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, 2020

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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 $3,057,878,108.

As of February 5, 2021, 159,237,889 ordinary shares were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2021 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, 2020
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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, payer, legislative, regulatory and policy landscape, and changes therein, related to our products, including competition from generic forms of our products or competitive products and competitive development programs, barriers to access or coverage of our products and changes in reimbursement of our products, and legislation, regulations, executive orders, guidance or other measures that may limit pricing and reimbursement of, and access to, our products;
- 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 expectations regarding 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 products and intellectual property ("IP"), including our patents;
- our expectations regarding the impact of the ongoing novel coronavirus ("COVID-19") pandemic on our business and operations; 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. In light of these risks, assumptions and uncertainties, the forward-looking events discussed in this Annual Report might not occur. 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. 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.

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks are described more fully in "Item 1A —Risk Factors" in this Annual Report, and include, but are not limited to, the following:

- Our business, financial condition and results of operations have been, and may continue to be, adversely affected by the COVID-19 pandemic or other similar outbreaks of contagious diseases;
- We receive substantial revenue from our key proprietary products and our success depends on our ability to maintain or increase sales of such products;
- 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;
- We face competition in the biopharmaceutical industry;
- There are many factors that could cause our revenues to decrease or grow at a slower than expected rate;
- 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;
- Clinical trials for our product candidates are expensive, may take several years to complete, and their outcomes are uncertain;
- 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 or based on subsequent audit and verification procedures, and may not be indicative of final data from such trials;
- The FDA or other regulatory agencies may not approve our products or may delay approval;
- The FDA or other regulatory agencies may impose limitations or post approval requirements on any product approval;
- We are subject to risks related to the manufacture of our products;
- We rely on third parties to provide services in connection with the manufacture and distribution of the products we manufacture;
- Patent and other IP protection for our products is key to our business and our competitive position but is uncertain;
- 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 negatively impact commercialization of our products, and could adversely affect our business;
- We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers;
- Litigation or arbitration filed against Alkermes, including securities litigation, or regulatory actions (such as citizens petitions) filed against regulatory agencies in respect of our products, may result in financial losses, harm our reputation, divert management resources, negatively impact the approval of our products, or otherwise negatively impact our business;
- If there are changes in, or 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;
- We may not become profitable on a sustained basis;
- Our level of indebtedness could adversely affect our business and limit our ability to plan for or respond to changes in our business;
- The business combination of Alkermes, Inc. and the drug technology business of Elan Corporation, plc may limit our ability to use our tax attributes to offset taxable income, if any, generated from such business combination;
- The market price for our ordinary shares has been volatile and may continue to be volatile in the future, and could decline significantly;

- Our business could be negatively affected as a result of the actions of activist shareholders; and
- Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

The material and other risks summarized above should be read together with the text of the full risk factors below in "Item 1A —Risk Factors" and in the other information set forth in this Annual Report, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. If any such material and other risks and uncertainties actually occur, our business, financial condition, cash flows or results of operations could be materially and adversely affected. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, cash flows or results of operations.

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 and product candidates 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®, LYBALVI™, 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; 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"); REXULTI®— H. Lundbeck A/S plc; PERSERIS®, SUBOXONE®, SUBUTEX® and SUBLOCADE®—Indivior plc (or its affiliates); VRAYLAR®— Forest Laboratories, LLC; ZEPOSIA®—Bristol-Myers Squibb Company; ZUBSOLV®—Orexo US, Inc.; and ZYPREXA® and ZYPREXA RELPREVV®—Eli Lilly and Company ("Lilly"). 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.

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 key licensed products, and key 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 have developed and commercialize products designed to address the unmet needs of patients suffering from opioid dependence, alcohol dependence and schizophrenia. See "Patents and Proprietary Rights" in "Item 1—Business" in this Annual Report for information with respect to the IP protection for our proprietary products.

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) leverages our proprietary NanoCrystal technology and provides an extended-release formulation of aripiprazole lauroxil in a smaller particle size compared to ARISTADA, thereby enabling faster dissolution and more rapid achievement of relevant levels of aripiprazole in the body. ARISTADA INITIO, combined 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. 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 2.4 million adults 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 and other IP protection for our products is key to our business and our competitive position but is uncertain," "—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 negatively impact commercialization of our products, and could adversely affect our business" and "—Litigation or arbitration filed against Alkermes, including securities litigation, or regulatory actions (such as citizens petitions) filed against regulatory agencies in respect of our products, 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 2019 U.S. National Survey on Drug Use and Health, an estimated 1.5 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 2019 U.S. National Survey on Drug Use and Health, an estimated 14.1 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. See "Patents and Proprietary Rights" in "Item 1—Business" in this Annual Report for information with respect to the IP protection for these 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.

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 dosed once every three months. INVEGA TRINZA/TREVICTA uses our proprietary technology and is manufactured by Janssen.

For a discussion of legal proceedings related to the patents covering INVEGA SUSTENNA and INVEGA TRINZA, 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 IP rights covering our products and competition from generic drug manufacturers."

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 IP rights covering our products and competition from generic drug manufacturers."

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

VUMERITY (diroximel fumarate) 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.

What is multiple sclerosis?

Multiple sclerosis, or MS, is an unpredictable, often disabling disease of the central nervous system (“CNS”), which interrupts the flow of information within the brain, and between the brain and body. 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 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. As part of our ongoing R&D efforts, we have devoted, and will continue to devote, significant resources to conducting preclinical 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.

LYBALVI (formerly referred to as ALKS 3831)

LYBALVI (olanzapine/samidorphan) 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. LYBALVI is composed of samidorphan, a novel, new molecular entity, co-formulated with the established antipsychotic agent, olanzapine, in a single bilayer tablet.

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

In November 2020, we received a Complete Response Letter (“CRL”), which included a request for information, from the U.S. Food and Drug Administration (“FDA”) regarding the LYBALVI New Drug Application (“NDA”), following its remote review of manufacturing records requested under Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (the “FDCA”) relating to the manufacture of LYBALVI at our Wilmington, Ohio facility. In December 2020, we resubmitted the NDA, and the FDA acknowledged receipt of our NDA resubmission and assigned the NDA a Prescription Drug User Fee Act (“PDUFA”) target action date of June 1, 2021. Following our NDA resubmission, the FDA issued a new request for records under Section 704(a)(4) of the FDCA to supplement the information that we previously provided.

The LYBALVI NDA is a 505(b)(2) NDA and includes data from the ENLIGHTEN clinical development program in patients with schizophrenia, as well as PK bridging data comparing LYBALVI and ZYPREXA. For more information about 505(b)(2) NDAs, see the “Regulatory, Hatch-Waxman Act” section of “Item 1—Business” in this Annual Report. We are seeking approval of LYBALVI 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, and of fixed dosage strengths of LYBALVI composed of 10 mg of samidorphan co-formulated with 5 mg, 10 mg, 15 mg or 20 mg of olanzapine.

nemvaleukin alfa (formerly referred to as ALKS 4230)

Nemvaleukin alfa ("nemvaleukin") is an investigational, novel, engineered fusion protein comprised of modified interleukin-2 ("IL-2") and the high affinity IL-2 alpha receptor chain, designed to selectively expand tumor-killing immune cells while avoiding the activation of immunosuppressive cells by preferentially binding to the intermediate-affinity IL-2 receptor complex. The selectivity of nemvaleukin is designed to leverage the proven antitumor effects of existing IL-2 therapy while mitigating certain limitations.

ARTISTRY is our clinical development program evaluating nemvaleukin in patients with advanced solid tumors. ARTISTRY-1 and ARTISTRY-2 are phase 1/2 studies evaluating the safety, tolerability, efficacy and pharmacokinetic and pharmacodynamic effects of nemvaleukin in patients with refractory advanced solid tumors, in both monotherapy and combination settings with the PD-1 inhibitor pembrolizumab. Nemvaleukin is being evaluated with intravenous administration in ARTISTRY-1 and with subcutaneous administration in ARTISTRY-2. ARTISTRY-3 is a phase 2 study evaluating the clinical and immunologic effects of nemvaleukin monotherapy administered intravenously on the tumor microenvironment in a variety of advanced, malignant solid tumors.

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.

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%.

Revenues from our collaborative arrangements with Janssen accounted for approximately 33%, 28% and 29% of our consolidated revenues for the years ended December 31, 2020, 2019 and 2018, respectively.

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 each of the following payments under our amended and restated license agreement with Acorda for achievement of the following milestones with respect to each of the third and fourth new indications for which the product is 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.

Revenues from Acorda related to this license and collaboration agreement accounted for approximately 5%, 3% and 10% of our consolidated revenues for the years ended December 31, 2020, 2019 and 2018, respectively.

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 that 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 certain milestones, including milestones relating 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 the patents that we 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. Biogen has elected to initiate a technology transfer and, following a transition period, assume responsibility 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 that portion 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.

Revenues from Biogen related to this license and collaboration agreement accounted for approximately 2%, 17% and 10% of our consolidated revenues for the years ended December 31, 2020, 2019 and 2018, respectively.

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 and in the development of our products.

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 the products we manufacture" 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 outsource 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 several products in our Athlone, Ireland facility that are marketed by third parties, including AMPYRA, FAMPYRA and VUMERITY. 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.

