the years ended December 31, 2019, 2018 and 2017, the Company recorded product sales, net, as follows:

(In thousands)	Year Ended December 31, 2019	2018	2017
VIVITROL	$ 335,365	$ 302,609	$ 269,321
ARISTADA/ARISTADA INITIO	189,134	147,725	93,513
Total product sales, net	$ 524,499	$ 450,334	$ 362,834

During the years ended December 31, 2019, 2018 and 2017, the Company recorded manufacturing and royalty revenues from its collaboration arrangements as follows:

(In thousands)	Year Ended December 31, 2019 Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ —	$ 256,947	$ 256,947
RISPERDAL CONSTA	50,433	15,950	66,383
AMPYRA/FAMPYRA	22,071	15,170	37,241
Other	31,750	55,561	87,311
	$ 104,254	$ 343,628	$ 447,882

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

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

The research and development revenue and license revenue recorded during the years ended December 31, 2019, 2018 and 2017 primarily related to revenue earned under the Company's license and collaboration agreement with Biogen for VUMERITY.

Under a license and collaboration agreement with Biogen, which the Company entered into in November 2017 and amended in October 2018, January 2019 and October 2019, the Company granted Biogen a worldwide, exclusive, sublicensable license to develop, manufacture and commercialize VUMERITY and other products covered by patents licensed to Biogen under the agreement. Upon entering into the November 2017 license and collaboration agreement, the Company received an up-front cash payment of $28.0 million and was also eligible to receive additional payments upon achievement of developmental milestones with respect to VUMERITY. In June 2018, the Company received an additional cash payment of $50.0 million following Biogen's review of preliminary gastrointestinal tolerability data from the clinical development program for VUMERITY. In November 2019, the Company also received an additional payment of $150.0 million following FDA approval of the NDA for VUMERITY and transfer of such NDA to Biogen. The Company is also eligible to receive additional payments upon achievement of developmental milestones with respect to the first two products other than VUMERITY covered by patents licensed to Biogen under the November 2017 license and collaboration agreement. Biogen paid a portion of the VUMERITY development costs the Company incurred in 2017 and, since January 1, 2018, Biogen has been responsible for all VUMERITY development costs the Company incurs, subject to annual budget limitations. Following FDA approval of the NDA for VUMERITY in October 2019, the NDA and any further development responsibilities with respect to VUMERITY were transferred to Biogen.

The Company evaluated the license and collaboration agreement under Topic 606 and determined that it had four deliverables: (i) the grant of a distinct, right-to-use license of IP to Biogen; (ii) future development services; (iii) clinical supply; and (iv) participation on a joint steering committee with Biogen. The Company's participation on the joint steering committee was considered to be perfunctory and thus not recognized as a performance obligation. The deliverables, aside from the participation in the joint steering committee which was considered to be perfunctory, were determined to be separate performance obligations as the license is separately identifiable from the development services and clinical supply, and the development services are not expected to significantly modify or customize the IP.

The Company allocated the arrangement consideration to each performance obligation using the standalone selling prices based on its estimate of selling price for the license and other deliverables. The Company used a discounted cash flow model to estimate the standalone selling price of the license in order to allocate the consideration to the performance obligations. To estimate the standalone selling price of the license, the Company assessed the likelihood of the FDA's approval of VUMERITY and estimated the expected future cash flows assuming FDA approval and maintenance of the IP protecting VUMERITY. The Company then discounted these cash flows using a discount rate of 8.0%, which it believes captures a market participant's view of the risk associated with the expected cash flows. The estimate of selling price of the development services and clinical supply were determined through third-party evidence. The Company believes that a change in the assumptions used to determine its estimate of selling price for the license most likely would not have a significant effect on the allocation of consideration transferred.

Under Topic 606, the Company allocated the $28.0 million up-front payment and the $50.0 million June 2018 payments as follows: $27.0 million and $48.3 million to the delivery of the license; $0.9 million and $1.5 million to future development services; and $0.1 million and $0.2 million to clinical supply, respectively.

In November 2019, following FDA acceptance of the NDA for VUMERITY and transfer of such NDA to Biogen, the Company received a $150.0 million milestone payment, $144.8 million of which was allocated to the delivery of the license; and $5.2 million of which was allocated to future development services and clinical supply. The amounts allocated to the license were recognized upon receipt of the payments as delivery of the license occurred upon entry into the agreement in 2017. The amounts allocated to the development services and clinical supply will be recognized over the course of the development work and as clinical supply is delivered to Biogen, which is expected to continue into 2020. The Company expects to earn an additional $0.3 million in research and development revenue under this agreement with Biogen through 2020.

In addition, the Company will receive a 15% royalty on worldwide net sales of VUMERITY, subject to, under certain circumstances, minimum annual payments for the first five years following FDA approval of VUMERITY. The Company is also entitled to receive royalties on net sales of products other than VUMERITY covered by patents licensed to Biogen under the license and collaboration agreement, at tiered royalty rates calculated as percentages of net sales ranging from high-single digits to sub-teen double digits. All royalties are payable on a product-by-product and country-by-country basis until the later of (i) the last-to-expire patent right covering the applicable product in the applicable country and (ii) a specified period of time from the first commercial sale of the applicable product in the applicable country. Royalties for all products and the minimum annual payments for VUMERITY are subject to customary reductions, as set forth in the license and collaboration agreement.

The Company determined that the future development milestones and sales-based royalties that it may be entitled to receive are variable consideration. The Company is using the most likely amount method for estimating the variable consideration to be received related to the milestones under this arrangement. The royalties are subject to the sales-based exception and will be recorded when the corresponding sale occurs.

Under the license and collaboration agreement, Biogen appointed the Company as the toll manufacturer of clinical and commercial supplies of VUMERITY, subject to Biogen's right to manufacture or have manufactured commercial supplies as a back-up manufacturer and subject to good faith agreement by the parties on the terms of such manufacturing arrangements. In October 2019, the Company entered into a commercial supply agreement with Biogen for the commercial supply of VUMERITY, an amendment to such commercial supply agreement and an amendment to the November 2017 license and collaboration agreement with Biogen. Under these agreements, Biogen has an option to assume responsibility, subject to a transition period, for the manufacture (itself or through a designee) of clinical supplies of VUMERITY and up to 100% of commercial supplies of VUMERITY in exchange for an increase in the royalty rate to be paid by Biogen to the Company on net sales of product that is manufactured by Biogen or its designee. The Company evaluated the commercial supply agreement and the related amendments under Topic 606 and determined that these agreements should be combined and accounted for as a separate contract since the commercial supply agreement and amendment to the November 2017 license and collaboration agreement were negotiated together to achieve a common economic objective and the additional performance obligations under the commercial supply agreement are considered distinct obligations priced at their standalone selling prices. The Company determined that it had two separate performance obligations, the commercial supply of VUMERITY and, upon an election by Biogen to commence a transfer of technology relating to the manufacture of

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

VUMERITY (a "Tech Transfer"), services to be performed by the Company in connection with such Tech Transfer. There are other deliverables under the agreements that were determined to be perfunctory or immaterial.

In connection with the entry into the commercial supply agreement and the related amendments, the Company received payments in the aggregate amount of $5.8 million in the fourth quarter of 2019 and, if Biogen opts to assume responsibility for the manufacture of VUMERITY, the Company will be eligible to receive an additional $5.0 million payment upon the earlier of successful completion of the Tech Transfer or a date in the fourth quarter of 2022. The $5.8 million received in the fourth quarter of 2019 plus amounts received in connection with the Tech Transfer, if any, will be allocated to each of the performance obligations using the standalone selling prices based on the Company's estimate of selling price for the commercial supply of VUMERITY and the services related to the Tech Transfer, and this additional arrangement consideration will be recognized as the Company delivers commercial supply of VUMERITY and/or provides services relating to the Tech Transfer. The Company expects to begin performing under this commercial supply agreement in the first quarter of 2020.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. INVESTMENTS

Investments consist of the following:

December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses: Less than One Year	Gross Unrealized Losses: Greater than One Year	Estimated Fair Value
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	$ 144,161	$ 676	$ —	$ —	$ 144,837
U.S. government and agency debt securities	112,948	434	(1)	(1)	113,380
International government agency debt securities	72,753	248	(10)	—	72,991
Total short-term investments	329,862	1,358	(11)	(1)	331,208
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	51,070	—	(45)	(7)	51,018
International government agency debt securities	20,806	—	(18)	—	20,788
U.S. government and agency debt securities	4,000	—	(4)	—	3,996
	75,876	—	(67)	(7)	$ 75,802
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Fixed term deposit account	1,667	102	—	—	1,769
	3,487	102	—	—	3,589
Total long-term investments	79,363	102	(67)	(7)	79,391
Total investments	$ 409,225	$ 1,460	$ (78)	$ (8)	$ 410,599

December 31, 2018					
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	$ 120,197	$ 57	$ (62)	$ (274)	$ 119,918
U.S. government and agency debt securities	80,055	115	(11)	(87)	80,072
International government agency debt securities	72,091	85	(8)	(117)	72,051
	272,343	257	(81)	(478)	272,041
Held-to-maturity securities:					
Corporate debt securities	492	—	—	—	492
Total short-term investments	272,835	257	(81)	(478)	272,533
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	53,505	—	(185)	(93)	$ 53,227
U.S. government and agency debt securities	18,474	—	(21)	(12)	18,441
International government agency debt securities	5,457	—	(4)	—	5,453
	77,436	—	(210)	(105)	77,121
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Fixed term deposit account	1,667	136	—	—	1,803
	3,487	136	—	—	3,623
Total long-term investments	80,923	136	(210)	(105)	80,744
Total investments	$ 353,758	$ 393	$ (291)	$ (583)	$ 353,277

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

(In thousands)	Year Ended December 31, 2019	2018	2017
Proceeds from the sales and maturities of marketable securities	$ 224,602	$ 444,456	$ 464,494
Realized gains	$ 997	$ 4	$ 9
Realized losses	$ 497	$ 268	$ 3

The Company's available-for-sale and held-to-maturity securities at December 31, 2019 had contractual maturities in the following periods:

	Available-for-sale		Held-to-maturity	
(In thousands)	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	$ 216,084	$ 216,764	$ 1,820	$ 1,820
After 1 year through 5 years	189,654	190,246	1,667	1,769
Total	$ 405,738	$ 407,010	$ 3,487	$ 3,589

At December 31, 2019, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted of U.S. government and agency debt securities, corporate debt securities and international government agency debt securities. The unrealized losses are a result of market conditions related to increasing interest rates. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including, but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; and the Company's intent not to sell these securities and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

In February 2016, the Company entered into a collaboration and license option agreement with Synchronicity Pharma, Inc. ("Synchronicity") formerly Reset Therapeutics, Inc., a related party. The Company made a $15.0 million investment in exchange for shares of Synchronicity's Series B Preferred Stock. The Company was accounting for its investment in Synchronicity under the equity method based on its percentage of ownership, its seat on the board of directors and its belief that it could exert significant influence over the operating and financial policies of Synchronicity.

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

In May 2014, the Company entered into an agreement whereby it is committed to provide up to €7.4 million to a partnership, Fountain Healthcare Partners II, L.P. of Ireland ("Fountain"), which was created to carry on the business of investing exclusively in companies and businesses engaged in the healthcare, pharmaceutical and life sciences sectors. As of December 31, 2019, the Company's total contribution in Fountain was equal to €6.0 million, and its commitment represents approximately 7% of the partnership's total funding. The Company is accounting for its investment in Fountain under the equity method. During the years ended December 31, 2019, 2018 and 2017 the Company recorded a reduction in its investment in Fountain of $0.4 million, an increase of $0.5 million and a reduction of $0.1 million, respectively, which represented the Company's proportional share of Fountain's net (losses) gains for the period. The Company's $5.9 million and $5.5 million net investment in Fountain at December 31, 2019 and 2018, respectively, was included within "Other assets" in the accompanying consolidated balance sheets.

5. FAIR VALUE

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

(In thousands)	December 31, 2019	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 8,064	$ 8,064	$ —	$ —
U.S. government and agency debt securities	117,376	73,795	43,581	—
Corporate debt securities	195,855	—	193,902	1,953
International government agency debt securities	93,779	—	93,779	—
Contingent consideration	32,400	—	—	32,400
Total	$ 447,474	$ 81,859	$ 331,262	$ 34,353

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

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

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

There were no transfers of any securities from Level 1 to Level 2 or from Level 2 to Level 1 during the year ended December 31, 2019. The following table is a rollforward of the fair value of the Company's investments whose fair value was determined using Level 3 inputs at December 31, 2019:

(In thousands)	Fair Value
Balance, January 1, 2019	$ 66,897
Purchase of corporate debt security	1,953
Change in the fair value of warrants	1,837
Change in the fair value of contingent consideration	(22,800)
Payments received from contingent consideration	(10,000)
Proceeds from the sale of shares acquired upon exercise of warrants	(3,042)
Impairment of corporate debt security	(492)
Balance, December 31, 2019	$ 34,353

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

In April 2015, the Company completed the sale of its Gainesville, GA manufacturing facility, the related manufacturing and royalty revenue associated with certain products manufactured at the facility, and the rights to IV/IM and parenteral forms of Meloxicam. On December 20, 2018, the Company entered into a Second Amendment to the Purchase and Sale Agreement ("Purchase and Sale Agreement Amendment") dated March 7, 2015 with Recro and Recro Gainesville LLC and a Second Amendment to the Asset Transfer and License Agreement dated April 10, 2015 with Recro Gainesville LLC (the "License Agreement Amendment" and, together with the Purchase and Sale Agreement Amendment, the "Amendments").

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

At December 31, 2019, the Company determined the value of the contingent consideration receivable using the following valuation approaches:

- Based upon the terms of the Amendments, the fair value of the regulatory milestone was estimated based on the likelihood of achieving this regulatory milestone and applying a discount rate from the expected time the milestone occurs to the balance sheet date. The Company received the first $5.0 million milestone payment in January 2019 and received the second $5.0 million in April 2019. Additionally, the Company expects the regulatory milestone event to occur in the first quarter of 2020 and to receive milestone payments on the subsequent seven anniversary years thereafter. A discount rate of 16.0% was utilized in this analysis;

- The Company is entitled to receive future royalties on net sales of Meloxicam Products. To estimate the fair value of the future royalties, the Company assessed the likelihood of a Meloxicam Product being approved for sale and estimated the expected future sales of such Meloxicam Product assuming approval and IP protection. The Company then discounted these expected payments using a discount rate of 16.0%, which it believes captures a market participant's view of the risk associated with the expected payments; and
- The Company is entitled to receive payments of up to $80.0 million upon achieving certain sales milestones on future sales of the Meloxicam Products. The fair value of the sales milestones was determined through the use of a real options approach, where net sales are simulated in a risk-neutral world. To employ this methodology, the Company used a risk-adjusted expected growth rate based on its assessments of expected growth in net sales of the approved Meloxicam Product, adjusted by an appropriate factor capturing their respective correlation with the market. A resulting expected (probability-weighted) milestone payment was then discounted at a cost of debt, which was 16.0%.

At December 31, 2019 and 2018, the Company determined that the value of the contingent consideration was $32.4 million and $65.2 million, respectively. The Company recorded a decrease of $22.8 million and $19.6 million and an increase of $21.6 million during the years ended December 31, 2019, 2018 and 2017, respectively, within "Change in the fair value of contingent consideration" in the accompanying consolidated statements of operations and comprehensive loss.

In November 2019, Recro completed a spin out of its acute care segment, Baudax Bio, Inc. ("Baudax"), a publicly traded pharmaceutical company. As part of this transaction, Recro's obligations to pay certain of the contingent consideration from the Gainesville Transaction were assigned and/or transferred to Baudax.

In addition to the signing of the Amendments, as described above, on December 20, 2018, the Company and Recro entered into a First Amendment to the Warrant to Purchase Stock (the "Warrant Amendment"), pursuant to which the exercise price of the warrant to purchase 350,000 shares of Recro's common stock, was decreased to a per share exercise price of $8.26 from $19.46, subject to adjustment as set forth therein. In November 2019, the Company elected to convert those warrants into shares and sell those shares. The Company sold the shares for $3.0 million and recorded a realized gain of $0.9 million within "Other (expense) income, net" in the accompanying consolidated statement of operations and comprehensive loss during the year ended December 31, 2019. During the years ended December 31, 2018 and 2017, the Company recorded a decrease of $0.2 million and an increase of less than $0.1 million, respectively, in the fair value of the warrants. These changes were recorded within "Other (expense) income, net" in the accompanying consolidated statements of operations and comprehensive loss.

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

The estimated fair value of the Company's long-term debt under the 2023 Term Loans, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and which may not be representative of actual values that could have been, or will be, realized in the future, was $277.9 million and $274.7 million at December 31, 2019 and 2018, respectively. Please refer to Note 11, *Long-Term Debt* within these "Notes to Consolidated Financial Statements" in this Annual Report.

6. INVENTORY

Inventory consists of the following:

(In thousands)	December 31, 2019	December 31, 2018
Raw materials	$ 34,577	$ 31,824
Work in process	54,061	38,019
Finished goods(1)	13,165	20,353
Total inventory	$ 101,803	$ 90,196

(1) At December 31, 2019 and 2018, the Company had $7.6 million and $11.0 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following:

(In thousands)	December 31, 2019	December 31, 2018
Land	$ 6,560	$ 6,486
Building and improvements	177,087	157,053
Furniture, fixtures and equipment	340,146	314,831
Leasehold improvements	20,737	20,105
Construction in progress	134,683	88,983
Subtotal	679,213	587,458
Less: accumulated depreciation	(317,045)	(277,471)
Total property, plant and equipment, net	$ 362,168	$ 309,987

Depreciation expense was $40.1 million, $38.5 million and $36.5 million for the years ended December 31, 2019, 2018 and 2017, respectively. Also, during the years ended December 31, 2019, 2018 and 2017, the Company wrote off furniture, fixtures and equipment that had a carrying value of approximately $0.9 million, $0.5 million and $0.1 million, respectively, at the time of disposition.

Amounts included as construction in progress in the consolidated balance sheets primarily include capital expenditures at the Company's manufacturing facility in Wilmington, Ohio. The Company continues to evaluate its manufacturing capacity based on expectations of demand for its products and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service. The Company continues to periodically evaluate whether facts and circumstances indicate that the carrying value of its long-lived assets to be held and used may not be recoverable.

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consist of the following:

(In thousands)	Weighted Amortizable Life (Years)	December 31, 2019 Gross Carrying Amount	December 31, 2019 Accumulated Amortization	December 31, 2019 Net Carrying Amount	December 31, 2018 Gross Carrying Amount	December 31, 2018 Accumulated Amortization	December 31, 2018 Net Carrying Amount
Goodwill		$ 92,873	$ —	$ 92,873	$ 92,873	$ —	$ 92,873
Finite-lived intangible assets:							
Collaboration agreements	12	$ 465,590	$ (348,595)	$ 116,995	$ 465,590	$ (319,311)	$ 146,279
NanoCrystal technology	13	74,600	(46,773)	27,827	74,600	(38,942)	35,658
OCR(1) technologies	12	42,560	(36,739)	5,821	42,560	(33,496)	9,064
Total		$ 582,750	$ (432,107)	$ 150,643	$ 582,750	$ (391,749)	$ 191,001

(1) OCR refers to the Company's oral controlled release technologies.

The Company's finite-lived intangible assets consist of collaborative agreements and the NanoCrystal and OCR technologies acquired as part of the EDT acquisition. The Company recorded $40.4 million, $65.2 million and $62.1 million of amortization expense related to its finite-lived intangible assets during the years ended December 31, 2019, 2018 and 2017, respectively. Based on the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheets at December 31, 2019 is expected to be approximately $40.0 million, $40.0 million, $35.0 million, $35.0 million and $1.0 million in the years ending December 31, 2020 through 2024, respectively. Although the Company believes such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future revenues, there is the potential for the Company's actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets will change in proportion to the change in revenues.

The Company performed its annual goodwill impairment test as of October 31, 2019. The Company elected to perform a qualitative assessment to determine whether it was necessary to perform a quantitative impairment test. Based on the weight of all available evidence, the Company determined that the fair value of the reporting unit more-likely-than-not exceeded its carrying value.

9. LEASES

The Company adopted Topic 842 on January 1, 2019. Upon adoption, the Company elected the package of transition practical expedients, which allowed it to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. The Company also elected the practical expedient to not reassess certain land easements and made an accounting policy election to not recognize leases with an initial term of 12 months or less within its consolidated balance sheets and to instead recognize those lease payments on a straight-line basis in its consolidated statements of operations over the lease term.

The Company elected to adopt this standard using the optional modified retrospective transition method with no restatement of its prior periods or cumulative adjustment to retained earnings. With the adoption of Topic 842, the Company's consolidated balance sheet now contains the following line items: Right-of-use assets, Operating lease liabilities—short-term and Operating lease liabilities—long-term.

The Company determined that it held the following significant operating leases of office and laboratory space as of January 1, 2019:

- An operating lease for 175,000 square feet of office and laboratory space in Waltham, Massachusetts that expires in 2021, with an option to extend the term for up to two five year periods, both of which the Company assumed would be exercised in its right-of-use asset and lease liability amounts;
- An operating lease for 67,000 square feet of office space in Waltham, Massachusetts that expires in 2020, with an option to extend the term for up to two one year periods, which the Company did not assume would be exercised in its right-of-use asset and lease liability amounts;
- An operating lease for 14,600 square feet of office space in Dublin, Ireland that expires in 2022, with an option to extend the term for an additional five year period which the Company did not assume would be exercised in its right-of-use asset and lease liability amounts; and
- An operating lease for 7,000 square feet of corporate office and administrative space in Washington, D.C. that expires in 2029 and includes an option to extend the term for an additional five year period which the Company did not assume would be exercised in its right-of-use asset and lease liability amounts.

The Company also has two additional operating leases that are included in its lease accounting but are not considered significant.

As all the existing leases subject to the new lease standard were previously classified as operating leases by the Company, they were similarly classified as operating leases under the new standard. The Company has determined that the identified operating leases did not contain non-lease components and require no further allocation of the total lease cost. Additionally, the agreements in place did not contain information to determine the rate implicit in the leases. As such, the Company calculated the incremental borrowing rate based on the assumed remaining lease term for each lease in order to calculate the present value of the remaining lease payments. At December 31, 2019, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 4.73% and 4.0 years, respectively.

On November 18, 2019, the Company entered into a definitive agreement to acquire Rodin Therapeutics, Inc. ("Rodin"), a privately held biopharmaceutical company focused on developing novel, small molecule therapeutics for synaptopathies. As part of this transaction, the Company assumed an operating lease for 5,300 square feet of office space in Boston, Massachusetts that expires in 2021, with an option to extend the term for an additional year.

As of December 31, 2019, right-of-use assets and liabilities arising from operating leases were $12.4 million and $13.8 million, respectively. During the year ended December 31, 2019, cash paid for amounts included for the measurement of lease liabilities was $9.1 million. The Company recorded operating lease expense of $8.1 million, $10.8 million and $9.4 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Future lease payments under non-cancelable leases as of December 31, 2019 consisted of the following:

(In thousands)	December 31, 2019
2020	$ 9,053
2021	2,727
2022	500
2023	509
2024	520
Thereafter	2,579
Total lease payments	$ 15,888
Less: imputed interest	(2,080)
Total operating lease liabilities	$ 13,808

For comparable purposes, future lease payments under non-cancelable leases as of December 31, 2018 consisted of the following:

(In thousands)	December 31, 2018
2019	$ 9,394
2020	10,717
2021	4,706
2022	2,455
2023	2,389
Thereafter	23,940
Total lease payments	$ 53,601

In March 2018, the Company entered into a lease agreement for approximately 220,000 square feet of office and laboratory space located in a building to be built at 900 Winter Street, Waltham, Massachusetts (“900 Winter Street”). The initial term of the lease commenced on January 20, 2020 (the “Commencement Date”). The initial lease term expires on January 31, 2035, with an option to extend for an additional ten years.

As the Company (a) did not have the right to obtain or control the leased premises during the construction period; (b) did not have the right of payment for the partially constructed assets and, thus, could have been potentially leased to another tenant; and (c) did not legally own or control the land on which the property improvements are being constructed, it was not included as a right-of-use asset at December 31, 2019. Additionally, the future lease payments, outlined above, did not include the 900 Winter Street payments as of December 31, 2019 under Topic 842.

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

(In thousands)	December 31, 2019	December 31, 2018
Accounts payable	$ 54,261	$ 39,767
Accrued compensation	72,072	67,613
Accrued sales discounts, allowances and reserves	153,902	152,911
Accrued other	92,802	73,471
Total accounts payable and accrued expenses	$ 373,037	$ 333,762

11. LONG-TERM DEBT

Long-term debt consists of the following:

(In thousands)	December 31, 2019	December 31, 2018
2023 Term Loans, due March 26, 2023	$ 277,138	$ 279,308
Less: current portion	(2,843)	(2,843)
Long-term debt	$ 274,295	$ 276,465

2023 Term Loans

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

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

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

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

Year Ending December 31:	
2020	$ 2,843
2021	2,843
2022	2,843
2023	270,747
2024	—
Total	$ 279,276

Beginning on January 1, 2014, the Company became subject to mandatory prepayments of principal if certain excess cash flow thresholds, as defined in the 2023 Term Loans, were met. To date, the Company has not been required to make any such mandatory prepayments.

The 2023 Term Loans have an incremental facility capacity in an amount of $175.0 million, plus additional amounts as long as the Company meets certain conditions, including a specified leverage ratio. The 2023 Term Loans include a number of restrictive covenants that, among other things and subject to certain exceptions and baskets, impose operating and financial restrictions on the Company and certain of its subsidiaries. The 2023 Term Loans also contain customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at December 31, 2019.

At December 31, 2019, the Company's balance of unamortized deferred financing costs and unamortized original issue discount costs were $0.6 million and $1.5 million, respectively. These costs are being amortized to interest expense over the estimated repayment period of the 2023 Term Loans using the effective interest method. During the years ended December 31, 2019, 2018 and 2017, the Company had amortization expense of $0.7 million, $0.7 million and $0.8 million, respectively, related to deferred financing costs and original issue discount.

12. LOSS PER SHARE

Basic loss per ordinary share is calculated based upon net loss available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the years ended December 31, 2019, 2018 and 2017, as the Company was in a net loss position, the diluted loss per share did not assume conversion or exercise of stock options and awards as they would have an anti-dilutive effect on loss per share.