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 manufacture 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 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 relevant 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, 2020 to Cardinal Health, McKesson Corporation and AmerisourceBergen Corporation ("AmerisourceBergen") represented approximately 23%, 21% and 13%, 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, 2020 to Cardinal Health, McKesson Corporation and AmerisourceBergen represented approximately 48%, 24% and 21%, 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, 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. In many cases, there are already products on the market that may be in direct competition with our commercial products or products in development. In addition, there are many companies developing products with similar technologies to ours or for use in similar indications with whom we and our licensees compete, many of whom are larger and have significantly greater financial and other resources than we do. Other smaller or earlier stage companies may also prove to be significant competitors, particularly through focused development programs and collaborative arrangements with large, established companies. Some of the products being developed by our competitors are being designed to work differently than our products and may turn out to be safer or more effective than our products, which may render our products or technology platforms obsolete or noncompetitive. 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, Teva Pharmaceuticals Industries Ltd., which is developing a risperidone extended-release injectable suspension for subcutaneous use and a once every two weeks injectable microsphere formulation, in each case for the treatment of schizophrenia and has filed an Abbreviated New Drug Application (“ANDA”) seeking approval to commercialize a generic version of VIVITROL (naltrexone for extended-release injectable suspension).

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 antipsychotic 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 Abbvie Inc.; 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; BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences; and ZUBSOLV (buprenorphine and naloxone) marketed by Orexo US, Inc. VIVITROL also competes with methadone, oral naltrexone and generic versions of SUBUTEX and SUBOXONE sublingual tablets. Other pharmaceutical companies are developing products that have shown promise in treating opioid dependence that, if approved by the FDA, would compete with VIVITROL.

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;

AUBAGIO and LEMTRADA from Sanofi-Aventis; and ZEPOSIA from Bristol-Myers Squibb Company.

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 non-U.S. 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
10,351,529	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
10,639,376	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
10,813,928	ARISTADA	2035
10,016,415	ARISTADA INITIO	2035
10,688,091	ARISTADA INITIO	2035
10,849,894	ARISTADA INITIO	2035

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. 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 one unexpired Orange-Book listed U.S. patent covering VIVITROL, which expires 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 remaining 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. For a discussion of legal proceedings related to the U.S. patent covering VIVITROL, see Note 19, *Commitments and Contingent Liabilities*, in the "Notes to Consolidated Financial Statements" in this Annual Report.

INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA

Our NanoCrystal technology patent portfolio, licensed to Janssen in relation to INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA, contains a number of granted patents and pending patent applications throughout the world, including in the U.S. and in countries outside of the U.S. The latest of the patents subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expires in 2030 in the U.S. and certain other countries and in 2022 in the EU. The latest to expire of the licensed patents covering INVEGA TRINZA/TREVICTA in the U.S. expired in 2017 and in the EU will expire in 2022. In addition, Janssen has other patents not subject to our license agreement, including one that covers INVEGA SUSTENNA in the U.S. and expires in 2031 and one that covers INVEGA TRINZA in the U.S. and expires in 2036. For a discussion of legal proceedings related to one of 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 non-U.S. 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 recently received a Paragraph IV certification related to VUMERITY. For a discussion of risks related to this certification, 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 also have worldwide patent protection for our Key Development Programs:

LYBALVI

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 LYBALVI. In addition, we own U.S. and worldwide patents and patent applications that claim formulations and methods of treatment that cover LYBALVI. The principal owned or licensed U.S. patents for LYBALVI and their expiration dates are as follows:

U.S. Patent No.	Product(s) Covered	Expiration Date
7,956,187	LYBALVI	2021
8,252,929	LYBALVI	2021
7,262,298	LYBALVI	2025
8,680,112	LYBALVI	2030
9,119,848	LYBALVI	2031
10,005,790	LYBALVI	2031
8,778,960	LYBALVI	2031
9,126,977	LYBALVI	2031
9,517,235	LYBALVI	2031
9,943,514	LYBALVI	2031
10,300,054	LYBALVI	2031
10,716,785	LYBALVI	2031

nemvaleukin alfa

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

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 or technologies. 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 or technologies, 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 the laws of the U.S.

We also rely on trade secrets, know-how and inventions, 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. However, any of these parties may breach such agreements and may disclose our confidential information or our competitors might learn of the information in some other way. If any trade secret, know-how or other invention 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, ARISTADA INITIO and LYBALVI are important to us and are generally covered by trademark applications or registrations with 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., preclinical 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.

Preclinical Testing: Before beginning testing of any compounds with potential therapeutic value in human subjects in the U.S., stringent government requirements for preclinical data must be satisfied. Preclinical 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: Preclinical 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 Application (“IND”), and are reviewed by the FDA prior to the commencement of human clinical trials. The preclinical 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 a 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 applicable 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 preclinical 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, recommendation as to whether the application should be approved or other guidance that the FDA may seek. The FDA is not bound by the recommendation of an advisory committee; however, historically, it has often 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 support the safe use of the drug.

In reviewing a BLA or NDA, the FDA may grant marketing approval, or issue a CRL to communicate to the applicant the reasons the application cannot be approved in its then-current form and provide input on the additional information that the FDA requires and/or changes that must be made before an application can be approved. Even if such additional information are submitted to the FDA or such changes made, the FDA may ultimately decide that the BLA or NDA still does not satisfy the FDA's 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 preclinical 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 for a given product. 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 also 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, other relevant regulatory authorities 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. In 2020, the COVID-19 pandemic has in some instances impacted the FDA's and other regulatory agencies' ability to conduct on-site inspections and has resulted in such agencies either delaying planned inspections or collecting the requisite information through review of written records in lieu of an on-site inspection, which in some instances has negatively impacted timelines for potential product approvals. Once approval from a regulatory agency is obtained, if 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 and may also request that certain information or records be provided in writing for review in lieu of an on-site visit. If, as a result of these inspections or records reviews, 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 in which 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 U.S. government under the 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 there are changes in, or 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 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 an increases in our financial obligation to payers could result in decreased sales of our products and decreased revenues" and "—The clinical study or 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 U.S. 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 U.S. 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 (including the Indian 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, 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 became effective 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, including any such 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.

Human Capital Resources

As a global biopharmaceutical company focused on developing innovative medicines in the fields of neuroscience and oncology, we have built, and continue to devote significant resources to further develop and enhance, a comprehensive cross-functional infrastructure designed to support product development from discovery through commercialization and lifecycle management. We seek to attract, hire, develop and retain qualified and highly skilled personnel with experience in areas such as R&D, including early discovery and clinical development capabilities; intellectual property prosecution, enforcement and defense; medical

affairs; manufacturing operations; U.S. federal and state government affairs; sales and marketing; and market access. Competition for such personnel in our industry and the geographic regions in which we operate is intense, with numerous companies also developing, launching or marketing products, including products against which our products directly compete. Supporting our employees' well-being in a transparent, diverse, inclusive, and collaborative culture and providing them with the training, support and resources they need to succeed professionally while appropriately balancing their professional and personal lives helps keep our employees connected and engaged and are critical to our success.

As of February 5, 2021, we had approximately 2,245 full time employees, of which approximately 1,834 were based in the U.S. and 411 were based in Ireland. Our 2020 voluntary attrition rate was below industry benchmarks. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

We are an equal opportunity employer and we are fundamentally committed to creating and maintaining a work environment in which employees are treated with respect and dignity. All human resources policies, practices and actions related to hiring, promotion, compensation, benefits and termination are administered in accordance with the principal of equal employment opportunity, meaning that they are made on the basis of individual skills, knowledge, abilities, job performance and other legitimate criteria and without regard to race, color, religion, sex, sexual orientation, gender expression or identity, ethnicity, national origin, ancestry, age, mental or physical disability, genetic information, any veteran status, any military status or application for military service, or membership in any other category protected under applicable law.

Recognizing the value of our employees and their important contributions to the achievement of our business objectives, we offer market-competitive comprehensive total rewards pay and benefits packages, including bonus opportunities at all levels tied to individual and company performance, and for employees at certain levels, company equity opportunities. We also offer healthcare and retirement savings plan benefits, paid time off, tuition reimbursement and other benefits designed to support healthy lifestyle choices, financial wellness and work-life balance.

Across all of our sites, we actively cultivate a work environment that reflects our values of collaboration at our core, respect for each voice and unwavering commitment. In 2019, we created a global Diversity, Inclusion & Belonging Steering Committee, comprised of representatives from all of our locations, including our field-based employees, and a variety of functional areas to create connections and celebrate our diverse workforce by developing and advancing practices, tools and resources that can be used to strengthen the sense of belonging among our employee base. In 2020, we established three employee-led resource groups: Pride@ Work, an LGBTQ+ and ally network; Mosaic, a multicultural network; and Women Inspired Network (WIN), a women's network, with a common purpose of supporting and enhancing the inclusiveness of our company culture and providing opportunities for professional development, networking and building deeper connections within Alkermes based on cross-functional employee involvement. As part of our increased focus on the importance of social and racial justice, diversity and inclusion, and in response to global events throughout 2020, we also held company-wide town hall conversations, sponsored recognition events and enhanced our company's diversity education and training.

We strive to foster a strong culture of active employee engagement to ensure that employees feel part of our mission and that they have a voice in the Alkermes community. Since 2017, we have conducted annual employee engagement surveys to understand employee sentiment regarding, and satisfaction with, their work and experience at Alkermes. In 2020, nearly 75% of our employees participated in the employee engagement survey and we have used the data collected to help inform our human capital management strategy.

We are committed to the professional growth and development of our employees. We conduct a comprehensive on-boarding experience that connects newly hired employees to our business, values, culture, and people. We organize frequent company-hosted trainings that cover topics including performance management, problem solving, leadership development, communication, and mentorship, as well as more specialized skills-based programs. We also encourage and support our employees in their efforts to seek out additional professional learning opportunities within Alkermes and externally.

Our culture is one of collaboration, compliance and trust, and we rely on our employees to help us promote and provide workplace environments that are safe and protective of the health and well-being of our people and in compliance with applicable laws, rules and regulations. We maintain extensive environmental, health safety and security policies, adhere to all health and safety standards set by regulators in the locations in which we operate and routinely train employees and monitor our sites to reduce the risk of workplace accidents.