The following potential ordinary equivalent shares were not included in the net loss per ordinary share calculation because the effect would have been anti-dilutive:

	Year Ended December 31,		
(In thousands)	2019	2018	2017
Stock options	13,814	11,331	9,540
Restricted stock units	3,177	2,592	2,119
Total	16,991	13,923	11,659

13. SHAREHOLDERS' EQUITY

Share Repurchase Program

On September 16, 2011, the board of directors authorized the continuation of the Alkermes, Inc. share repurchase program to repurchase up to $215.0 million of the Company's ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. At December 31, 2019, approximately $101.0 million was available to repurchase ordinary shares pursuant to the repurchase program. All shares repurchased are recorded as treasury stock. The repurchase program has no set expiration date and may be suspended or discontinued at any time. During the years ended December 31, 2019 and 2018, the Company did not acquire any ordinary shares under the repurchase program.

14. SHARE-BASED COMPENSATION

Share-Based Compensation Expense

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

	Year Ended December 31,		
(In thousands)	2019	2018	2017
Cost of goods manufactured and sold	$ 9,948	$ 9,174	$ 7,596
Research and development	29,924	32,943	22,635
Selling, general and administrative	61,105	63,240	53,686
Total share-based compensation expense	$ 100,977	$ 105,357	$ 83,917

During the years ended December 31, 2019, 2018 and 2017, $1.5 million, $2.7 million and $0.4 million, respectively, of share-based compensation expense was capitalized and recorded as "Inventory" in the accompanying consolidated balance sheets.

Share-Based Compensation Plans

The Company has two share-based compensation plan pursuant to which awards are currently being made: the 2011 Stock Option and Incentive Plan, as amended (the "2011 Plan") and the 2018 Stock Option and Incentive Plan, as amended (the "2018 Plan"). The Company has one share-based compensation plan pursuant to which outstanding awards have been made, but from which no further awards can or will be made: the 2008 Stock Option and Incentive Plan, as amended. The 2018 Plan and the 2011 Plan allow for the issuance of non-qualified and incentive stock options, restricted stock, restricted stock units, cash-based awards and performance shares to employees, officers and directors of, and consultants to, the Company in such amounts and with such terms and conditions as may be determined by the compensation committee of the Company's board of directors, subject to the provisions of the 2018 Plan and the 2011 Plan, as applicable.

At December 31, 2019, there were 10.6 million ordinary shares available for issuance in the aggregate under the Company's stock plans. The 2018 Plan and the 2011 Plan each provide that awards other than stock options will be counted against the total number of shares available under the plan in a 1.8-to-1 ratio.

Stock Options

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

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 2019	14,852,457	$ 40.48
Granted	3,812,103	$ 31.49
Exercised	(1,515,957)	$ 12.55
Expired	(1,104,967)	$ 48.42
Forfeited	(807,791)	$ 42.32
Outstanding, December 31, 2019	15,235,845	$ 40.34
Exercisable, December 31, 2019	9,874,065	$ 39.15

The weighted average grant date fair value of stock options granted during the years ended December 31, 2019, 2018 and 2017 was $15.57, $30.47 and $25.81, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2019, 2018 and 2017 was $21.3 million, $35.5 million and $40.4 million, respectively.

At December 31, 2019, there were 5.2 million stock options expected to vest with a weighted average exercise price of $42.64 per share, a weighted average contractual remaining life of 8.5 years with an aggregate intrinsic value of less than $0.1 million. At December 31, 2019, the aggregate intrinsic value of stock options exercisable was $12.9 million with a weighted average remaining contractual term of 4.5 years. The number of stock options expected to vest was determined by applying the pre-vesting forfeiture rate to the total outstanding options. The intrinsic value of a stock option is the amount by which the market value of the underlying stock exceeds the exercise price of the stock option.

At December 31, 2019, there was $48.0 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of 1.9 years. Cash received from option exercises under the Company's award plans during the years ended December 31, 2019, 2018 and 2017 was $18.9 million, $20.9 million and $23.5 million, respectively.

Time-Vested Restricted Stock Units

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

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, January 1, 2019	2,266,286	$ 55.32
Granted	2,826,092	$ 30.47
Vested	(791,484)	$ 53.62
Forfeited	(556,094)	$ 41.44
Unvested, December 31, 2019	3,744,800	$ 38.99

The weighted average grant date fair value of time-vested RSUs granted during the years ended December 31, 2019, 2018 and 2017 were $30.47, $63.01 and $54.85, respectively. The total fair value of time-vested RSUs that vested during the years ended December 31, 2019, 2018 and 2017, was $42.4 million, $34.5 million and $31.5 million, respectively.

At December 31, 2019, there was $66.6 million of total unrecognized compensation cost related to unvested time-vested RSUs, which will be recognized over a weighted average remaining contractual term of 1.9 years.

Performance-Based Restricted Stock Units

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

A summary of performance-based RSU activity is presented in the following table:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, January 1, 2019	626,168	$ 54.75
Granted	—	$ —
Forfeited	(81,000)	$ 54.77
Vested	(1,614)	$ 48.48
Unvested, December 31, 2019	543,554	$ 54.75

The grant date fair value of the performance-based RSUs was equal to the closing price of the Company's stock on the Nasdaq Global Select Market on the date of grant.

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

In the first quarter of 2020, the compensation committee of the Company's board of directors will meet to determine whether the two remaining performance criteria were achieved. At December 31, 2019, the Company does not consider it probable that the performance criteria will be met on these remaining performance obligations and has not recognized any additional share-based compensation expense related to these performance-based RSUs. At December 31, 2019, there was $29.8 million of unrecognized compensation cost related to the remaining unvested portion of the performance-based RSUs, which would be recognized in accordance with the terms of the award should the Company deem that the performance criteria were met. The unvested awards will expire if it is determined that the performance conditions were not met on or before the three year anniversary of the grant date.

15. RESTRUCTURING

On October 18, 2019, the Company approved a restructuring plan following a review of its operations, cost structure and growth opportunities (the "Restructuring"). The Restructuring included a reduction in headcount of approximately 160 employees across the Company. The Company recorded a charge of $13.4 million in the fourth quarter of 2019 as a result of the Restructuring, which consisted of one-time termination benefits for employee severance, benefits and related costs, all of which are expected to result in cash expenditures and substantially all of which will be paid out over the next 12 months. Restructuring activity during the year ended December 31, 2019 was as follows:

(In thousands)	
Balance, January 1, 2019	$ —
Restructuring charge	13,401
Amounts paid during the period:	
Severance	(3,621)
Outplacement services	(398)
Benefits	(181)
Balance, December 31, 2019	$ 9,201

At December 31, 2019, $9.0 million and $0.2 million of the restructuring accrual were included within "Accounts payable and accrued expenses" and "Other long-term liabilities" in the accompanying consolidated balance sheets, respectively.

16. ACQUISITION

On November 18, 2019, the Company entered into a definitive agreement to acquire Rodin, a privately held biopharmaceutical company focused on developing novel, small molecule therapeutics for synaptopathies. The acquisition was completed on November 25, 2019 and, under the terms of the agreement, the Company made an upfront cash payment of $98.1 million to Rodin's security holders and may make up to $850.0 million in future payments, $225.0 million of which are triggered upon achievement by the development candidates acquired in the acquisition of Rodin of certain specified clinical milestones, $300.0 million of which are triggered by the development candidates acquired in the acquisition of Rodin of certain regulatory milestones and $325.0 million of which are triggered upon the attainment of certain sales thresholds.

The Company accounted for the transaction, as an asset acquisition as substantially all of the fair value of Rodin's gross assets acquired were concentrated in its in-process research and development ("IPR&D"), which is largely in the pre-clinical stage. As the IPR&D was determined to not have an alternative future use, the Company recorded a charge to R&D expense in the accompanying consolidated statements of operations and comprehensive loss of $86.6 million, which was the amount determined to be the relative fair value of the $98.1 million payment attributed to the acquired IPR&D. The Company has not recorded any of the $850.0 million in contingent consideration as a liability in the accompanying consolidated balance sheet as none of the future events which would trigger a milestone payment are considered probable of occurring at December 31, 2019.

The following were the amounts allocated to the assets acquired, liabilities assumed and amounts expensed at the acquisition date based on their respective fair values:

(In thousands)	
Cash	2,658
Prepaid expenses and other current assets	461
Deferred tax assets	11,642
Right-of-use assets	637
Other assets	137
Accounts payable and accrued expenses	(3,364)
Operating lease liabilities—short-term	(400)
Operating lease liabilities—long-term	(237)
Research and development expense	86,594

17. COLLABORATIVE ARRANGEMENTS

The Company has entered into several collaborative arrangements to develop and commercialize products and, in connection with such arrangements, to access technologies, financial, marketing, manufacturing and other resources. Refer to the "Patents and Proprietary Rights" section in "Item 1— Business" of this Annual Report for information with respect to IP protection for these products. The collaboration revenue the Company has earned in the years ended December 31, 2019, 2018 and 2017 is summarized in Note 3, *Revenue from Contracts with Customers* within the notes to the consolidated financial statements in this Annual Report.

The Company's significant collaborative arrangements are described below:

Janssen

INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA

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

Under this license agreement, the Company received milestone payments upon the achievement of certain development goals from Janssen; there are no further milestones to be earned under this agreement. The Company receives tiered royalty payments between 5% and 9% of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA end-market net sales in each country where the license is in effect, with the exact royalty percentage determined based on aggregate worldwide net sales. The tiered royalty payments consist of a patent royalty and a know-how royalty, both of which are determined on a country-by-country basis. The patent royalty, which equals 1.5% of net sales, is payable in each country until the expiration of the last of the patents claiming the product in such country. The know-how royalty is a tiered royalty of 3.5%, 5.5% and 7.5% on aggregate worldwide net sales of below $250 million, between $250 million and $500 million, and greater than $500 million, respectively. The know-how royalty rate resets to 3.5% at the beginning of each calendar year and is payable until 15 years from first commercial sale of a product, subject 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 expiration of the last of the patents subject to the agreement. After expiration, Janssen retains a non-exclusive, royalty-free license to develop, manufacture and commercialize the products.

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

RISPERDAL CONSTA

Under a product development agreement, the Company collaborated with Janssen on the development of RISPERDAL CONSTA. Under the development agreement, Janssen provided funding to the Company for the development of RISPERDAL CONSTA and Janssen is responsible for securing all necessary regulatory approvals for the product.

Under two license agreements, the Company granted Janssen and an affiliate of Janssen exclusive worldwide licenses to use and sell RISPERDAL CONSTA. Under its license agreements with Janssen, the Company receives royalty payments equal to 2.5% of Janssen's end-market net sales of RISPERDAL CONSTA in each country where the license is in effect based on the quarter when the product is sold by Janssen. This royalty may be reduced in any country based on lack of patent coverage and significant competition from generic versions of the product. Janssen can terminate the license agreements upon 30 days' prior written notice to the Company. Either party may terminate the license agreements by written notice following a breach which continues for 90 days after the delivery of written notice thereof or upon the other party's insolvency. The licenses granted to Janssen expire on a country-by-country basis upon the later of: (i) the expiration of the last patent claiming the product in such country; or (ii) 15 years after the date of the first commercial sale of the product in such country, provided that in no event will the license granted to Janssen expire later than the twentieth anniversary of the first commercial sale of the product in each such country, with the exception of Canada, France, Germany, Italy, Japan, Spain and the United Kingdom, in each case where the fifteen-year minimum shall pertain regardless. After expiration, Janssen retains a non-exclusive, royalty-free license to manufacture, use and sell RISPERDAL CONSTA.

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

Biogen

Under a license and collaboration agreement with Biogen, which the Company entered into in November 2017 and amended in October 2018, January 2019 and October 2019, the Company granted Biogen a worldwide, exclusive, sublicensable license to develop, manufacture and commercialize VUMERITY and other products covered by patents licensed to Biogen under the agreement.

Under this license and collaboration agreement, the Company received an upfront cash payment of $28.0 million in November 2017, and milestone payments of $50.0 million, $150.0 million and $5.0 million in June 2018, November 2019 and December 2019, respectively, upon the achievement of certain developmental milestones, including FDA approval of the NDA for VUMERITY in October 2019, and amendment of the license and collaboration agreement in October 2019. The Company is also eligible to receive additional payments upon achievement of milestones with respect to the first two products, other than VUMERITY, covered by patents licensed to Biogen under the license and collaboration agreement.

In addition, the Company receives a 15% royalty on worldwide net sales of VUMERITY, subject to, under certain circumstances, minimum annual payments for the first five years following FDA approval of VUMERITY. The Company is also entitled to receive royalties on net sales of products other than VUMERITY covered by patents licensed to Biogen under the license and collaboration agreement, at tiered royalty rates calculated as percentages of net sales ranging from high-single digits to sub-teen double digits. All royalties are payable on a product-by-product and country-by-country basis until the later of (i) the last-to-expire patent right covering the applicable product in the applicable country and (ii) a specified period of time from the first commercial sale of the applicable product in the applicable country. Royalties for all products and the minimum annual payments for VUMERITY are subject to customary reductions, as set forth in the license and collaboration agreement.

Except in limited circumstances, we were responsible for the development of VUMERITY until it was approved by the FDA. Following FDA approval of VUMERITY in October 2019 and except for the manufacturing responsibilities discussed below, Biogen is now responsible for all development and commercialization activities for VUMERITY and all other products covered by patents licensed to Biogen.

Under the license and collaboration agreement, Biogen appointed the Company as the toll manufacturer of clinical and commercial supplies of VUMERITY, subject to Biogen's right to manufacture or have manufactured commercial supplies as a back-up manufacturer and subject to good faith agreement by the parties on the terms of such manufacturing arrangements. In October 2019, the Company entered into a commercial supply agreement with Biogen for the commercial supply of VUMERITY, an amendment to such commercial supply agreement and an amendment to the November 2017 license and collaboration agreement with Biogen. Under these agreements, Biogen has an option to assume responsibility, subject to a transition period, for the manufacture (itself or through a designee) of clinical supplies of VUMERITY and up to 100% of commercial supplies of VUMERITY in exchange for an increase in the royalty rate to be paid by Biogen to the Company on net sales of product that is manufactured by Biogen or its designee.

If VUMERITY discontinuations due to gastrointestinal adverse events in VUMERITY's long-term safety clinical trial exceed a certain pre-defined threshold, then "GI Inferiority" shall be deemed to exist, and (i) Biogen shall have the right to recapture from the Company its $50.0 million option payment through certain temporary reductions in royalty rates, and (ii) the minimum annual payments Biogen owes to the Company shall terminate.

Unless earlier terminated, the license and collaboration agreement will remain in effect until the expiry of all royalty obligations. Biogen has the right to terminate the license and collaboration agreement at will, on a product-by-product basis or in its entirety upon 180 days' prior notice to the Company. Either party has the right to terminate the license and collaboration agreement following any governmental prohibition of the transactions effected by the agreement, or in connection with an insolvency event involving the other party. Upon termination of the license and collaboration agreement by either party, then, at the Company's request, the VUMERITY program will revert to the Company.

Acorda

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

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

Acorda has the right to terminate the amended and restated license agreement upon 90 days' written notice. The Company has the right to terminate the amended and restated license agreement for countries in which Acorda fails to launch a product within a specified time after obtaining the necessary regulatory approval or fails to file regulatory approvals within a commercially reasonable time after completion of and receipt of positive data from all pre-clinical and clinical studies required for filing a marketing authorization application. Either party has the right to terminate the amended and restated license agreement by written notice following a material breach of the other party, which is not cured within a certain time period, or upon the other party's entry into

bankruptcy or dissolution proceedings. If the Company terminates Acorda's license in any country, the Company is entitled to a license from Acorda of its patent rights and know-how relating to the product as well as the related data, information and regulatory files, and to market the product in the applicable country, subject to an initial payment equal to Acorda's cost of developing such data, information and regulatory files and to ongoing royalty payments to Acorda. Subject to the termination of the amended and restated license agreement, licenses granted under the license agreement terminate on a country-by-country basis upon the expiration of the last to expire of our patents or the existence of a threshold level of competition in the marketplace.

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

The Company is entitled to receive the following milestone payments under its amended and restated license agreement with Acorda for each of the third and fourth new indications of the product developed thereunder:

- initiation of a phase 3 clinical trial: $1.0 million;
- acceptance of 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.

18. INCOME TAXES

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

(In thousands)	Year Ended December 31, 2019	2018	2017
Current income tax (benefit) provision:			
U.S. federal	$ (471)	$ (53)	$ 6,964
U.S. state	354	1,774	350
Rest of world	—	—	123
Deferred income tax (benefit) provision:			
U.S. federal	(1,503)	10,624	8,188
U.S. state	881	62	(933)
Ireland	303	(63)	(21)
Total tax (benefit) provision	$ (436)	$ 12,344	$ 14,671

The income tax benefit in 2019 and the income tax provision in 2018 and 2017 were primarily due to U.S. federal and state taxes. The favorable change in income taxes in 2019, as compared to 2018, was primarily due the foreign derived intangible income proposed regulations issued by the U.S. Department of the Treasury and the U.S. Internal Revenue Service ("IRS") in March 2019. The favorable change in income taxes in 2018, as compared to 2017, was due to the one-off nature of a $21.5 million tax expense in 2017 from the enactment of the Tax Cuts and Jobs Act, partially offset by increased taxes on income earned in the U.S.

No provision for income tax has been provided on undistributed earnings of the Company's foreign subsidiaries because such earnings are indefinitely reinvested in the foreign operations or may be repatriated to Ireland without incurring any tax liability. Cumulative unremitted earnings of overseas subsidiaries totaled approximately $418.1 million at December 31, 2019. In the event of a repatriation of those earnings in the form of dividends or otherwise, the Company may be liable for income taxes, subject to adjustment, if any, for foreign tax credits and foreign withholding taxes payable to foreign tax authorities. The Company estimates that approximately $12.9 million of income taxes would be payable on the repatriation of the unremitted earnings to Ireland.

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

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

(In thousands)	Year Ended December 31, 2019	2018	2017
Ireland	$ (141,869)	$ (180,195)	$ (172,363)
U.S.	(55,102)	53,287	2,414
Rest of world	(85)	(59)	26,675
Loss before (benefit) provision for income taxes	$ (197,056)	$ (126,967)	$ (143,274)

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

(In thousands)	December 31, 2019	December 31, 2018
Deferred tax assets:		
NOL carryforwards	$ 227,872	$ 198,633
Tax credits	57,385	52,395
Share-based compensation	45,214	44,873
Accrued expenses and reserves	20,337	15,892
Other	8,756	8,669
Less: valuation allowance	(242,059)	(219,093)
Total deferred tax assets	117,505	101,369
Deferred tax liabilities:		
Intangible assets	—	—
Property, plant and equipment	(19,926)	(14,533)
Other	(1,590)	(1,274)
Total deferred tax liabilities	(21,516)	(15,807)
Net deferred tax assets	$ 95,989	$ 85,562

In February 2016 the FASB issued Topic 842, *Leases*, which includes the requirement for lessees to record a right-of-use asset and lease liability for virtually all leases. In addition, lessees are required to record deferred taxes resulting from any book versus tax basis differences upon the adoption of the standard. On January 1, 2019, the Company adopted this standard and recorded a cumulative-effect adjustment of $4.3 million to deferred tax asset in respect of the accrued lease liability and a $4.3 million deferred tax liability in respect of the right to use asset. There was no net impact to the income statement or to equity as a result of the adoption.

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

(In thousands)	Balance at Beginning of Period	Additions (1)	Balance at End of Period
Deferred tax asset valuation allowance for the year ended December 31, 2017	$ (141,859)	$ (30,938)	$ (172,797)
Deferred tax asset valuation allowance for the year ended December 31, 2018	$ (172,797)	$ (46,296)	$ (219,093)
Deferred tax asset valuation allowance for the year ended December 31, 2019	$ (219,093)	$ (22,966)	$ (242,059)

(1) The additions in each of the periods presented relate primarily to Irish NOLs. Additionally, in 2019 the Company's valuation allowance was increased by $3.0 million as a result of the attributes acquired as part of the acquisition of Rodin.

At December 31, 2019, the Company maintained a valuation allowance of $17.3 million against certain U.S. state deferred tax assets and $224.8 million against certain Irish deferred tax assets as the Company has determined that it is more-likely-than-not that these net deferred tax assets will not be realized. If the Company demonstrates consistent profitability in the future, the evaluation of the recoverability of these deferred tax assets could change and the remaining valuation allowances could be released in part or in whole. If the Company incurs losses in the U.S. in the future, or experiences significant excess tax benefits arising from the future exercise of stock options and/or the vesting of RSUs, the evaluation of the recoverability of the U.S. deferred tax assets could change and a valuation allowance against the U.S. deferred tax assets may be required in part or in whole.

As of December 31, 2019, the Company had $1.5 billion of Irish NOL carryforwards, $49.5 million of U.S. federal NOL carryforwards, $44.5 million of state NOL carryforwards, $49.6 million of federal R&D credits and $18.0 million of state tax credits which will either expire on various dates through 2039 or can be carried forward indefinitely. These loss and credit carryforwards are available to reduce certain future Irish and foreign taxable income and tax. These loss and credit carryforwards are subject to review

and possible adjustment by the appropriate taxing authorities. These loss and credit carryforwards, which may be utilized in a future period, may be subject to limitations based upon changes in the ownership of the Company's ordinary shares.

As a result of the acquisition of Rodin, the Company acquired $51.4 million of U.S. federal NOL carryforwards, $43.3 million of state NOL carryforwards, $0.8 million of U.S. federal R&D credit carryforwards and $0.4 million of state R&D credit carryforwards. These attributes are subject to multiple limitations based upon prior changes in the ownership of the ordinary shares of Rodin.

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

(In thousands, except percentage amounts)	Year Ended December 31, 2019	2018	2017
Statutory tax rate	12.5 %	12.5 %	12.5 %
Income tax provision at statutory rate	$ (24,632)	$ (15,871)	$ (17,909)
Change in valuation allowance	19,882	28,371	26,771
In-process R&D(1)	10,824	—	—
Share-based compensation	6,287	1,163	(1,205)
Foreign rate differential(2)	5,390	5,405	(682)
U.S. state income taxes, net of U.S. federal benefit	1,051	1,732	(558)
Foreign derived intangible income	(3,450)	—	—
Intercompany amounts(3)	(1,125)	(751)	(5,041)
R&D credit	(8,846)	(7,698)	(9,326)
Federal tax law change(4)	(8,111)	—	21,453
Irish rate differential(5)	(146)	(2,350)	(2,675)
Impairment on equity method investment	—	—	1,662
Other permanent items(6)	2,440	2,343	2,181
Income tax (benefit) provision	$ (436)	$ 12,344	$ 14,671
Effective tax rate	0.2 %	(9.7) %	(10.2) %

(1) Represents the tax effect of the research and development expense recorded on the acquisition of Rodin.
(2) Represents income or losses of non-Irish subsidiaries, including U.S. subsidiaries, subject to tax at a rate other than the Irish statutory rate.
(3) Intercompany amounts include cross-territory eliminations, the pre-tax effect of which has been eliminated in arriving at the Company's consolidated loss before taxes.
(4) During the year ended December 31, 2019, federal tax law change represents federal income tax benefit related to the foreign derived intangible income deductions for 2018 following the publications by the IRS and the Department of Treasury of proposed regulations in March 2019. During the year ended December 31, 2017, federal tax law change resulted in a $21.5 million deferred tax expense related to the reduction in the U.S. federal tax rate from 35% to 21%.
(5) Represents income or losses of Irish companies subject to tax at a rate other than the Irish statutory rate.
(6) Other permanent items include, but are not limited to, non-deductible meals and entertainment expenses, non-deductible lobbying expenses, the impact of the tax treatment of the FDA branded prescription drug fee and non-deductible compensation of senior officers of the Company.

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

(In thousands)	Unrecognized Tax Benefits
Balance, December 31, 2016	$ 4,688
Reductions based on tax positions related to prior periods	(47)
Additions based on tax positions related to the current period	877
Balance, December 31, 2017	$ 5,518
Additions based on tax positions related to prior periods	4
Additions based on tax positions related to the current period	559
Balance, December 31, 2018	$ 6,081
Additions based on tax positions related to prior periods	38
Additions based on tax positions related to the current period	738
Balance, December 31, 2019	$ 6,857

The unrecognized tax benefits at December 31, 2019, if recognized, would affect the Company's effective tax rate. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. The Company has elected to include interest and penalties related to uncertain tax positions as a component of its provision for taxes. For the years ended December 31, 2019, 2018 and 2017, the Company's accrued interest and penalties related to uncertain tax positions were not material.

The Company's major taxing jurisdictions include Ireland and the U.S. (federal and state). These jurisdictions have varying statutes of limitations. In the U.S., the 2016 through 2019 fiscal years remain subject to examination by the respective tax authorities. In Ireland, the years 2015 to 2019 remain subject to examination by the Irish tax authorities. Additionally, because of the Company's Irish and U.S. loss carryforwards and credit carryforwards, certain tax returns from fiscal years 1999 onward may also be examined. These years generally remain open for three to four years after the loss carryforwards and credit carryforwards have been utilized.

The years ended December 31, 2018 and 2017 for Alkermes U.S. Holdings, Inc. are currently under examination by the State of California. The years ended December 31, 2015 and 2014 for Alkermes U.S. Holdings, Inc. are currently under examination by the State of Illinois. There are no uncertain tax positions or adjustments associated with the audits at this time.

19. COMMITMENTS AND CONTINGENT LIABILITIES

Litigation

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. On a quarterly basis, the Company reviews the status of each significant matter and assesses its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, the Company would accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on the Company's best estimates based on available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, the Company may reassess the potential liability related to these matters and may revise these estimates, which could result in material adverse adjustments to the Company's operating results. At December 31, 2019, there were no potential material losses from claims, asserted or unasserted, or legal proceedings that the Company determined were probable of occurring.

INVEGA SUSTENNA ANDA Litigation

In January 2018 and in August 2019, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated patent infringement lawsuits in the United States District Court for the District of New Jersey against Teva entities (Teva Pharmaceuticals USA, Inc.("Teva") and Teva Pharmaceuticals Industries, Ltd. ("Teva PI")) and Mylan entities (Mylan Laboratories Limited ("Mylan Labs"), Mylan Pharmaceuticals Inc. ("Mylan"), and Mylan Institutional LLC), respectively, following filings by each of Teva and Mylan Labs of an abbreviated new drug application ("ANDA") seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of U.S. Patent No. 9,439,906. Requested judicial remedies in each of the lawsuits included recovery of litigation costs and injunctive relief. The Company is not a party to either of these proceedings.

For information about risks relating to the INVEGA SUSTENNA Paragraph IV litigation, see "Item 1A—Risk Factors" in this Annual Report and specifically the section entitled "—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers."