In 2020, employee health, safety and wellness were of particular focus and importance for the company. Following the emergence of the COVID-19 pandemic, we adapted our business practices to support uninterrupted supply of, and patient access to, our marketed products for people living with addiction and serious mental illness. We also adopted a series of precautionary measures to protect and support our employees, including those performing essential tasks in our laboratories and manufacturing facilities who could not perform their work remotely. For additional information about actions taken by the Company to support its employees and

other stakeholders in response to the COVID-19 pandemic, see the "COVID-19 Update" included in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report.

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.

Risks Related to Our Business and our Industry

Our business, financial condition and results of operations have been, and may continue to be, adversely affected by the COVID-19 pandemic or other similar outbreaks of contagious diseases.

Outbreaks of contagious diseases and other adverse public health developments affecting us and/or the third parties on which we rely, could have a material and adverse effect on our business, financial condition and results of operations. The COVID-19 pandemic has impacted, and is continuing to impact, many aspects of society, including the operation of the healthcare system and other business and economic activity worldwide. Almost all U.S. states, many local jurisdictions and countries across the world have, at various times throughout the pandemic, issued "shelter-in-place" orders, quarantines, and restrictions and recommendations for their residents to control the spread of COVID-19, resulting in widespread closures of businesses, work stoppages, slowdowns and delays, work-from-home policies and travel restrictions, among other effects.

The COVID-19 pandemic has had, and may continue to have, an adverse impact on our financial condition and results of operations. For example, commercial sales of the medicines from which we derive revenue—consisting primarily of injectable medications administered by healthcare professionals—have been, and we expect will continue to be, adversely impacted as a result of developments that have transpired, and may continue to transpire, related to this pandemic, including travel restrictions and social distancing measures, many of which have contributed to limited access to healthcare providers and locations where injectable medications may be administered. Further, this pandemic and measures to mitigate the spread of COVID-19 have had, and may continue to have, an adverse effect on global economic conditions, which could have an adverse effect on our business and financial condition, including the demand for, and ability of patients to access, our and our licensees' medicines, or our ability to obtain financing, if needed, on favorable terms or at all.

The COVID-19 pandemic has, to varying degrees, disrupted our business operations and the business operations of the third parties on which we rely, including our suppliers, packagers, distributors, contract research organizations, customers, clinical site investigators, community advocacy partners, and others, and may continue to do so for so long as the pandemic and its impacts persist. For example, the third-party sites and investigators involved in our clinical trials have experienced, and may continue to experience, interruptions which have impacted, and may continue to impact, the conduct of our clinical trials and our ability to complete them in a timely manner or at all. If our clinical programs are significantly delayed as a result of such impacts, there could be adverse effects on our expected timelines for regulatory review and potential approval of our product candidates.

The COVID-19 pandemic has also impacted, and may continue to impact, the regulatory agencies with which we interact in the development, manufacture, regulatory review and commercialization of our medicines. For example, travel restrictions and social distancing measures have impacted the manner in which the FDA, the HPRA and other regulatory agencies conduct their pre- or post-approval inspections of manufacturing facilities, relying more heavily on remote record reviews than in-person interactions. If such regulatory agencies do not find the results of such remote reviews to be sufficient for their regulatory purposes, our manufacturing activities or expected timelines for regulatory review and approval of our product candidates may be delayed, which could have an adverse effect on our business and the market price for our ordinary shares. For example, we received a CRL from the FDA, which included a request for information, regarding the NDA for LYBALVI following the FDA's remote review of records relating to the manufacture of LYBALVI at our Wilmington, Ohio facility. We subsequently resubmitted our NDA, and the FDA assigned the application a PDUFA target action date of June 1, 2021. Following our resubmission, the FDA issued a new request for records to supplement information that we previously provided. There is no guarantee that the FDA's remote review of our resubmission and additional records will be sufficient to meet the FDA's requirements for approval of LYBALVI without the conduct of a pre-approval inspection.

Despite the spread of COVID-19 across the U.S., we have begun to observe, and expect to continue to observe, a gradual normalization in patient and healthcare provider practices, as providers and patients have adapted their behaviors and procedures to the evolving circumstances and as COVID-19 vaccines continue to be administered. However, the degree to which the ongoing COVID-19 pandemic may continue to impact our business, financial condition and results of operations will depend on the ultimate severity and duration of this pandemic and the manner in which it continues to evolve, and future developments in response thereto, which are highly uncertain and cannot be predicted as of the date of this Annual Report and which may include, among other things, governmental, business or other actions that have been, or will be, taken in response to this pandemic, including continued restrictions on travel and mobility, business closures and imposition of social distancing measures; impacts of the pandemic on our employees, the vendors or distribution channels in our supply chain and on our ability to continue to manufacture and supply our products; impacts of the pandemic on the conduct of our clinical trials, including with respect to enrollment rates, availability of investigators and clinical

trial sites, and monitoring of data; impacts of the pandemic on healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia; impacts of the pandemic on the regulatory agencies with which we interact in the development, review, approval and commercialization of our medicines; impacts of the pandemic on reimbursement for our products, including our Medicaid rebate liability, and for services related to the use of our products; and impacts of the pandemic on the U.S., Irish and/or global economies more broadly. For example, if the U.S. Consumer Price Index—Urban (CPI-U) becomes negative, this would increase our Medicaid rebate liability. For a discussion of the Medicaid rebate liability, please see the "Pricing and Reimbursement" section in "Item 1—Business" in this Annual Report.

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

Sales of our proprietary products comprise an increasingly significant portion of our revenues. We developed and exclusively manufacture VIVITROL for the treatment of alcohol dependence and opioid dependence, ARISTADA for the treatment of schizophrenia, and ARISTADA INITIO for initiation onto ARISTADA for the treatment of schizophrenia, and we exclusively commercialize these products in the U.S. Our success depends in large part on our ability to continue to successfully manufacture and increase sales of such products in the complex markets into which they are sold. Any significant negative developments relating to these products could have a material adverse effect on our revenues from these products and, in turn, on our business, financial condition, cash flows and results of operations and the market price of our ordinary shares.

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 to market and/or successfully commercializing products using our proprietary technologies and from which we receive manufacturing and/or royalty revenue. We rely on these licensees in various respects, including commercializing such products, conducting development activities with respect to new formulations or new indications for such products, and/or managing the regulatory approval process for such products.

We earn significant royalty and/or manufacturing revenue from sales by our licensees of our licensed products and third-party products incorporating our proprietary technologies. The revenues we receive from such products depend primarily upon the success of our licensees in commercializing such products. For example, we receive substantial revenue from Janssen's sales of RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA and upon sales of FAMPYRA by Biogen. We have no involvement in the commercialization efforts for these and other products sold by third parties from which we receive revenue, and cannot control the extent or effectiveness of such commercialization efforts.

Disputes may also arise between us and a licensee involving the ownership of technology developed under a license, the terms and amounts of royalty payments to be paid under a license, or other issues arising out of any licenses or other collaborative agreements. Such disputes may delay related development programs, impact commercialization or manufacturing activities for the related products or result in expensive arbitration or litigation, which may not be resolved in our favor and may adversely impact our financial condition. Further, certain of our license agreements may be terminated without cause, or assigned in connection with a change in control, and we cannot guarantee that any of these relationships will continue or that our licensees will be able or willing to continue to perform their obligations under such agreements. Any significant negative developments relating to our relationships with our licensees or our collaborative arrangements could have a material adverse effect on our business, financial condition, cash flows and results of operations.

For these and other reasons that may be outside of our control, our revenues from products sold by our licensees may fall below our expectations, the expectations of our licensees or those of our shareholders, which could have a material adverse effect on our results of operations and the market price of our ordinary shares.

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 other biopharmaceutical companies, including companies with similar technologies or medicines, and manufacturers of generic drugs. Some of these competitors are also our licensees, who control the commercialization of products from which we receive manufacturing and/or royalty revenues. For example, our proprietary product ARISTADA competes directly with RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA, products from which we receive significant manufacturing and/or royalty revenues.

The biopharmaceutical industry is characterized by intensive research, development and commercialization efforts and rapid and significant technological change. In many cases, there are already products on the market that may be in direct competition with our commercial products or products in development. In addition, there are many companies developing generic versions of our products, or products with similar technologies to ours or for use in similar indications with whom we and our licensees compete, many of whom are larger and have significantly greater financial and other resources than we do. Other smaller or earlier stage companies may also prove to be significant competitors, particularly through focused development programs and collaborative arrangements with large, established companies. Some of the products being developed by our competitors are being designed to work differently than

our products and may turn out to be safer or more effective than our products, which may render our products or technology platforms obsolete or noncompetitive. For a detailed discussion of the competition that we face with respect to our current marketed products, technology platforms and product indications, please see the section entitled "*Competition*" in "Item 1—Business" in this Annual Report. If we are unable to compete successfully in this highly competitive biopharmaceutical industry, our business, financial condition, cash flows and results of operations could be materially adversely affected.

There are many factors that could cause our revenues to decrease or grow at a slower than expected rate.