AMPYRA ANDA Litigation

Eleven separate Paragraph IV Certification Notices had been received by the Company and/or its partner Acorda from: Accord Healthcare, Inc. ("Accord"); Actavis Laboratories FL, Inc. ("Actavis"); Alkem Laboratories Ltd. ("Alkem"); Apotex Corporation and Apotex, Inc. (collectively, "Apotex"); Aurobindo Pharma Ltd. ("Aurobindo"); MicroLabs Limited ("MicroLabs"); Mylan; Par Pharmaceutical, Inc. ("Par"); Roxane Laboratories, Inc. ("Roxane"); Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. (collectively, "Sun"); and Teva (collectively with Accord, Actavis, Alkem, Apotex, Aurobindo, MicroLabs, Mylan, Par, Roxane and Sun, the "ANDA Filers") advising that each of the ANDA Filers had submitted an ANDA to the FDA seeking marketing approval for generic versions of AMPYRA (dalfampridine) Extended-Release Tablets, 10 mg. The ANDA Filers challenged the validity of one or more of the Orange Book-listed patents for AMPYRA, and they also asserted that their generic versions do not infringe certain claims of these patents. In response, the Company and/or Acorda filed lawsuits against the ANDA Filers asserting infringement of one or more of the Orange Book-listed patents for AMPYRA. Requested judicial remedies included recovery of litigation costs and injunctive relief.

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

The Company and/or Acorda entered into a settlement agreement with each of Accord, Actavis, Alkem, Apotex, Aurobindo, MicroLabs, Par and Sun to resolve the patent litigation that the Company and/or Acorda brought against these settling ANDA Filers. The settlements with these settling ANDA Filers did not impact the patent litigation that the Company and Acorda brought against the remaining ANDA Filers, including as described below.

In March 2017, after a bench trial, the U.S. District Court for the District of Delaware (the "Delaware Court") issued an opinion (the "Delaware Court Decision"), which, among other things, invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. The Delaware Court also upheld the validity of the U.S. Patent No. 5,540,938, which pertained to the formulation of AMPYRA, but that patent expired on July 30, 2018. In May 2017, Acorda filed an appeal with the Federal Circuit of the Delaware Court Decision with respect to the findings on U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. On September 10, 2018, the Federal Circuit affirmed the Delaware Court Decision, which invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. In October 2018, Acorda filed a petition for rehearing and rehearing en banc of the Federal Circuit's decision. In January 2019, the Federal Circuit denied Acorda's petition. In April 2019, Acorda filed a petition for writ of certiorari to the Supreme Court of the United States (the "Supreme Court"). On October 7, 2019, the Supreme Court denied Acorda's petition requesting review of the case, rendering the Federal Circuit decision as final.

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

RISPERDAL CONSTA European Opposition Proceedings

In December 2016, Nanjing Luye Pharmaceutical Co., Ltd., Pharmathen SA, Teva PI and Dehns Ltd (a law firm representing an unidentified opponent) filed notices of opposition with the European Patent Office (the "EPO") in respect of EP 2 269 577 B (the "EP '577" Patent), which is a patent directed to certain risperidone microsphere compositions, including RISPERDAL CONSTA. Following a hearing on the matter in January 2019, the EPO issued a written decision revoking the EP'577 Patent in April 2019. The Company filed a notice of appeal of the decision to the EPO's Technical Boards of Appeal in June 2019. Pharmathen SA submitted a reply on November 5, 2019. The Company will continue to vigorously defend the EP '577 Patent. For information about risks relating to the EP '577 Patent opposition proceedings see "Item 1A—Risk Factors" in this Annual Report, including the sections entitled "—Patent protection for our products is important and uncertain" and "—Uncertainty over intellectual property in the biopharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable, could significantly delay or prevent approval or commercialization of our products, and could adversely affect our business."

RISPERDAL CONSTA ANDA Litigation

On July 17, 2019, the Company, together with Janssen Pharmaceuticals, Inc., initiated a patent infringement lawsuit in the United States District Court for the District of Delaware (the "Delaware District Court") against Luye Pharma Group Ltd., Luye Pharma (USA) Ltd., Nanjing Luye Pharmaceutical Co., Ltd. and Shandong Luye Pharmaceutical Co., Ltd. (collectively, "Luye"). Luye filed a 505(b)(2) NDA seeking approval to market a competing product to RISPERDAL CONSTA before the expiration of U.S. Patent No. 6,667,061. Requested judicial remedies included, among other things, recovery of litigation costs and injunctive relief. On July 23, 2019, Luye filed its answer and affirmative defenses. On November 22, 2019, the parties submitted a stipulation and order of dismissal to the Delaware District Court stating that the parties had resolved the litigation. On December 2, 2019, the Delaware District Court signed the stipulation and order of dismissal terminating the lawsuit.

Government Matters

On June 22, 2017 and January 17, 2019, the Company received a subpoena and a civil investigative demand, respectively, each from an Office of the U.S. Attorney for documents related to VIVITROL. The Company is cooperating with the government.

Securities Litigation

In December 2018 and January 2019, purported stockholders of the Company filed putative class actions against the Company and certain of its officers in the United States District Court for the Eastern District of New York (the "EDNY District Court") captioned *Karimian v. Alkermes plc, et al., No. 1:18-cv-07410* and *McDermott v. Alkermes plc, et al., No. 1:19-cv-00624*, respectively. In March 2019, the EDNY District Court consolidated the two cases and appointed a lead plaintiff. The plaintiff filed an amended complaint on July 9, 2019 naming one additional officer of the Company and one former officer of the Company as defendants. The amended complaint was filed on behalf of a putative class of purchasers of Alkermes securities during the period of July 31, 2014 through November 1, 2018 and alleges violations of Sections 10(b) and 20(a) of the Exchange Act based on allegedly false or misleading statements and omissions regarding the Company's clinical methodologies and regulatory submission for ALKS 5461 and the FDA's review and consideration of that submission. The lawsuit seeks, among other things, unspecified money damages, prejudgment and postjudgment interest, reasonable attorneys' fees, expert fees and other costs. In August 2019, the defendants filed a pre-motion letter (in respect of a requested motion to dismiss filing) with the EDNY District Court and plaintiff filed a response. On November 27, 2019, the defendants served the plaintiff with a motion to dismiss, and on December 27, 2019, the plaintiff served the defendants with its opposition to such motion. On January 17, 2020, the defendants filed the fully-briefed motion, including a reply to the plaintiff's opposition, with the EDNY District Court. For information about risks relating to this action, see "Item 1A—Risk Factors" in the Annual Report, including the section entitled "—Litigation or arbitration against Alkermes, including securities litigation, or citizen petitions filed with the FDA, may result in financial losses, harm our reputation, divert management resources, negatively impact the approval of our products, or otherwise negatively impact our business."

Purchase Commitments

The Company has open purchase orders for materials, supplies, services and property, plant and equipment as part of the normal course of business. At December 31, 2019, the Company had open purchase orders totaling $395.3 million and $33.5 million for non-capital and capital commitments, respectively.

DESCRIPTION OF ALKERMES PLC ORDINARY SHARES

The following is a summary description of the ordinary shares of Alkermes plc. This summary does not purport to be complete and is qualified in its entirety by reference to the Irish Companies Act 2014 (the "Companies Act") and the complete text of our memorandum and articles of association, as they may be amended from time to time (together, the "Constitution"). A copy of the Constitution has been filed with the Securities and Exchange Commission (the "SEC") as exhibit 3.1 to the Annual Report on Form 10-K of which this Exhibit 4.1 is a part. You should read the Companies Act and our Constitution carefully. Use of terms such as "us," "we," "our," "Alkermes" or the "Company" in this Exhibit 4.1 is meant to refer to Alkermes plc.

Capital Structure

Authorized Share Capital

Our authorized share capital is €40,000 and $5,000,000, which is divided into 40,000 ordinary shares with a nominal value of €1.00 each, 450,000,000 ordinary shares with a nominal value of $0.01 each and 50,000,000 undesignated preferred shares with a nominal value of $0.01 each. Our ordinary shares are registered under Section 12(b) of the Securities Exchange Act of 1934, as amended.

We may issue shares subject to the maximum authorized share capital contained in our Constitution. Our authorized share capital may be increased or reduced by a resolution approved by a simple majority of the votes of the Company's shareholders cast at a general meeting (referred to under Irish law as an "ordinary resolution"). As a matter of Irish law, the board of directors of a company may issue new ordinary or preferred shares without shareholder approval once authorized to do so by the constitution or by an ordinary resolution adopted by the shareholders at a general meeting. The authorization may be granted for a maximum period of five years, after which it must be renewed by the shareholders by an ordinary resolution. Our current authorization extends until May 2022.

The rights and restrictions applicable to our ordinary shares are prescribed in our Constitution. Our Constitution permits the board of directors of the Company (the "Board"), without shareholder approval, to determine the terms of the preferred shares issued by us. Our Board is authorized, without obtaining any vote or consent of the holders of any class or series of shares, unless expressly provided by the terms of that class or series of shares, to provide from time to time for the issuance of other classes or series of preferred shares and to establish the characteristics of each class or series, including the number of shares, designations, relative voting rights, dividend rights, liquidation and other rights, redemption, repurchase or exchange rights and any other preferences and relative, participating, optional or other rights and limitations not inconsistent with applicable law.

Irish law does not recognize fractional shares held of record. Accordingly, our Constitution does not provide for the issuance of fractional shares, and our official Irish register of members will not reflect any fractional shares.

Preemption Rights, Share Warrants and Share Options

Under Irish law, certain statutory preemption rights apply automatically in favor of shareholders where shares are to be issued for cash. We have opted out of these preemption rights in our Constitution as permitted under Irish law. However, Irish law requires this opt-out to be renewed at least every five years by a resolution approved by not less than 75% of the votes of our shareholders cast at a general meeting (referred to under Irish law as a "special resolution"). If the opt-out is not renewed, shares issued

for cash must be offered to our existing shareholders on a pro rata basis to their existing shareholding before the shares can be issued to any new shareholders. Our current authorization extends until May 2022. The statutory preemption rights do not apply where shares are issued for non-cash consideration (such as in a stock-for-stock acquisition) and do not apply to the issue of non-equity shares (that is, shares that have the right to participate only up to a specified amount in any income or capital distribution) or where shares are issued pursuant to an employee stock option or similar equity plan.

Our Constitution provides that, subject to any shareholder approval requirement under any laws, regulations or the rules of any stock exchange to which we are subject, the Board is authorized, from time to time, in its discretion, to grant such persons, for such periods and upon such terms as the Board deems advisable, options to purchase such number of shares of any class or classes or of any series of any class as the Board may deem advisable, and to cause warrants or other appropriate instruments evidencing such options to be issued. The Companies Act provides that a board of directors may issue share warrants or options without shareholder approval once authorized to do so by its constitution or an ordinary resolution of shareholders. We are subject to the applicable rules and regulations of The Nasdaq Stock Market ("Nasdaq") and the Internal Revenue Code of 1986, as amended, that require shareholder approval of certain equity plan and share issuances. Our Board may issue shares upon exercise of warrants or options without shareholder approval or authorization (up to the relevant authorized share capital limit).

Dividends

Under Irish law, dividends and distributions may only be made from distributable reserves. Distributable reserves generally means accumulated realized profits less accumulated realized losses and includes reserves created by way of capital reduction. In addition, no distribution or dividend may be made unless our net assets are equal to, or in excess of, the aggregate of our called-up share capital plus undistributable reserves and the distribution does not reduce our net assets below such aggregate. Undistributable reserves include the share premium account, the capital redemption reserve fund and the amount by which our accumulated unrealized profits, so far as not previously utilized by any capitalization, exceed our accumulated unrealized losses, so far as not previously written off in a reduction or reorganization of capital.

The determination as to whether or not we have sufficient distributable reserves to fund a dividend must be made by reference to our "relevant accounts." The "relevant accounts" will be either the last set of unconsolidated annual audited financial statements or other financial statements properly prepared in accordance with the Companies Act, which give a "true and fair view" of our unconsolidated financial position and accord with accepted accounting practice. The relevant accounts must be filed in the Companies Registration Office (the official public registry for companies in Ireland).

Our Constitution authorizes the Board to declare dividends, out of funds lawfully available for distribution, without shareholder approval to the extent they appear justified by the profits of the Company. The Board may also recommend a dividend to be approved and declared by the shareholders at a general meeting. The Board may direct that the payment be made by distribution of assets, shares or cash and no dividend issued may exceed the amount recommended by the Board. Dividends may be declared and paid in the form of cash or non-cash assets and may be paid in United States Dollars or any other currency.

Our Board may deduct from any dividend payable to any shareholder any amounts payable by such shareholder to us in relation to our shares.

The Board may also authorize us to issue shares with preferred rights to participate in dividends we declare. The holders of preferred shares may, depending on their terms, rank senior to our ordinary shares

in terms of dividend rights and/or be entitled to claim arrears of a declared dividend out of subsequently declared dividends in priority to ordinary shareholders.

Share Repurchases, Redemptions and Conversions

Overview

Our Constitution provides that any ordinary share that Alkermes has agreed to acquire shall be deemed to be a redeemable share, unless the Board elects to treat such share acquisition otherwise. Accordingly, for Irish law purposes, a repurchase of ordinary shares by us would technically be effected as a redemption of those shares as described below under *"—Our Repurchases and Redemptions."* If our Constitution did not contain such provision, our repurchases would be subject to many of the same rules that apply to purchases of our ordinary shares by subsidiaries described below under *"—Purchases by Our Subsidiaries"* including the shareholder approval requirements described below and the requirement that any open-market purchases be effected on a "recognized stock exchange." Except where otherwise noted, references elsewhere in this prospectus to repurchasing or buying back our ordinary shares refer to our or one of our subsidiaries' redemption of ordinary shares, in each case in accordance with our Constitution and Irish law as described below.