We cannot be assured that our products will be, or will continue to be, accepted in the U.S. or markets outside the U.S. or that we will be able to maintain or increase sales of our products. Factors that may cause revenues from our products to grow at a slower than expected rate, decrease or cease all together, include, among others:

- 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;
- unfavorable publicity concerning us, our licensees, our products, similar classes of drugs or the industry generally;
- the cost-effectiveness of our products and reimbursement policies of government and third-party payers that may impact use of our products;
- the cost and availability of raw materials necessary for the manufacture of our products;
- the successful manufacture of our products on a timely and cost-effective basis;
- the size of the markets for our products, and patient and physician satisfaction with our products;
- significant changes in the competitive landscape for our products, including any approval of generic versions of our products or other branded products that may compete with our 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 engage third parties to package and/or distribute our products on acceptable terms;
- the unfavorable outcome of investigations, litigation or other legal proceedings, including government requests for information regarding VIVITROL, securities litigation relating to ALKS 5461, IP litigation, including so-called "Paragraph IV" litigation relating to VIVITROL, INVEGA SUSTENNA and INVEGA TRINZA, and litigation or other proceedings before the U.S. Patent and Trademark Office's (the "USPTO") Patent Trial and Appeal Board (the "PTAB") or its equivalent in other jurisdictions outside of the U.S., including opposition proceedings in the EU relating to RISPERDAL CONSTA and any other litigation related to any of our products;
- regulatory developments and actions related to the manufacture, commercialization or continued use of our products, including FDA actions such as the issuance of a REMS or warning letter, or conduct of an audit by the FDA or another regulatory authority in which a manufacturing or quality deficiency is identified;
- the extent and effectiveness of the sales, marketing and distribution support for our products, including our licensees' decisions as to the timing and volume of product orders and 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 manufacturing and/or royalty revenue and the amounts to be paid with respect to such products;
- exchange rate valuations and fluctuations;
- U.S. and global political changes and/or instability, including the recent change in the U.S. presidential administration and 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.;
- the impact that the COVID-19 pandemic may have on the manufacture and commercialization of our products; and
- any other material adverse developments with respect to the commercialization of our products.

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, 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 and coverage restrictions that may be imposed for such product, are uncertain, as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement or other access barriers 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. Over the past several years, a number of states have enacted drug pricing transparency laws that require companies to report on drug price increases and justify how drug prices were set. We expect additional state drug pricing initiatives to be proposed and enacted in 2021 and beyond. 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 2021, we may face uncertainties as a result of continued federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA, the outcome of existing litigation related to 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.

In addition, the outcome or settlement of litigation could impact the practices of healthcare providers and patients, and the policies and practices of third-party payers, including Medicare, Medicaid, managed care providers and private insurance plans, in a manner detrimental to our products, which in turn could materially and adversely affect our business and financial condition. For example, one or more defendants in the opioid multi-district litigation has offered large volumes of generic buprenorphine free of charge to state plaintiffs as settlement compensation, which, if agreed to and approved, could negatively impact state reimbursement policies, healthcare provider practices, and patient access to alternative FDA-approved medications to generic buprenorphine, which includes VIVITROL, for the treatment of opioid dependence.

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.

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 preclinical testing and clinical trials, that our products are safe and effective for use in humans. Designing, conducting and completing a clinical development program is often a lengthy, time-consuming and expensive process. We have incurred, and we will continue to incur, substantial expense for preclinical testing and clinical trials and other activities related to our clinical development programs.

Our preclinical and clinical development efforts may take several years or more, varying substantially with the type, complexity, novelty and intended use of the product and the clinical study designs and methodologies employed, and may not be successfully completed in a timely manner or at all. Timelines for the initiation, conduct and completion of clinical trials may be delayed by many factors, including:

- issues with the opening, operation or inspection of a new or ongoing clinical trial site;
- delays or failures of third-party CROs and other third-party service providers and clinical investigators to manage and conduct the trials, perform oversight of the trials, including data audit and verification procedures, or to meet expected deadlines;
- an inability to recruit clinical trial participants at the expected rate or at all, or to adequately follow participants following treatment;
- unforeseen safety or tolerability issues;
- an inability to manufacture or obtain sufficient quantities of materials used for clinical trials;
- unforeseen governmental or regulatory issues or concerns, including those of the FDA, DEA and other regulatory agencies; and
- global instability, including instability relating to political events or a global pandemic or other contagious disease, such as COVID-19, in or near 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. In these instances, we must depend on third parties, including independent clinical investigators, CROs and other third-party service providers, to successfully conduct our clinical trials and to audit, verify and accurately report results from such trials. Though we do not have much control over many aspects of such third-party activities, 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 planned activities on schedule or conduct our trials in accordance with regulatory requirements or our stated protocols.

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

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

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 or based on subsequent audit and verification procedures, and may not be indicative of final data from such trials.

From time to time, we may announce, publish or report preliminary, topline or interim data from our clinical trials, including those we are conducting in oncology. Such data are subject to the risk that one or more of the clinical outcomes may materially change as patients continue progressing through the study (for example, a patient may progress from a complete or partial response to progressive disease), as patient enrollment continues and/or as more patient data become available, and such data may not be indicative of final data from such trials. Such 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 disclose. As a result, all 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 could significantly harm 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. The U.S. FDA and DEA (to the extent a product is a controlled substance), and comparable regulatory agencies in other jurisdictions, impose substantial and rigorous requirements for the development, manufacture and commercialization of medicines, the satisfaction of which can take 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 plans for product development, manufacture and/or commercialization. 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 and the ultimate decision by the FDA or other regulatory agencies regarding drug approval may not be consistent with prior communications.

The product approval process can last many years, be very costly and still be unsuccessful. Regulatory approval by the FDA or non-U.S. regulatory agencies 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 preclinical 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, plans for accelerated development timelines, 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 to meet their requirements for product approval;
- the FDA or other regulatory agencies might not approve our or our licensees' manufacturing processes or facilities, or those of the CROs and contract manufacturing organizations who conduct research or manufacturing work on our or our licensees' behalf;
- any failure by our clinical investigational sites and the records kept at such sites, including any clinical trial data, to be in compliance with the FDA's GCP, or EU legislation governing GCP, or to pass FDA, EMA or EU member state inspections of clinical trials;
- the FDA or other regulatory agencies may change their requirements for approval or post-approval marketing; and
- adverse medical events during the trials could lead to requirements that trials be repeated or extended, or that a program be terminated or placed on clinical hold, even if other studies or trials relating to the program are successful.

In addition, disruptions at the FDA and other regulatory agencies that are unrelated to our company or our products, including those relating to COVID-19 or other political or economic conditions, could cause delays to the regulatory approval process for our products. As of June 23, 2020, the FDA noted it is continuing to ensure timely review of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals; however, FDA may not be able to continue its current pace and approval timelines could be extended, including in instances when a pre-approval inspection or an inspection of clinical trial sites is required and due to COVID-19 pandemic-related restrictions, the FDA may be unable to complete such required inspections during the review period. In addition, if a prolonged U.S. government shutdown occurs as a result of political or economic conditions or if the COVID-19 pandemic increases in severity or impact, the FDA's ability to timely review and process our regulatory submissions could be significantly impacted.

For example, in December 2020, we resubmitted our NDA for LYBALVI for the treatment of adults with schizophrenia and adults with bipolar I disorder, following receipt from the FDA in November 2020 of a CRL, which included an information request, relating to the manufacture of LYBALVI at our manufacturing facility in Wilmington, Ohio. The FDA accepted the NDA resubmission and assigned the application a PDUFA target action date of June 1, 2021 and subsequently issued a new request for records under Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act to supplement records that we previously provided. The FDA review process for this NDA involves uncertainties and risks, particularly in the current COVID-19 environment, including whether the FDA's remote review of our resubmission and additional records will be sufficient to meet the FDA's requirements for approval of LYBALVI without the conduct of a pre-approval inspection, whether the FDA will have additional requests for records or information in order to complete its review of the NDA, or whether the NDA will be approved in a timely manner, or at all.

Any failure to obtain, or delay in obtaining, regulatory approval for our products will prevent or delay their commercialization and could have a material adverse effect on our business, financial condition, cash flows and results of operations. In addition, any failure to obtain, or delay in obtaining, approval for our products could have a material impact on our shareholders' confidence in the strength of our development capabilities and/or our ability to generate significant revenue from our development program and could result in a significant decline in our share price.

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 approved label may not be consistent with our initial expectations or commercial plans, including limitations on the clinical data that may be included or the indicated uses for which, or the manner in which, the product may be marketed, or the approval may impose 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, as a result, the FDA or other regulatory agencies require us to change the label for our products, or if such post-approval requirements significantly 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. For example, LYBALVI, our product currently under review by the FDA, contains samidorphan, which is currently a scheduled substance. The DEA issued a proposed ruling to deschedule samidorphan in December 2020; however, even if LYBALVI is approved by the FDA, until the DEA issues a final ruling, we will not be able to commercialize LYBALVI as a non-controlled substance. In addition, a final designation that is more restrictive than we expect could adversely affect our ability to commercialize such product and could materially adversely affect our business, financial condition, cash flows and results of operations.

In addition, legislation and regulatory policies relating to post-approval requirements and restrictions on promotional activities for pharmaceutical products, or FDA or DEA regulations, guidance or interpretations with respect to such legislation or regulatory policy, may change, which may impact the development and commercialization of our products.

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, the supply and quality of API, drug product and other product components; failures relating to materials, manufacturing equipment or processes, vendor error, operator error, labor shortages or transportation, physical or electronic security breaches; natural disasters or global disruptions such as the current global pandemic; and many other factors. Problems with manufacturing processes, whether at our facilities or those of our licensees or other third parties which manufacture products or components of products on our behalf, could result in product defects, manufacturing failures or products not being manufactured to their applicable 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 issues in a timely manner, or 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, including LYBALVI. We rely solely on our manufacturing facility in Athlone, Ireland for the manufacture of many products, including AMPYRA, FAMPYRA and VUMERITY and other products using our NanoCrystal or 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 need to shift production among our facilities or transition our manufacturing processes to a third party could take a significant amount of time and money, may not be successful, and could cause significant delay in our ability to supply product.

Our manufacturing facilities also require specialized personnel and are expensive to operate and maintain. Any delay in a regulatory approval or commercial launch, or recall or suspension of sales, of products manufactured in our facilities may cause operating losses as we continue to operate these facilities and retain the required specialized personnel. In addition, any interruption in manufacturing, whether resulting from issues with equipment, materials, personnel or manufacturing processes, or internal or external quality audits or reviews, could result in delays in meeting our contractual obligations and could damage our relationships with our licensees, including the loss of manufacturing and supply rights.

We are also dependent in certain cases on third parties who manufacture or distribute certain products from which we receive revenue. For example, in the cases of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA, we do not have manufacturing rights or any control over the manufacturing, supply or distribution of the product. Supply or manufacturing issues related to such products could materially and adversely affect sales of such products, and in turn our revenue from such products.

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

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 that play a role in our manufacturing activities, and some of these materials and services for our products are currently only available from a single source or a limited number of qualified sources. Although we actively manage these third-party relationships to ensure continuity, quality and compliance with applicable regulations, events beyond our control could result in the complete or partial failure of these goods and services. Any such failure could materially adversely affect our business, financial condition, cash flows and results of operations.

The manufacture of products and product components, including the procurement of bulk drug product and other materials used in the manufacture, packaging, storage and distribution of our products, requires successful coordination among us and multiple third-party providers. Lack of capacity available at such third-party providers or any other issues with the quality or 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.

We endeavor to qualify and register new vendors and to develop contingency plans so that production is not materially impacted by third-party issues. Nonetheless, any such issues could increase our costs, cause us to lose revenue or market share and damage our reputation and may have a material adverse effect on our business, financial condition, cash flows and results of operations.

In addition, we rely heavily on the three largest pharmaceutical wholesalers in the U.S. market, Cardinal Health Inc., AmerisourceBergen Corp. and McKesson Corp, in the distribution of the products that we market and sell. If we are unable to maintain our business relationships with these wholesalers on commercially acceptable terms, if the buying patterns of these wholesalers fluctuate due to seasonality or any other reason 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.

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 non-U.S. 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. Any of our products that are scheduled by the DEA as controlled substances make us subject to the DEA's regulations. We and our third-party providers are subject to unannounced inspections by the FDA, the DEA and comparable U.S. state and non-U.S. agencies in other jurisdictions to confirm compliance with all applicable laws. Any changes to our suppliers or modifications of methods of manufacturing require amendments to our NDAs to the FDA or other regulatory agencies, and ultimate acceptance by such agencies of such amendments, 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, obtain and maintain regulatory authority approval of, and commercialize or supply, products. This could increase our costs, cause us to lose revenue or market share and damage our reputation with our collaboration partners or in the market generally.

In March 2020, in response to the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law in the U.S., and served to increase the FDA's existing authority with respect to drug shortage measures. Under the CARES Act, for each facility where marketed products for certain serious diseases or conditions are manufactured, or where components of such products are manufactured, we are required to have a risk management plan in place that identifies and evaluates risks to the supply of such products or product components, which plans may be subject to review during any FDA inspection. Each of our facilities operates in accordance with a comprehensive quality management system, which includes risk assessment, preventive actions and regular review of inventory levels for each of the marketed products that we manufacture; however, there is no guarantee that the FDA will consider our risk management program to be sufficient upon inspection or that we will not experience shortages in the supply of marketed products that we manufacture, which could materially adversely impact the patients who rely on such marketed products and our business, financial condition, cash flows and results of operations. 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.

Adverse financial market conditions may exacerbate certain risks inherent to our business, including risk of payment from licensees and reimbursement for our products.

Due to volatility in the financial markets, there may be disruptions or delays in the performance of our third-party contractors, suppliers or licensees, or reductions in the availability or extent of reimbursement available to us. For example, we depend on our licensees for significant portions of our revenue. The contracts with our licensees pursuant to which we supply product, or under which we are eligible for certain development or sales milestones, or royalties, related to products that incorporate our proprietary technologies, may not be secured by collateral or other security. Accordingly, we bear the risk that our licensees may not be able to pay amounts due to us under such contracts.

In addition, 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, U.S. 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. If such licensees or other third parties are unable to pay amounts owed to us or satisfy their commitments to us, or if there are reductions to such payments or commitments, our business, financial condition, cash flows and results of operations would be adversely affected.

Our business strategy may involve future transactions which may harm the market price of our ordinary shares or require us to seek additional funds, and such funding may not be available on commercially favorable terms or at all and may cause dilution to our existing shareholders.

In order to achieve our business strategy, we regularly review potential transactions related to technologies, products or product rights, and businesses that are complementary to our business, including mergers, acquisitions, licensing agreements and co-promotion agreements, among others. 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.

In order to finance such transactions, we may require additional funds, and we may seek such funds through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets, monetization of royalty streams 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, our shareholders will suffer dilution of their investment, and it may adversely affect the market price of our ordinary shares. In addition, future investors or lenders may demand, and may be granted, rights superior to those of existing shareholders. If we issue additional debt securities, 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 curtail our operations. We cannot be certain that additional financing will be available from any of these sources when needed or, if available, will be on acceptable terms. 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.

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, 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.

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.

Risks Related to Intellectual Property

Patent and other IP protection for our products is key to our business and our competitive position but is uncertain.

Receiving and maintaining patent and/or trademark protection for our products and technologies, including those that are subject to our licensing arrangements, maintaining our trade secrets, not infringing on the proprietary rights of others, and preventing others from infringing our proprietary rights are each key to our success and our competitive position.

Patent protection 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 products or 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.

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 our products achieve greater commercial sales, potential competitors are more likely to seek to challenge our patents. The laws of certain countries may not protect our IP rights to the same extent as the laws of the U.S., and any patents that we own or license from others may not provide any protection against competitors. 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.

Although 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. If patents exist or are issued that cover our products or technologies, 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 may also require that we redesign affected products, enter into costly settlement or license agreements, 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 that may serve 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 on reasonable terms or at all, or substitute similar technology from another source, our business, financial condition, cash flows and results of operations could be materially adversely affected.

We also rely on trade secrets, know-how and inventions, 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. However, any of these parties may breach such agreements and may 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 invention 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.

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 negatively impact 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, validity and enforceability 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.

Stemming in part from this uncertainty, there has been, and we expect that there may continue to be, significant litigation and an increasing number of *inter partes* reviews ("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, and litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights.

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. Litigation and trial proceedings, such as so-called Paragraph IV litigation and IPRs, concerning patents and other intellectual property rights may be expensive, protracted with no certainty of success, and distracting to management. As a result, we may at times give up certain rights with respect to our IP in order to avoid or resolve timely and costly litigation or IPR proceedings. For example, in July 2019, in order to resolve an IPR instituted by Amneal with the PTAB, 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. Ultimately, the outcome of such litigation and proceedings, or any settlement arrangement with respect thereto, 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, Teva entities filed an ANDA seeking approval to engage in the commercial manufacture, use or sale of a generic version of VIVITROL and alleging that one of our Orange-Book patents related to VIVITROL is invalid, unenforceable and/or will not be infringed by Teva's proposed product. In September 2020, we initiated a Paragraph IV lawsuit against Teva to dispute such claims. Janssen is similarly involved in Paragraph IV litigation with companies seeking approval to market generic versions of INVEGA SUSTENNA and INVEGA TRINZA, products from which we receive significant revenue.

Although we intend to vigorously defend our IP rights, and we expect our licensees to do the same, there can be no assurance that we or our licensees will prevail. 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 Teva or other ANDA filers were to receive FDA approval to sell a generic version of our products or the products from which we receive revenue and/or prevail in any patent litigation with respect to such products, such products would become subject to increased competition, and our business, financial condition, cash flows and results of operations could be materially adversely affected.

Risks Related to Regulatory or Legal Matters

Litigation or arbitration filed against Alkermes, including securities litigation, or regulatory actions (such as citizens petitions) filed against regulatory agencies in respect of our products, 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 are, and may in the future become, involved in various legal proceedings, including those asserting violations of securities and/or fraud and abuse laws and those asserting claims related to product liability, intellectual property and/or contractual arrangements. Such proceedings may involve claims for, or the possibility of, damages or fines and penalties involving substantial amounts of money or other relief, including but not limited to civil or criminal fines and penalties. 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 alleging 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. This and other legal proceedings, and the preparation therefor, could result in substantial costs and a diversion of management's attention and resources, which could harm our business. Moreover, if any of these legal proceedings were to result in an adverse outcome, it could have a material adverse effect on our results of operations and harm our business.

We have been, and may continue to be, the subject of certain government inquiries or requests for documentation. For example, we have received a subpoena and civil investigative demands from U.S. state and federal authorities for documents related to VIVITROL. We are cooperating with the government in each instance. If, as a result of government requests, proceedings are initiated, including under the U.S. federal anti-kickback statute and False Claims Act and state False Claims Acts, 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 U.S. federal funded healthcare programs such as Medicare and Medicaid, 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 those of our sales force, which could have a material adverse 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 have been, and may again 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 may 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.

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

We cannot predict whether the clinical or 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 study participants or patients for a prolonged period of time. Additionally, incidents of product misuse may occur.

These events, among others, could result in product recalls or additional regulatory controls (including additional regulatory scrutiny, REMS programs, and requirements for additional labeling) or product liability actions. 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 the development or 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.

If there are changes in, or 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 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. 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, including audits, records requests and inspections of manufacturing facilities, 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.

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 laws and regulations, and interpretations of the applicability of these laws to our products, operations and 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, access to healthcare, 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 new administration may seek to address such costs through new legislative and/or administrative measures. Such changes in laws, regulations or decisions or in the interpretation of existing laws, regulations and decisions 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. We have developed and implemented a proprietary risk mitigation program to preemptively identify and address environmental, health, safety and security risks; however, there can be no assurance that a violation of current or future environmental, health or safety laws or regulations, will not occur. Any violations, even if inadvertent or accidental, or the cost of compliance with any resulting order, fine or liability that may be imposed, could materially adversely affect our business, financial

condition, cash flows and results of operations.