Our Repurchases and Redemptions

Under Irish law, a company may issue redeemable shares and redeem them out of distributable reserves or the proceeds of a new issue of shares for that purpose. Please see also the *"—Dividends"* section above. We may only issue redeemable shares if the nominal value of the issued share capital that is not redeemable is not less than 10% of the nominal value of our total issued share capital. All redeemable shares must also be fully-paid. Redeemable shares may, upon redemption, be canceled or held in treasury. Based on the provision of our Constitution described above, shareholder approval will not be required to redeem our shares.

We may also be given an additional general authority to purchase our own shares on the open-market which would take effect on the same terms and be subject to the same conditions as applicable to purchases by our subsidiaries as described below.

Our Board may also issue preferred shares that may be redeemed at our option or the option of the preferred shareholder, depending on the terms of such preferred shares. Please see *"—Authorized Share Capital"* above for additional information on preferred shares.

Under Irish law, repurchased and redeemed shares may be canceled or held as treasury shares. The nominal value of treasury shares held by us at any time must not exceed 10% of the nominal value of our issued share capital. We may not exercise any voting rights in respect of any shares held as treasury shares. Treasury shares may be canceled by us or re-issued subject to certain conditions.

Purchases by Our Subsidiaries

Under Irish law, an Irish or non-Irish subsidiary may purchase our shares either on-market or off-market. For one of our subsidiaries to make on-market purchases of our ordinary shares, our shareholders must provide general authorization for such purchase by way of ordinary resolution. However, as long as this general authority has been granted, no specific shareholder authority for a particular on-market purchase by a subsidiary of our ordinary shares is required. For an off-market purchase by one of our subsidiaries, the proposed purchase contract must be authorized by special resolution of the shareholders before the contract is entered into. The person whose shares are to be bought back cannot vote in favor of the special resolution and, for at least 21 days prior to the special resolution being passed, the purchase contract must be on display or must be available for inspection by shareholders at our registered office.

In order for one of our subsidiaries to make an on-market purchase of our shares, such shares must be purchased on a "recognized stock exchange." The Nasdaq Global Select Market, on which our shares are listed, is specified as a recognized stock exchange for this purpose by Irish law.

The number of shares held by our subsidiaries at any time will be included in any calculation of the permitted treasury share threshold of 10% of the nominal value of our issued share capital. While a subsidiary holds our shares, it cannot exercise any voting rights in respect of those shares. The acquisition of our shares by a subsidiary must be funded out of distributable reserves of the subsidiary.

Share Repurchase Program

Our share repurchase program authorizes us to repurchase up to $215 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. As of December 31, 2019, we had purchased a total of 8,866,342 ordinary shares under this program at a cost of $114,029,664.

As noted above, shareholder approval for such repurchases will not be required because a repurchase of our shares will be effected as a redemption pursuant to our Constitution.

Bonus Shares

Under our Constitution, the Board may resolve to capitalize any amount standing to the credit of the reserves of the Company (including, but not limited to, the share premium account, capital redemption reserve, capital conversion reserve and profit and loss account), whether or not available for distribution, for any purpose, including, but not limited to, for the purposes of effecting any exchange of any rights and applying any such sum arising from such capitalization to pay up any shares of the Company and allot them, credited as fully paid, to any holders of such rights.

Lien on Shares, Calls on Shares and Forfeiture of Shares

Our Constitution provides that we will have a first and paramount lien on every share that is not a fully paid up share for all amounts payable at a fixed time or called in respect of that share. Subject to the terms of their allotment, our Board may call for any unpaid amounts in respect of any shares to be paid, and if payment is not made, the shares may be forfeited. These provisions are standard inclusions in the constitution of an Irish company limited by shares such as ours and will only be applicable to our shares that have not been fully paid up.

Consolidation and Division; Subdivision

Under our Constitution, we may, by ordinary resolution, consolidate and divide all or any of our share capital into shares of larger nominal value than our existing shares or subdivide our shares into smaller amounts than is fixed by our Constitution.

Reduction of Share Capital

We may, by ordinary resolution, reduce our authorized share capital in any way provided that such resolution does not reduce the authorized share capital to an amount less than the issued share capital at such time. We also may, by special resolution and subject to confirmation by the Irish High Court, reduce or cancel our issued share capital in any way we think expedient.

Annual Meetings of Shareholders

We are required to hold annual general meetings at intervals of no more than 15 months, provided that an annual general meeting is held in each calendar year and no more than nine months after our fiscal year-end. Any annual general meeting may be held outside Ireland, provided that the Company makes all necessary arrangements to ensure that shareholders can participate in such meeting by technological means without leaving Ireland.

Notice of each annual general meeting must be given to all our shareholders and to our auditors. Our Constitution provides for a minimum notice period of 21 days, which is the minimum permitted under Irish law.

The only matters which must, as a matter of Irish law, be transacted at an annual general meeting are: (i) the consideration of the Company's statutory financial statements and the report of the Board and the report of the statutory auditors on those statements and that report; (ii) the review by the members of the Company's affairs; (iii) the declaration of a dividend (if any) of an amount not exceeding the amount recommended by the Board; (iv) the authorization of the Board to approve the remuneration of the statutory auditors; and (v) the election and/or re-election of members of the Board. If no resolution is made in respect of the reappointment of an existing auditor at an annual general meeting, the existing auditor will be deemed to have continued in office.

Extraordinary General Meetings of Shareholders

Extraordinary general meetings of our shareholders may be convened by: (i) the Board; (ii) at the request of shareholders holding not less than 10% of our paid-up share capital carrying voting rights; or (iii) at the request of our auditors in certain circumstances in accordance with the Companies Act. Extraordinary general meetings are generally held for the purposes of approving shareholder resolutions as may be required from time to time. At any extraordinary general meeting only such business shall be conducted as is set forth in the notice thereof.

Notice of an extraordinary general meeting must be given to our shareholders and to our auditors. Under Irish law and our Constitution, the minimum notice periods are 21 days' notice in writing for an extraordinary general meeting to approve a special resolution and 14 days' notice in writing for any other extraordinary general meeting.

In the case of an extraordinary general meeting convened by our shareholders, the proposed purpose of the meeting must be set out in the requisition notice. Upon receipt of this required notice, the Board has 21 days to convene a meeting of our shareholders to vote on the matters set out in the required notice. This meeting must be held within two months of the receipt of the requisition notice. If the Board does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of our receipt of the requisition notice.

If the Board becomes aware that our net assets are not greater than half of the amount of our called-up share capital, our Board must convene an extraordinary general meeting of our shareholders not later than 28 days from the date that they learn of this fact to consider how to address the situation.

Quorum for General Meetings

Our Constitution provides that no business shall be transacted at any general meeting unless a quorum is present. One or more shareholders present in person or by proxy holding not less than a majority of our issued and outstanding shares entitled to vote at the meeting in question constitute a quorum for such meeting.

Voting

Our Constitution provides that the Board or the chairman of the Board may determine the manner in which the poll is to be taken at each meeting and the manner in which the votes are to be counted.

Every shareholder is entitled to one vote for each ordinary share that he or she holds as of the record date for the meeting. Voting rights may be exercised by shareholders registered in our share register as of the record date for the meeting or by a duly appointed proxy, which proxy need not be a shareholder. Where interests in shares are held by a nominee trust company, this company may exercise the rights of the beneficial holders on their behalf as their proxy. All proxies must be appointed in the manner prescribed by our Constitution, which permit shareholders to notify us of their proxy appointments electronically in such manner as may be approved by the Board.

In accordance with our Constitution, our Board may from time to time authorize us to issue preferred shares. These preferred shares may have such voting rights as may be specified in the terms of such preferred shares (e.g., they may carry more votes per share than ordinary shares or may entitle their holders to a class vote on such matters as may be specified in the terms of the preferred shares). Treasury shares or shares of the Company that are held by our subsidiaries will not be entitled to be voted at general meetings of shareholders.

Irish law requires special resolutions of the shareholders at a general meeting to approve certain matters. Examples of matters requiring special resolutions include:

a) amending our objects or memorandum of association;

b) amending our articles of association;

c) approving a change of our name;

d) authorizing the entering into of a guarantee or provision of security in connection with a loan, quasi-loan or credit transaction to a director or connected person;

e) opting out of preemption rights on the issuance of new shares;

f) authorizing the issuance of new shares;

g) our re-registration from a public limited company to a private company;

h) variation of class rights attaching to classes of shares (where the Constitution do not provide otherwise);

i) purchase of our own shares off-market;

j) reduction of issued share capital;

k) sanctioning a compromise/scheme of arrangement;

l) resolving that we be wound up by the Irish courts;

m) resolving in favor of a shareholders' voluntary winding-up;

n) re-designation of shares into different share classes; and

o) setting the re-issue price of treasury shares.

Variation of Rights Attaching to a Class or Series of Shares

Under our Constitution and the Companies Act, any variation of class rights attaching to our issued shares must be approved by a special resolution of the shareholders of the affected class or with the consent in writing of the holders of three-quarters of all the votes of that class of shares.

The provisions of our Constitution relating to general meetings apply to general meetings of the holders of any class of shares except that the necessary quorum is determined by reference to the shares of the holders of the class. Accordingly, for general meetings of holders of a particular class of shares, a quorum consists of the holders present in person or by proxy representing not less than a majority of the issued shares of that class entitled to vote at the meeting.

Acquisitions

An Irish public limited company may be acquired in a number of ways, including:

a) a court-approved scheme of arrangement under the Companies Act. A scheme of arrangement with shareholders requires a court order from the Irish High Court and the approval of a majority in number representing 75% in value of the shareholders present and voting in person or by proxy at a meeting called to approve the scheme;

b) through a tender or takeover offer by a third party for all of our shares. Where the holders of 80% or more of our shares have accepted an offer for such shares, the remaining shareholders may also be statutorily required to transfer their shares. If the bidder does not exercise its “squeeze out” right, then the non-accepting shareholders also have a statutory right to require the bidder to acquire their shares on the same terms. If our shares were to be listed on the Irish Stock Exchange or another regulated stock exchange in the EU, this threshold would be increased to 90%; and

c) by way of a merger with a company incorporated in the European Economic Area (“EEA”) under the EU Cross-Border Mergers Directive (EU) 2017/1132 or with another Irish company under the Companies Act. Such a merger must be approved by a special resolution of the shareholders. Under certain circumstances, shareholders also may be entitled to have their shares acquired for cash.

Irish law does not generally require shareholder approval for a sale, lease or exchange of all or substantially all of a company’s property and assets.

Appraisal Rights

Generally, under Irish law, shareholders of an Irish company do not have dissenters’ or appraisal rights. Under the European Communities (Cross-Border Mergers) Regulations 2008 governing the merger of an Irish company limited by shares such as we are and a company incorporated in the EEA, a shareholder: (i) who voted against the special resolution approving the merger; or (ii) of a company in which 90% of the shares are held by the other party to the merger, has the right to request that the company acquire its shares for cash at a price determined in accordance with the share exchange ratio set out in the merger agreement.

Disclosure of Interests in Shares

Under the Companies Act, shareholders must notify us if, as a result of a transaction, the shareholder will become interested in 3% or more of our shares; or if as a result of a transaction a shareholder who was interested in more than 3% of our shares ceases to be so interested. Where a shareholder is interested in more than 3% of our shares, the shareholder must notify us of any alteration of his or her interest that brings his or her total holding through the nearest whole percentage number, whether an increase or a reduction. The relevant percentage figure is calculated by reference to the aggregate nominal value of the shares in which the shareholder is interested as a proportion of the entire nominal value of our issued share capital of (or any such class of share capital in issue). Where the percentage level of the shareholder's interest does not amount to a whole percentage this figure may be rounded down to the next whole number. We must be notified within five business days of the transaction or alteration of the shareholder's interests that gave rise to the notification requirement. If a shareholder fails to comply with these notification requirements, the shareholder's rights in respect of any shares it holds will not be enforceable, either directly or indirectly. However, such person may apply to the court to have the rights attaching to such shares reinstated.

In addition to these disclosure requirements, we may, under the Companies Act, by notice in writing, require a person whom we know or have reasonable cause to believe to be, or at any time during the three years immediately preceding the date on which such notice is issued to have been, interested in shares comprised in our relevant share capital to: (i) indicate whether or not it is the case; and (ii) where such person holds or has during that time held an interest in our shares, to provide additional information, including the person's own past or present interests in our shares. If the recipient of the notice fails to respond within the reasonable time period specified in the notice, we may apply to court for an order directing that the affected shares be subject to certain restrictions, as prescribed by the Companies Act, as follows:

a) any transfer of those shares or, in the case of unissued shares, any transfer of the right to be issued with shares and any issue of shares, shall be void;

b) no voting rights shall be exercisable in respect of those shares;

c) no further shares shall be issued in right of those shares or in pursuance of any offer made to the holder of those shares; and

d) no payment shall be made of any sums due from us on those shares, whether in respect of capital or otherwise.

The court may also order that shares subject to any of these restrictions be sold with the restrictions terminating upon the completion of the sale.

In the event that we are in an offer period pursuant to the Irish Takeover Rules made under the Irish Takeover Panel Act 1997 (the "Irish Takeover Rules"), accelerated disclosure provisions apply for persons holding an interest in our securities of 1% or more.

In addition, the beneficial ownership disclosures of the U.S. federal securities laws will apply with respect to beneficial ownership of our shares.

Anti-Takeover Provisions

Irish Takeover Rules and Substantial Acquisition Rules

A transaction in which a third party seeks to acquire 30% or more of our voting rights will be governed by the Irish Takeover Panel Act 1997 and the Irish Takeover Rules made thereunder and will be

regulated by the Irish Takeover Panel. The "General Principles" of the Irish Takeover Rules and certain important aspects of the Irish Takeover Rules are described below.

General Principles

The Irish Takeover Rules are built on the following general principles (the "General Principles"), which will apply to any transaction regulated by the Irish Takeover Panel:

a) in the event of an offer, all holders of securities of the target company should be afforded equivalent treatment and, if a person acquires control of a company, the other holders of securities must be protected;

b) the holders of the securities of the target company must have sufficient time and information to enable them to reach a properly informed decision on the offer; where it advises the holders of securities, the board of the target company must give its views on the effects of implementation of the offer on employment, conditions of employment and the locations of the target company's places of business;

c) the board of the target company must act in the interests of the company as a whole and must not deny the holders of securities the opportunity to decide on the merits of the offer;

d) false markets must not be created in the securities of the target company, the bidder or of any other company concerned by the offer in such a way that the rise or fall of the prices of the securities becomes artificial and the normal functioning of the markets is distorted;

e) a bidder must announce an offer only after ensuring that he or she can fulfill in full, any cash consideration, if such is offered, and after taking all reasonable measures to secure the implementation of any other type of consideration;

f) a target company must not be hindered in the conduct of its affairs for longer than is reasonable by an offer for its securities; and

g) a substantial acquisition of securities (whether such acquisition is to be effected by one transaction or a series of transactions) shall take place only at an acceptable speed and shall be subject to adequate and timely disclosure.

Mandatory Bid

Under certain circumstances, a person who acquires our shares may be required under the Irish Takeover Rules to make a mandatory cash offer for our remaining outstanding shares at a price not less than the highest price paid for the shares by the acquirer (or any parties acting in concert with the acquirer) during the previous twelve months. This mandatory bid requirement is triggered if an acquisition of shares would increase the aggregate holding of an acquirer (including the holdings of any parties acting in concert with the acquirer) to shares representing 30% or more of our voting rights, unless the Irish Takeover Panel otherwise consents. An acquisition of shares by a person holding (together with its concert parties) shares representing between 30% and 50% of our voting rights would also trigger the mandatory bid requirement if, after giving effect to the acquisition, the percentage of the voting rights held by that person (together with its concert parties) would increase by 0.05% within a twelve-month period. Any person (excluding any parties acting in concert with the holder) holding shares representing more than 50% of the voting rights of a company is not subject to these mandatory offer requirements.

Voluntary Bid; Requirements to Make a Cash Offer and Minimum Price Requirements

If a person makes a voluntary offer to acquire our outstanding ordinary shares, the offer price must be no less than the highest price paid for our ordinary shares by the bidder or its concert parties during the three-month period prior to the commencement of the offer period. The Irish Takeover Panel has the power to extend the "look back" period to twelve months if the Irish Takeover Panel, taking into account the General Principles, believes it is appropriate to do so.

If the bidder or any of its concert parties has acquired our ordinary shares: (i) during the period of twelve months prior to the commencement of the offer period which represent more than 10% of our total ordinary shares; or (ii) at any time after the commencement of the offer period, the offer must be in cash (or accompanied by a full cash alternative) and the price per ordinary share must not be less than the highest price paid by the bidder or its concert parties during, in the case of (i), the 12-month period prior to the commencement of the offer period and, in the case of (ii), the offer period. The Irish Takeover Panel may apply this rule to a bidder who, together with its concert parties, has acquired less than 10% of our total ordinary shares in the 12-month period prior to the commencement of the offer period if the Irish Takeover Panel, taking into account the General Principles, considers it just and proper to do so.

An offer period will generally commence from the date of the first announcement of the offer or proposed offer.

Substantial Acquisition Rules

The Irish Takeover Rules also contain rules governing substantial acquisitions of shares which restrict the speed at which a person may increase his or her holding of shares and rights over shares to an aggregate of between 15% and 30% of our voting rights. Except in certain circumstances, an acquisition or series of acquisitions of shares or rights over shares representing 10% or more of our voting rights is prohibited, if such acquisition(s), when aggregated with shares or rights already held, would result in the acquirer holding 15% or more but less than 30% of our voting rights and such acquisitions are made within a period of seven days. These rules also require accelerated disclosure of acquisitions of shares or rights over shares relating to such holdings.

Shareholder Rights Plan

Under our Constitution, the Board is authorized to adopt a shareholder rights plan (a "Shareholder Rights Plan"), upon such terms and conditions as the Board deems expedient and in the best interests of the Company, subject to applicable law, including the grant of rights (including approving the execution of any documents relating to the grant of such rights) to subscribe for ordinary shares or preferred shares in the share capital of the Company in accordance with the terms of any Shareholder Rights Plan. The Board or any duly appointed committee thereof may effect an exchange of rights in accordance with such Shareholder Rights Plan.

Frustrating Action

Under the Irish Takeover Rules, our Board is not permitted to take any action which might frustrate an offer for our shares once the Board has received an approach which may lead to an offer or has reason to believe an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as: (i) the issue of shares, options or convertible securities; (ii) material acquisitions or disposals; (iii) entering into contracts other than in the ordinary course of business; or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any time during which the Board has reason to believe an offer is imminent. Exceptions to this prohibition are available where:

a) the action is approved by our shareholders at a general meeting; or

b) the Irish Takeover Panel has given its consent, where:

1. it is satisfied the action would not constitute frustrating action;

2. the holders of 50% of the voting rights state in writing that they approve the proposed action and would vote in favor of it at a general meeting;

3. the action is taken in accordance with a contract entered into prior to the announcement of the offer; or

4. the decision to take such action was made before the announcement of the offer and either has been at least partially implemented or is in the ordinary course of business.

Certain other provisions of Irish law or our Constitution may be considered to have anti-takeover effects, including those described under the following captions: *"—Authorized Share Capital"* (regarding issuance of preferred shares), *"—Preemption Rights, Share Warrants and Share Options," "—Disclosure of Interests in Shares,"* and *"—Corporate Governance."*

Appointment of Directors of the Board

The directors of the Board are divided into three classes, each class consisting, as nearly as may be possible, of one-third of the total number of directors constituting the entire Board. At each annual general meeting, successors to the class of directors whose term expires at that annual general meeting are elected for a three-year term. Except as otherwise permitted in our Constitution, directors will be elected by way of ordinary resolution at a general meeting. If the number of directors is changed, any increase or decrease shall be apportioned among the classes so as to maintain the number of directors in each class as nearly equal as possible. In no case will a decrease in the number of directors shorten the term of any incumbent director. A director shall hold office until the annual general meeting for the year in which her or his term expires and until her or his successor shall be elected and shall qualify, subject, however, to prior death, resignation, retirement, disqualification or removal from office. Any vacancy on the Board, including a vacancy that results from an increase in the number of directors or from the death, resignation, retirement, disqualification or removal of a director, shall be deemed a casual vacancy. Subject to the terms of any one or more classes or series of preferred shares, any casual vacancy shall only be filled by decision of a majority of the Board then in office, provided that a quorum is present. Any director of any class elected to fill a vacancy resulting from an increase in the number of directors of such class shall hold office for a term that shall coincide with the remaining term of that class. Any director elected to fill a vacancy not resulting from an increase in the number of directors shall have the same remaining term as that of her predecessor. A director retiring at a meeting shall retain office until the close or adjournment of the meeting.

During any vacancy in the Board, the remaining directors have full power to act as the Board. If, at any general meeting of the Company, the number of directors is reduced below the minimum prescribed by the Board due to the failure of any persons nominated to be directors to be elected, then in those circumstances, the nominee or nominees who receive the highest number of votes in favor of election shall be elected in order to maintain the prescribed minimum number of directors and each such director shall remain a director (subject to the provisions of the Companies Act and our Constitution) only until the conclusion of the next annual general meeting of the Company unless such director is elected by the Members (as defined in our Constitution) during such meeting.

Duration; Dissolution; Rights upon Liquidation

Our duration is unlimited. We may be dissolved and wound up at any time by way of a shareholders' voluntary winding up or a creditors' winding up. In the case of a shareholders' voluntary winding-up, a special resolution of shareholders is required. We may also be dissolved by way of court order on the application of a creditor, or by the Companies Registration Office as an enforcement measure where we have failed to file certain returns.

The rights of the shareholders to a return of our assets on dissolution or winding up, following the settlement of all claims of creditors, may be prescribed in our Constitution or the terms of any preferred shares issued by our Board from time to time. The holders of preferred shares in particular may have the right to priority in our dissolution or winding up. If the Constitution contain no specific provisions in respect of a dissolution or winding up then, subject to the priorities of

any creditors, the assets will be distributed to shareholders in proportion to the paid-up nominal value of the shares held. Our Constitution provide that our ordinary shareholders are entitled to participate pro rata in a winding up, but their right to do so may be subject to the rights of any preferred shareholders to participate under the terms of any series or class of preferred shares.

Uncertificated Shares

Pursuant to the Companies Act, a shareholder is entitled to be issued a share certificate on request and subject to payment of a nominal fee.

No Sinking Fund

Our ordinary shares have no sinking fund provisions.

No Liability for Further Calls or Assessments

Our ordinary shares are duly and validly issued and fully-paid.

Transfer and Registration of Shares

Our transfer agent maintains our share register, which is determinative of ownership of our shares. Our shareholders who hold shares beneficially are not the holders of record of such shares. Instead, the depository (for example, Cede & Co., as nominee for DTC) or other nominee is the holder of record of those shares. Accordingly, a transfer of shares from a person who holds such shares beneficially to a person who also holds such shares beneficially through a depository or other nominee will not be registered in our official share register, as the depository or other nominee will remain the record holder of any such shares.

A written instrument of transfer is required under Irish law in order to register on our official share register any transfer of shares: (i) from a person who holds such shares directly to any other person; (ii) from a person who holds such shares beneficially to a person who holds such shares directly; or (iii) from a person who holds such shares beneficially to another person who holds such shares beneficially where the transfer involves a change in the depository or other nominee that is the record owner of the transferred shares. An instrument of transfer is also required for a shareholder who directly holds shares to transfer those shares into his or her own broker account (or vice versa). Such instruments of transfer may give rise to Irish stamp duty, which must be paid prior to registration of the transfer on our official Irish share register. However, a shareholder who directly holds shares may transfer those shares into his or her own broker account (or vice versa) without giving rise to Irish stamp duty provided there is no change in the ultimate beneficial ownership of the shares as a result of the transfer and the transfer is not made in contemplation of a sale of the shares.

Any transfer of our ordinary shares that is subject to Irish stamp duty will not be registered in the name of the buyer unless an instrument of transfer is duly stamped and provided to the transfer agent. Our Constitution allows us, in our absolute discretion, to create an instrument of transfer and pay (or procure the payment of) any stamp duty, which is the legal obligation of a buyer. In the event of any such payment, we are (on our behalf or on behalf of our affiliates) entitled to: (i) seek reimbursement from the buyer or seller (at our discretion); (ii) set-off the amount of the stamp duty against future dividends payable to the buyer or seller (at our discretion); and (iii) claim a lien against the ordinary shares on which we have paid stamp duty. Parties to a share transfer may assume that any

stamp duty arising in respect of a transaction in our ordinary shares has been paid unless one or both of such parties is otherwise notified by us.

Our Constitution delegates to our secretary the authority to execute an instrument of transfer on behalf of a transferring party.

In order to help ensure that the official share register is regularly updated to reflect trading of our ordinary shares occurring through normal electronic systems, we intend to regularly produce any required instruments of transfer in connection with any transactions for which we pay stamp duty (subject to the reimbursement and set-off rights described above). In the event that we notify one or both of the parties to a share transfer that we believe stamp duty is required to be paid in connection with the transfer and that we will not pay the stamp duty, the parties may either themselves arrange for the execution of the required instrument of transfer (and may request a form of instrument of transfer from us for this purpose) or request that we execute an instrument of transfer on behalf of the transferring party in a form determined by us. In either event, if the parties to the share transfer have the instrument of transfer duly stamped (to the extent required) and then provide it to our transfer agent, the buyer will be registered as the legal owner of the relevant shares on our official Irish share register (subject to the matters described below).

The Board may suspend registration of transfers from time to time, with such suspensions not to exceed 30 days in aggregate each year.

Exhibit 10.10.3

In accordance with Item 601(b)(2)(ii) of Regulation S-K, certain information (indicated by "[**]") has been excluded from this exhibit because it is both not material and would likely cause competitive harm to the registrant if publicly disclosed.

THIRD AMENDMENT TO LICENSE AND COLLABORATION AGREEMENT

THIS THIRD AMENDMENT (the "Amendment") is made and entered into as of October 30, 2019 (the "Amendment Effective Date") to amend that certain License and Collaboration Agreement dated November 27, 2017, as amended (the "Agreement"), by and between ALKERMES PHARMA IRELAND LIMITED ("Alkermes") and BIOGEN SWISS MANUFACTURING GMBH ("Biogen"). Unless explicitly noted otherwise, capitalized terms used but not defined herein shall have the meanings set forth in the Agreement.

RECITALS:

WHEREAS, Alkermes and Biogen have entered into the Agreement;

WHEREAS, Alkermes and Biogen now wish to amend the Agreement to effect the transfer of Manufacturing of Clinical Supplies and up to one-hundred percent (100%) of Commercial Supplies of the Alkermes 8700 Product from Alkermes to Biogen;

NOW, THEREFORE, in consideration of the mutual promises contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Section 1.1 of the Agreement is hereby amended to add the following new defined terms:

"***Commercial Supply Agreement***" means that certain Commercial Supply Agreement dated October 30, 2019, as may be amended, by and among Biogen, Biogen International GmbH and Alkermes.