Risks Related to our Financial Condition and Tax Matters

We may not become profitable on a sustained basis.

At December 31, 2020, our accumulated deficit was $1.5 billion, which was primarily the result of net losses incurred from 1987, the year Alkermes, Inc., was founded, through December 31, 2020, partially offset by net income over certain fiscal periods.

Our ability to achieve sustained profitability in the future will depend on our ability to grow and diversify our revenue and effectively and efficiently manage our costs. Factors that may impact our future revenue, and in turn our future profitability, include our or our licensees' (as applicable) ability to:

- successfully commercialize VIVITROL, the ARISTADA product family, RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, FAMPYRA and any other marketed products for which we earn revenue in the countries in which such products are approved;
- successfully develop, and obtain and maintain regulatory approval for, products both in the U.S. and in other countries;
- manufacture our products and third-party products efficiently and in a cost-effective manner;
- obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third-party payers; and
- achieve certain product development and sales milestones under our collaborative arrangements.

Factors that may impact our future spend, and in turn our future profitability, include:

- the scope of our research and development activities, including the number of products, indications or new technologies that we may pursue, and our ability to share development costs through potential collaborations;
- the time and expense required to pursue FDA and/or other regulatory approvals for our products;
- the time and expense required to prosecute, enforce, defend and/or challenge patent and other IP rights;
- the cost of operating and maintaining our manufacturing and research facilities;
- the costs of doing business with third-party vendors, including suppliers, manufacturers, packagers and distributors;
- the cost of possible licenses or acquisitions of technologies, compounds or product rights or the potential acquisition of other assets, including equipment, facilities or businesses;
- the costs related to potential litigation, arbitration or government requests for information;
- the costs of defending against potential proxy contests or other activist shareholder actions; and
- the costs associated with recruiting, compensating and retaining a highly skilled workforce in an environment where competition for such employees is intense.

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 changed 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 are not entirely certain. These changes to the 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.

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

At December 31, 2020, we had $111.2 million of amortizable intangible assets and $92.9 million of goodwill. Under accounting principles generally accepted in the U.S. ("GAAP"), we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite-lived intangible assets have been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

Our effective tax rate may increase.

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

Our deferred tax assets may not be realized.

As of December 31, 2020, we had $86.2 million in net deferred tax assets in the U.S. Included in this amount was approximately $2.1 million of U.S. federal net operating loss ("NOL") carryforwards and $40.9 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 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 valuation 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 $86.2 million an amount of $40.5 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" in this Annual Report for details of the price of our ordinary shares). Unless the price of our ordinary shares increases, we will incur a deferred tax expense as our U.S.-based employees exercise or forfeit their stock options and their restricted stock unit awards 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.

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, 2020, our borrowings consisted of $276.4 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 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 2023. 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.

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.

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.

Risks Related to our Ordinary Shares

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

The market price for our ordinary shares has fluctuated significantly from time to time. During the year ended December 31, 2020, the closing price of our ordinary shares on the Nasdaq Global Select Market ranged from $13.06 to $22.00 per share. 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, our ability to achieve profitability, 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, and potential legislation to regulate drug pricing, 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. We have also experienced significant volatility in the market price of our ordinary shares based on our business performance, including in relation to our commercial sales and the financial guidance that we issue for such sales, results from our clinical development programs, and events relating to regulatory actions and interactions related to our product candidates and commercial products. For example, a series of adverse actions by the FDA in 2018 relating to our NDA for ALKS 5461, our investigational product for the treatment of major depressive disorder, caused the market price of our ordinary shares to decline significantly.

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 our industry over the last several years. Activist shareholders may agitate, either publicly or privately, for changes to a company's board of directors, management, structure, spend or strategic direction, among other things. Such actions may cause significant disruption to a company's operations and cause a company to expend a significant amount of time and resources in responding to their requests.

In December 2020, we engaged in extensive dialogue with an activist shareholder, resulting in our entry into a cooperation agreement with such activist in which we agreed on certain matters relating to our Board and affirmed our commitment to, and plans for, meeting certain financial targets over a multi-year period. These discussions resulted in the expenditure of significant time and energy by management and our Board and required dedication by the Company of significant resources. We have undertaken, and will continue to implement, several initiatives in order to achieve the financial targets, but there is no assurance that we will achieve these targets, or that doing so will decrease the likelihood of activist shareholder engagement in the future.

If faced with a proxy contest or other activist shareholder request or action in the future, we may not be able or willing to respond successfully to the contest, action, or request, which could be significantly disruptive to our business. Even if we are successful, our business could be adversely affected by any proxy contest or activist shareholder request or 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 the future direction of the Company or its business 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.

Any such activist shareholder contests, actions or requests, or the mere public presence of activist shareholders among our shareholder base, could cause the market price for our ordinary shares to experience periods of significant volatility.

Risks Related to Information Security and Data Privacy

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. In addition, the COVID-19 pandemic has required us to implement a global remote work policy for our employees who are able to work remotely. Our partners and third-party providers also possess certain of our sensitive data. The secure maintenance of all such information and the secure performance of our information technology ("IT") systems are critical to our operations and business strategy.

As the dependency on our IT systems increases, the confidentially, integrity and availability of systems and the data that they store is critical to managing our business. While we take prudent measures to secure our IT systems, the risk still exists that such systems may become compromised by successful breaches, malfeasance, human error or technological fault. Certain types of attacks or breaches on our IT systems or infrastructure may go undetected for a prolonged period. Any breakdown, invasion, corruption, destruction or breach of our, our partners' or our third-party providers' technology systems could compromise such IT systems and the information stored there could be accessed, modified, publicly disclosed, lost or stolen, which could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disrupt our operations, damage our reputation and adversely affect our business. Although we retain cybersecurity insurance to cover costs and expenses related to a breach or similar event, any such costs and expenses may exceed the insurance available.

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, the GDPR governs the processing of personal data. The GDPR imposes significant obligations on controllers and processors of personal data, including, high standards for obtaining consent from individuals to process their personal data, robust notification requirements to individuals about the processing of their personal data, a strong 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.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

We lease approximately 14,600 square feet of corporate office space in Dublin, Ireland, which houses our corporate headquarters. This lease expires in 2022 and includes a tenant option to extend the term for an additional five-year period.

We lease two properties in Waltham, Massachusetts. One facility has approximately 180,000 square feet of space and houses corporate offices, administrative areas and laboratories. This lease expires in 2026 and includes a tenant option to extend the term for an additional five-year period. The second property has approximately 220,000 square feet of office space and laboratory space. This lease, which commenced in January 2020 (the "900 Winter Street Lease"), expires in 2035 and includes a tenant option to extend the term for an additional ten-year period.

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.

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 preclinical, 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 5, 2021. In addition, the last reported sale price of our ordinary shares as reported on the Nasdaq Global Select Market on February 5, 2021 was $22.33.

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, 2020. As of December 31, 2020, 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, 2020, we acquired 5,367 Alkermes ordinary shares, at an average price of $17.54 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 4, 2021, 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

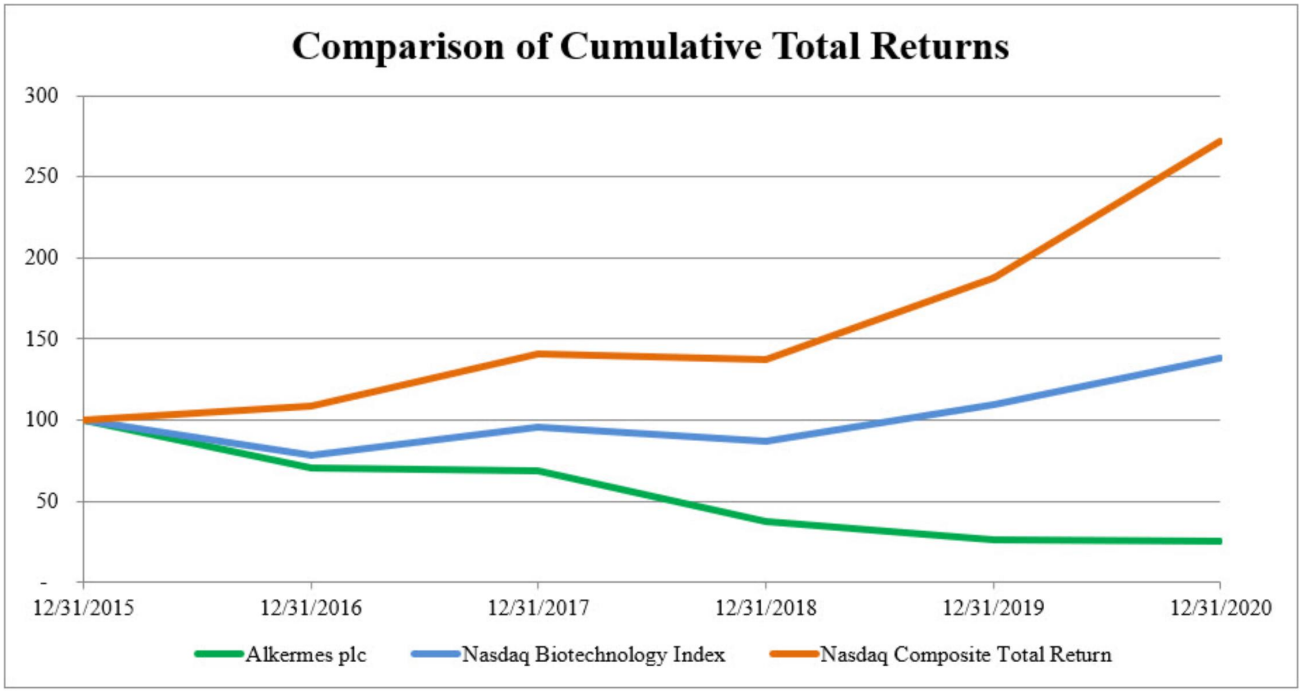
Irish stamp duty, if any, may become payable in respect of ordinary share transfers. However, a transfer of our ordinary shares from a seller who holds shares through DTC to a buyer who holds the acquired shares through DTC should not be subject to Irish stamp duty. A transfer of our ordinary shares (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, 2015 through December 31, 2020 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, 2015 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,					
	2015	2016	2017	2018	2019	2020
Alkermes	100	70	69	37	26	25
Nasdaq Composite Total Return	100	109	141	137	187	272
Nasdaq Biotechnology Index	100	79	96	87	109	138