"***Equipment***" means Existing Equipment and New Equipment as such terms are defined in the Commercial Supply Agreement.

"***Exclusive Manufacturing End Date***" means the earlier of (i) the date of [**] and (ii) [**] after the date of [**].

"***Technology Transfer***" means the transfer from Alkermes to Biogen or its designee of all technology Controlled by Alkermes that is necessary to enable Manufacture of the Alkermes 8700 Product and other then-existing Products in accordance with Section 3.2.3(iv) of the Agreement. For the avoidance of doubt, the term "technology" as used in this definition shall not include Equipment.

2. A new Section 4.5 is hereby added to the Agreement with the following text:

4.5. Forecasting. For the Alkermes 8700 Product, Biogen will provide Alkermes with (a) a [**] written forecast of Biogen's anticipated product demand, in units, broken down on a country-by-country basis for each month of such period, which forecast will be updated by Biogen [**] and provided to Alkermes no later than [**]; (b) an [**] good faith [**] written forecast in respect of Biogen's anticipated product demand, in units, broken down by U.S., Europe and rest-of-world, which forecast will be updated by Biogen [**] and provided to Alkermes no later than [**]; and (c) a quarterly inventory report providing inventory levels for work in progress (including, but not limited to, active pharmaceutical ingredients and drug product) and finished goods, which will be updated by Biogen and provided to Alkermes on a quarterly basis.

3. Section 5.1.2 of the Agreement is deleted in its entirety and replaced with the following text:

5.1.2 Commercial Supplies. Pursuant to this Agreement, Biogen has the right to Manufacture or have Manufactured Commercial Supplies. Biogen has considered in good faith, and hereby appoints, Alkermes as the toll manufacturer for such Commercial Supplies for Commercialization in the Territory at a site outside of the United States, and Biogen and its Affiliates and Sublicensees will purchase Commercial Supplies exclusively from Alkermes; *provided that*, (A) with respect to the Alkermes 8700 Product only and subject to the Manufacturing transition plan referenced in this Section 5.1.2, Biogen's appointment of Alkermes as toll manufacturer, Alkermes' obligation to Manufacture, and the obligations of Biogen and its Affiliates and Sublicensees to purchase Clinical Supplies and Commercial Supplies exclusively from Alkermes will each expire on the Exclusive Manufacturing End Date and (B) for Products other than the Alkermes 8700 Product, Biogen may qualify to Manufacture, or engage and qualify a Third Party to Manufacture, Commercial Supplies as a back-up manufacturer so long as such Third Party Manufacturer does not Manufacture more than [**] percent ([**]%) of Commercial Supplies in the aggregate in any Calendar Year, except in the event of a Force Majeure Delay or a Serious Failure to Supply.

Upon Biogen's written request, Alkermes and Biogen shall work in good faith to (a) enter into a technology transfer plan pursuant to which Alkermes will undertake a Technology Transfer in accordance with Section 3.2.3(iv) of the Agreement, including the reimbursement provisions therein, as promptly as reasonably practicable and, in any event, to be completed no later than [**] after Biogen's written request to transition manufacturing and enter into a technology transfer plan, and (b) enter into a Manufacturing transition plan ([**]) to ensure the orderly transition after the Exclusive Manufacturing End Date to Biogen or its designee of Manufacturing responsibility for Clinical Supplies and Commercial

Supplies of the Alkermes 8700 Product in an effort to prevent any interruption in the supply of such product.

Notwithstanding anything to the contrary set forth in this Section 5.1.2, if (i) Alkermes foregoes its exclusive right to Manufacture or have Manufactured Commercial Supplies, (ii) Alkermes undergoes a Change of Control in which the acquirer is a competitor of Biogen set forth on Schedule 5.1 or a Third Party toll manufacturer that Manufactures a competing fumarate product or (iii) there is a Serious Failure to Supply, then in any case ((i)-(iii)), (a) Biogen and its Affiliates and Sublicensees will have no further obligation to exclusively purchase Commercial Supplies from Alkermes, (b) Biogen will have the exclusive right to Manufacture or have Manufactured Commercial Supplies and (c) Alkermes will promptly conduct a transfer (to the extent not already conducted pursuant to any Technology Transfer) of all necessary Manufacturing technology to Biogen or its designee to enable Biogen or such designee to Manufacture Commercial Supplies. In addition, in the event of a Force Majeure Delay (and for the duration thereof), until such time as Alkermes is able to resume sufficient Manufacturing to meet Biogen's demand for Commercial Supplies, Biogen may Manufacture itself or have Manufactured by its back-up manufacturer, all Commercial Supplies for so long as Alkermes is unable to meet Biogen's demand.

4. Section 9.4 of the Agreement is hereby deleted in its entirety and replaced with the following text:

9.4 Milestone Payments.

9.4.1 Commercial Milestones for the Alkermes 8700 Product. As further consideration of the grant of the licenses set forth in Section 6.1 and the performance of Alkermes' other obligations hereunder, Biogen will pay to Alkermes the amounts set forth below no later than [**] days after the earliest date on which the corresponding milestone event has first been achieved:

Commercial Milestone Event	**Amount**
Parties' execution of amendments to the Commercial Supply Agreement and the Clinical Supply Agreement reflecting the transition of Manufacturing of Clinical Supplies and up to 100% of Commercial Supplies of the Alkermes 8700 Product to Biogen	$5,000,000
Exclusive Manufacturing End Date	$5,000,000

9.4.2 Development Milestones for Products other than the Alkermes 8700 Product. As further consideration of the grant of the licenses set forth in Section 6.1 and the performance of Alkermes' other obligations

hereunder, Biogen will pay to Alkermes the amounts set forth below no later than [**] days after the earliest date on which the corresponding milestone event has first been achieved with respect to the first two Products other than the Alkermes 8700 Product:

Development Milestone Event	**Amount**
The first administration to the first patient in a Clinical Trial of such Product.	$[**]
The first administration of such Product to the first patient in a phase 3 Clinical Trial.	$[**]
Receipt of Regulatory Approval of an NDA from the FDA in the U.S. for such Product.	$[**]

The milestone payments set forth in this Section 9.4.2 will be paid on a Product-by-Product basis on the first occurrence of each such applicable milestone for each of the first two Products other than the Alkermes 8700 Product.

5. Section 9.5.1(i) of the Agreement is hereby deleted in its entirety and replaced with a new Section 9.5.1(i)(A) and a new Section 9.5.1(i)(B) with the following text:

(i) **(A) Royalty Percentages for Alkermes 8700 Product Manufactured by Alkermes**. As further consideration of the grant of the licenses set forth in Section 6.1 and the performance of Alkermes' other obligations hereunder for Alkermes 8700 Product Manufactured by Alkermes, Biogen will pay to Alkermes royalty payments on Net Sales of the Alkermes 8700 Product in the Territory on a country-by-country basis during the applicable Royalty Term at the rate of fifteen percent (15%) of Net Sales. Notwithstanding the foregoing, in the event of a determination of GI Inferiority, then the royalty rate during each Royalty Term for the Alkermes 8700 Product in each country in the Territory will be [**] percent ([**]%) of Net Sales until such time as the aggregate royalty payments paid to Alkermes across all countries equal Fifty Million U.S. Dollars ($50,000,000), after which time such royalty rate will return to its prior level, before the determination of GI Inferiority that resulted in such royalty rate of [**] percent ([**]%) (but subject in any event to Section 9.5.5, Section 9.5.6 and Section 9.5.7).

(B) Royalty Percentages for Alkermes 8700 Product Manufactured by Biogen. As further consideration of the grant of the licenses set forth in Section 6.1 and the performance of Alkermes' other obligations hereunder with respect to the Alkermes 8700 Product Manufactured by Biogen or its designee, Biogen will pay to Alkermes royalty payments on Net Sales of the Alkermes 8700 Product in the Territory on a country-by-country basis

during the applicable Royalty Term at the rate of [**] percent ([**]%) of Net Sales. Notwithstanding the foregoing, in the event of a determination of GI Inferiority, then the royalty rate during the Royalty Term for the Alkermes 8700 Product in each country in the Territory will be [**] percent ([**]%) of Net Sales until such time as the aggregate royalty payments paid to Alkermes across all countries equal Fifty Million U.S. Dollars ($50,000,000), after which time such royalty rate will return to its prior level, before the determination of GI Inferiority that resulted in such royalty rate of [**] percent ([**]%) (but subject in any event to Section 9.5.5, Section 9.5.6 and Section 9.5.7).

6. Section 9.6 of the Agreement is hereby deleted in its entirety and replaced with a new Section 9.6 with the following text:

9.6. Reporting and Paying Net Sales. For each Calendar Quarter for which royalties are payable by Biogen to Alkermes pursuant to Section 9.5.1(i) or Section 9.5.2, Biogen will (i) deliver to Alkermes, within five (5) days after the end of each such Calendar Quarter, a nonbinding estimated report prepared in good faith, (ii) deliver to Alkermes, within forty-five (45) days after the end of each such Calendar Quarter a true and accurate report, in each case of (i) and (ii), providing in reasonable detail (A) an accounting of all Net Sales made on a country-by-country and Product-by-Product basis in the Territory during such Calendar Quarter, including the amount of gross sales of Products and the aggregate allowable deductions therefrom, (B) the number of units of Products sold, (C) the currency conversion rates used, (D) the U.S. Dollar-equivalent of such Net Sales during such Calendar Quarter and (E) a calculation of the amount of royalty payment due on such Net Sales, and (iii) within forty-five (45) days after the end of each such Calendar Quarter, pay Alkermes the royalties due under Section 9.5.1(i) and Section 9.5.2 with respect to such Calendar Quarter as provided for in the report delivered under (ii) above. Each of the reports set forth in (i) and (ii) of this Section 9.6 will be organized to distinguish whether the Alkermes 8700 Product was Manufactured by Alkermes or Biogen or their respective designees and, in the case of the report set forth in (ii), the amount of Alkermes 8700 Product in inventory as of the end of the Calendar Quarter to which the report relates. In addition, within forty-five (45) days after the end of the first Calendar Quarter following each twelve (12)-month period during the Minimum Annual Payment Term, Biogen shall pay Alkermes any amount due under Section 9.5.1(ii) for such twelve (12)-month period. Each report delivered hereunder shall be considered Confidential Information of Biogen, subject to the terms and conditions of Article 8. Any payments due hereunder for less than a full Calendar Quarter will be prorated.

7. The Parties agree that all terms relating to the Manufacture of Commercial Supplies of the Alkermes 8700 Product are set forth in the Commercial Supply Agreement and that the terms set forth in Exhibit E of the Agreement do not apply to the Manufacture of Commercial Supplies of the Alkermes 8700 Product.

8. **Governing Law**. This Amendment shall be governed by and construed in accordance with the laws of the State of New York without regard to its conflict of law provisions.

9. **Integration**. Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Agreement shall continue in full force and effect as provided therein. The Agreement (as amended by this Amendment), this Amendment, the Clinical Supply Agreement and the Commercial Supply Agreement constitute the entire agreement between the parties hereto and thereto relating to the subject matter hereof and thereof and supersede all prior and contemporaneous negotiations, agreements, representations, understandings and commitments with respect thereto.

[Signature page follows]

IN WITNESS WHEREOF, Alkermes and Biogen have executed and delivered this Amendment effective as of the Amendment Effective Date.

ALKERMES PHARMA IRELAND LIMITED

By: /s/ Kevin Brady

Name: Kevin Brady

Title: Director

BIOGEN SWISS MANUFACTURING GMBH

By:/s/ Peter Puype

Name: Peter Puype

Title: VP, Global Supply Chain

Exhibit 21.1

SUBSIDIARIES

Name	Jurisdiction
Alkermes Ireland Holdings Limited	Ireland
Alkermes Pharma Ireland Limited	Ireland
Alkermes Finance Ireland Limited	Ireland
Daravita Pharma Ireland Limited	Ireland
Alkermes Finance Ireland (No. 3) Limited	Ireland
Alkermes Science Four Limited	Ireland
Alkermes Science Five Limited	Ireland
Daravita Limited	Ireland
Alkermes Finance S.à r.l.	Luxembourg
Alkermes Finance Ireland (No. 2) Limited	Ireland
Alkermes US Holdings, Inc.	Delaware
Alkermes, Inc.	Pennsylvania
Alkermes Controlled Therapeutics, Inc.	Pennsylvania
Alkermes Europe, Ltd.	United Kingdom
Rodin Therapeutics, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-179545, 333-184621, 333-200777, 333-214952, 333-226359 and 333-232831) of Alkermes plc of our report dated February 13, 2020 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
February 13, 2020

Exhibit 31.1

CERTIFICATIONS

I, Richard F. Pops, certify that:

1. I have reviewed this annual report on Form 10-K of Alkermes plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Richard F. Pops
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: February 13, 2020

Exhibit 31.2

CERTIFICATIONS

I, James M. Frates, certify that:

1. I have reviewed this annual report on Form 10-K of Alkermes plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ James M. Frates
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Date: February 13, 2020

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Alkermes plc (the "Company") for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Richard F. Pops, Chairman and Chief Executive Officer of the Company, and James M. Frates, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to our knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Richard F. Pops
Richard F. Pops
Chairman and Chief Executive Officer
(Principal Executive Officer)

By: /s/ James M. Frates
James M. Frates
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Date: February 13, 2020