Item 6. *Selected Financial Data*

The selected historical financial data set forth below at December 31, 2020 and 2019 and for the years ended December 31, 2020, 2019 and 2018 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, 2018 and for the years ended December 31, 2017 and 2016 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)	**2020**	**2019**	**2018**	**2017**	**2016**
Consolidated Statements of Operations Data:					
REVENUES(1):					
Product sales, net	$ 551,760	$ 524,499	$ 450,334	$ 362,834	$ 256,146
Manufacturing and royalty revenues (2)	484,000	447,882	526,675	505,308	487,247
Research and development revenue	1,946	52,816	68,895	7,232	2,301
License revenue	1,050	145,750	48,370	28,000	—
Total revenues	1,038,756	1,170,947	1,094,274	903,374	745,694
EXPENSES:					
Cost of goods manufactured and sold	178,316	180,385	176,420	154,748	132,122
Research and development(3)	394,588	512,833	425,406	412,889	387,148
Selling, general and administrative	538,827	599,449	526,408	421,578	374,130
Amortization of acquired intangible assets	39,452	40,358	65,168	62,059	60,959
Restructuring(4)	—	13,401	—	—	—
Total expenses	1,151,183	1,346,426	1,193,402	1,051,274	954,359
OPERATING LOSS	(112,427)	(175,479)	(99,128)	(147,900)	(208,665)
OTHER INCOME (EXPENSE), NET	15,890	(21,577)	(27,839)	4,626	(5,722)
LOSS BEFORE INCOME TAXES	(96,537)	(197,056)	(126,967)	(143,274)	(214,387)
PROVISION (BENEFIT) FOR INCOME TAXES	14,324	(436)	12,344	14,671	(5,943)
NET LOSS	$ (110,861)	$ (196,620)	$ (139,311)	$ (157,945)	$ (208,444)
LOSS PER ORDINARY SHARE:					
BASIC AND DILUTED	$ (0.70)	$ (1.25)	$ (0.90)	$ (1.03)	$ (1.38)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:					
BASIC AND DILUTED	158,803	157,051	155,112	153,415	151,484
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 659,807	$ 614,370	$ 620,039	$ 590,716	$ 619,165
Total assets	1,949,730	1,805,403	1,825,007	1,797,227	1,726,423
Long-term debt	274,961	277,138	279,308	281,436	283,666
Shareholders' equity	1,066,982	1,085,442	1,171,285	1,202,808	1,209,481

(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").

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 2018 financial condition and results of operations, and of 2019 year-over-year changes as compared to 2018, 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, 2019, which was filed with the SEC on February 13, 2020.

Overview

We earn revenue on net sales of VIVITROL, ARISTADA and ARISTADA INITIO, which are proprietary products that we manufacture, market and sell in the U.S., and manufacturing and/or royalty revenues on net sales of products commercialized by our licensees. Our key marketed products are expected to generate significant revenues for us in the near- and medium-term and we believe are singular or competitively advantaged products in their classes. In 2020, these key marketed products consisted of VIVITROL; ARISTADA and ARISTADA INITIO; INVEGA SUSTENNA/XEPLION; INVEGA TRINZA/TREVICTA; and RISPERDAL CONSTA.

In 2020, we incurred an operating loss of $112.4 million, as compared to $175.5 million in 2019. Revenues decreased by 11% in 2020, as compared to 2019, which was primarily due to revenue earned in 2019 under our license and collaboration agreement with Biogen for VUMERITY and reduced net sales of VIVITROL in 2020 due to the impact of COVID-19. This was partially offset by increased net sales of ARISTADA in 2020. Also contributing to the decrease in our operating loss in 2020 as compared to 2019, was a 15% decrease in operating expenses, which was primarily due to a $60.6 million decrease in SG&A expense in 2020, a $86.6 million charge related to the IPR&D acquired as part of the acquisition of Rodin Therapeutics, Inc. ("Rodin") in 2019 and a $13.4 million charge in 2019 related to the Restructuring. These items are discussed in further detail within the "Results of Operations" section below.

In December 2020, we announced a value enhancement plan designed to drive growth, improve operational and financial performance and enhance shareholder value. The value enhancement plan includes a commitment to certain multi-year profitability targets, a review and optimization of our cost structure, potential monetization of our non-core assets, and continued governance enhancements. A newly formed committee of our board of directors is responsible for overseeing achievement of the profitability targets and the potential monetization of our non-core assets.

We have already undertaken several important initiatives to support this plan, including a reorganization of our commercial infrastructure in November 2020 and an ongoing review of our operations and cost structure, both internally and with external advisors, to identify potential areas for improved efficiencies. We are also exploring a broad range of strategic opportunities, including potential strategic collaborations for nemvaleukin and monetization of our non-core assets, whether through divestment or other means. Any such collaboration or monetization, if effected, may impact our financial condition and operating results and may result in impairment charges related to our long-lived assets and/or adverse impacts on our liquidity.

COVID-19 Update

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization. To date, COVID-19 has surfaced in nearly all regions around the world and resulted in travel restrictions and business slowdowns and/or shutdowns in affected areas. All U.S. states, and many local jurisdictions and countries around the world, including Ireland, have, at times during the pandemic, issued "shelter-in-place" orders, quarantines, executive orders and similar government orders, restrictions, and recommendations for their residents to control the spread of COVID-19. Such orders, restrictions and/or recommendations, and/or the perception that additional orders, restrictions or recommendations could occur, have resulted in widespread closures of businesses, including healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia, work stoppages, slowdowns and/or delays, work-from-home policies and travel restrictions, among other effects.

We continue to closely monitor and rapidly respond to the ongoing impact of COVID-19 on our employees, our communities and our business operations. We have adopted a series of precautionary measures and will continue to do so as the circumstances warrant, in an effort to protect our employees and mitigate the potential spread of COVID-19 in a community setting. For example, we instituted a global remote work policy for those of our employees who are able to work remotely. Certain of our field-based employees have since resumed in-person interactions, as appropriate and on a voluntary basis, in accordance with location-specific guidance.

At the same time, we have worked to continue our critical business functions, including continued operation of our manufacturing facilities and our laboratories, and have continued to conduct our discovery efforts and supply our medicines. For those

of our employees who work in our manufacturing facilities and laboratories or who otherwise enter any of our sites, we have instituted, and will continue to institute as we deem appropriate and as required, additional safety precautions, including increased sanitization of our facilities, use of personal protective equipment, implementation of a daily health screening application and physical distancing practices to help protect their health and safety. We have also taken actions to support people living with schizophrenia, opioid dependence and alcohol dependence to help assure that they have access to the information, resources and medicines that may assist in their treatment.

The marketed products from which we derive revenue, including manufacturing and royalty revenue, are primarily injectable medications administered by healthcare professionals. Given developments that have transpired to date, and may continue to transpire, in response to the pandemic, including the implementation of "shelter-in-place" policies, social distancing requirements and other restrictive measures, commercial sales of these marketed products have been adversely impacted to varying degrees and we expect commercial sales of these marketed products to continue to be adversely impacted while the pandemic persists.

As it relates to our proprietary marketed products, during the three months ended December 31, 2020, we saw a decrease of 5% in the number of VIVITROL units sold compared to the three months ended September 30, 2020. ARISTADA units sold during the three months ended December 31, 2020 increased 12% compared to the three months ended September 30, 2020. During the three months ended December 31, 2020, we continued to take actions to support uninterrupted access to our proprietary marketed products. However, we currently expect commercial sales of our marketed products, particularly VIVITROL, to continue to be impacted by the COVID-19 pandemic over the next few quarters. These items are discussed in greater detail later in the "Results of Operations" section in this "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report.

While we continue to conduct R&D activities, including our ongoing clinical trials, the COVID-19 pandemic has impacted, and may continue to impact, the timelines of certain of our early-stage discovery efforts and clinical trials. We are working with our internal teams, our clinical investigators, R&D vendors and critical supply chain vendors to continually assess, and mitigate, the potential impact of COVID-19 on our manufacturing operations and R&D activities.

Due to numerous uncertainties surrounding the ongoing COVID-19 pandemic, the actual impact on our financial condition and operating results resulting from the pandemic may differ from our current projections. These uncertainties include, among other things, the ultimate severity and duration of the pandemic; governmental, business or other actions that have been, are being, or will be, taken in response to the pandemic, including restrictions on travel and mobility, business closures and operating restrictions and imposition of social distancing measures; impacts of the pandemic on our employees, the vendors or distribution channels in our supply chain and on our ability to continue to manufacture our products; impacts of the pandemic on the conduct of our clinical trials, including with respect to enrollment rates, availability of investigators and clinical trial sites, and monitoring of data; impacts of the pandemic on healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia; impacts of the pandemic on the regulatory agencies with which we interact in the development, review, approval and commercialization of our medicines; impacts of the pandemic on reimbursement for our products, including our Medicaid rebate liability, and for services related to the use of our products; and impacts of the pandemic on the U.S., Irish and global economies more broadly. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, our financial condition or our results of operations, see "Item 1A—Risk Factors" in this Annual Report.

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, 2020 and 2019:

	Year Ended December 31,			
(In millions, except for % of Sales)	**2020**	**% of Sales**	**2019**	**% of Sales**
Product sales, gross	$ 1,136.2	100.0 %	$ 1,019.4	100.0 %
Adjustments to product sales, gross:				
Medicaid rebates	(291.1)	(25.6) %	(237.0)	(23.3) %
Chargebacks	(100.0)	(8.8) %	(84.4)	(8.3) %
Product discounts	(88.2)	(7.8) %	(78.9)	(7.7) %
Medicare Part D	(56.6)	(5.0) %	(45.2)	(4.4) %
Other	(48.5)	(4.2) %	(49.4)	(4.8) %
Total adjustments	(584.4)	(51.4) %	(494.9)	(48.5) %
Product sales, net	$ 551.8	48.6 %	$ 524.5	51.5 %

Our product sales, net for VIVITROL and ARISTADA and ARISTADA INITIO in 2020 were $310.7 million and $241.0 million, respectively, as compared to $335.4 million and $189.1 million in 2019, respectively.

The increase in product sales, gross was due to a 39% increase in ARISTADA and ARISTADA INITIO gross sales, partially offset by a 4% decrease in VIVITROL gross sales. The increase in ARISTADA and ARISTADA INITIO gross sales was due to a 30% increase in the number of ARISTADA and ARISTADA INITIO units sold and a 6% price increase that went into effect in April 2020. The decrease in VIVITROL gross sales was due to an 8% decrease in the number of VIVITROL units sold, primarily as a result of COVID-19-related disruptions, partially offset by a 6% increase in the selling price of VIVITROL, which went into effect in June 2020. The increase in Medicaid rebates, as a percentage of sales, is primarily due to factors related to the COVID-19 pandemic.

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 the latest to expire of our patents covering VIVITROL in Europe will expire in 2021. 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. We are currently engaged in Paragraph IV litigation with certain Teva entities in respect of the last to expire patent covering VIVITROL in the U.S. For a discussion of these legal proceedings, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Annual Report and for information regarding the risks relating to these legal proceedings, see "Risks Related to our Intellectual Property—We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers". 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 are mostly 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 earned on our licensees' net sales of third-party products using our proprietary technologies are generally 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, 2020 and 2019:

(In millions)	Year Ended December 31, 2020	2019	Change 2020–2019
Manufacturing and royalty revenues:			
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ 274.2	$ 256.9	$ 17.3
RISPERDAL CONSTA	71.4	66.4	5.0
AMPYRA/FAMPYRA	47.9	37.2	10.7
Other	90.5	87.4	3.1
Manufacturing and royalty revenues	$ 484.0	$ 447.9	$ 36.1

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 $3.7 billion and $3.3 billion during the years ended December 31, 2020 and 2019, respectively. 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. Each of INVEGA SUSTENNA and INVEGA

TRINZA are currently subject to Paragraph IV litigation in response to companies seeking to market generic versions of such products. For a discussion of these legal proceedings, 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 these legal proceedings, see "Item 1A—Risk Factors" in this Annual Report, and specifically the section entitled "Risks Related to Intellectual Property—We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

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, in the period that the end-market sale of RISPERDAL CONSTA occurs. The increase in RISPERDAL CONSTA revenue was due to a 13% increase in manufacturing revenue, partially offset by a 9% decrease in royalty revenue. The increase in manufacturing revenue was primarily due to an increase 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 $642.0 million and $688.0 million during the years ended December 31, 2020 and 2019, 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 "Risks Related to our Intellectual Property—We or our licensees may face claims against IP rights covering our products and competition from generic drug manufacturers."

We expect revenues from our long-acting, atypical franchise to decrease over time. While we expect continued growth from sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA in the near term, we are aware of potential generic competition for RISPERDAL CONSTA that may lead to reduced unit sales and increased pricing pressure in 2021. We are also aware of generic challenges to INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. For a discussion of legal proceedings related to RISPERDAL CONSTA, INVEGA SUSTENNA and INVEGA TRINZA, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Annual Report. In addition, a number of companies, including us, are working to develop new products to treat schizophrenia and/or bipolar disorder that may compete with INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA. Increased competition from new products or generic versions of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA or RISPERDAL CONSTA may lead to reduced unit sales of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA, and increased pricing pressure.

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 increase in the amount of manufacturing and royalty revenue from AMPYRA and FAMPYRA was primarily due to an $11.3 million increase in AMPYRA revenue in 2020, $6.7 million of which was manufacturing revenue and $4.6 million of which was royalty revenue, in each case related to increased batches of AMPYRA manufactured in 2020, compared to 2019 in which we did not manufacture any batches of AMPYRA due to the entry of generic forms of AMPYRA into the U.S. market in 2018.. We expect revenues from AMPYRA to decline due to the availability of generic forms of AMPYRA in the U.S. The latest of the patents covering FAMPYRA expires in 2025 in the EU.

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 and "Item 1A—Risk Factors" in this Annual Report, and specifically the section entitled "Risks Related to our Financial Condition and Tax Matters—Currency exchange rates may affect revenues and expenses" for risks related to currency exchange rates.

License Revenue

(In millions)	Year Ended December 31, 2020	Year Ended December 31, 2019	Change 2020 - 2019
License revenue	$ 1.1	$ 145.8	$ (144.7)

The decrease in license revenue in 2020 was primarily due to the absence in 2020 of any milestone payments under our license and collaboration agreement with Biogen for VUMERITY, as compared to the $150.0 million milestone payment we received under such agreement in 2019 upon FDA approval of the NDA for VUMERITY, of which $145.8 million was allocated to the delivery of the license and the remaining $4.2 million was allocated to R&D services.

Research and Development Revenue

(In millions)	Year Ended December 31, 2020	2019	Change 2020 - 2019
Research and development revenue	$ 1.9	$ 52.8	$ (50.9)

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 $0.7 million and $50.0 million in the years ended December 31, 2020 and 2019, respectively, and the decrease in revenue was due to a decrease in services performed given FDA approval of VUMERITY in October 2019.

Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Year Ended December 31, 2020	2019	Change 2020 - 2019
Cost of goods manufactured and sold	$ 178.3	$ 180.4	$ (2.1)

The decrease in cost of goods manufactured and sold was primarily due to a 6% decrease in cost of goods manufactured and sold related to VIVITROL, which was primarily due to a decrease in VIVITROL units sold, partially offset by a 10% increase in cost of goods manufactured and sold related to ARISTADA, primarily due to an increase in ARISTADA units sold, as described in the Product Sales, net section, above.

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, 2020 and 2019 listed by the nature of such expenses:

(In millions)	Year Ended December 31, 2020	2019	Change 2020 - 2019
External R&D Expenses:			
Development programs:			
nemvaleukin	$ 74.6	$ 45.2	$ 29.4
LYBALVI	35.3	33.4	1.9
ALKS 5461	6.0	21.3	(15.3)
VUMERITY	0.1	27.7	(27.6)
IPR&D acquired from Rodin	—	86.6	(86.6)
Other external R&D expenses	66.5	72.7	(6.2)
Total external R&D expenses	182.5	286.9	(104.4)
Internal R&D expenses:			
Employee-related	158.8	175.8	(17.0)
Occupancy	20.8	12.3	8.5
Depreciation	15.1	14.0	1.1
Other	17.4	23.8	(6.4)
Total internal R&D expenses	212.1	225.9	(13.8)
Research and development expenses	$ 394.6	$ 512.8	$ (118.2)

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 preclinical and/or clinical trials and our expectations regarding the likelihood of their regulatory approval and commercial viability, among other factors.

The increase in expenses related to nemvaleukin was primarily due to the advancement of the ARTISTRY development program for the product. The increase in expenses related to LYBALVI was primarily due to the write-off of approximately $7.7 million of inventory that was expected to be sold commercially but, in the fourth quarter of 2020 we determined that certain lots were no longer probable of being sold commercially, partially offset by a decrease in clinical activity across the LYBALVI program following original submission of the NDA in November 2019. The decrease in expenses related to ALKS 5461 was primarily due to a

decrease in activity within the program following receipt in January 2019 of a CRL from the FDA relating to our NDA seeking marketing approval of ALKS 5461 for the adjunctive treatment of major depressive disorder, and subsequent winding down of ongoing clinical activity in the development program. The decrease in expenses related to VUMERITY was primarily due to the completion of our elective, randomized, head-to-head phase 3 study in 2019. The FDA approved the NDA for VUMERITY in the fourth quarter of 2019. For additional detail on the status of our key development programs, see "Item 1—Business" in this Annual Report and specifically the section entitled "Key Development Programs".

Included in external R&D expenses in 2019 was 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 decrease in employee-related expenses was primarily due to a decrease in R&D headcount of 10% from December 31, 2019 to December 31, 2020, as a result of the Restructuring. The increase in occupancy expenses in the year ended December 31, 2020, as compared to the year ended December 31, 2019, was primarily due to the commencement of the 900 Winter Street Lease in January 2020.

Selling, General and Administrative Expenses

(In millions)	Year Ended December 31, 2020	Year Ended December 31, 2019	Change 2020 - 2019
Selling and marketing expense	$ 338.5	$ 389.5	$ (51.0)
General and administrative expense	200.3	209.9	(9.6)
Selling, general and administrative expense	$ 538.8	$ 599.4	$ (60.6)

The decrease in selling and marketing expense was primarily due to a decrease in marketing expense of $40.4 million, a decrease in employee-related expenses of $7.6 million and a decrease in professional service fees of $4.2 million. The decrease in marketing expense was primarily due to cost saving measures taken in 2020 and a reduction in the number of speaker programs and speaker trainings and a reduction in conference-related spend primarily due to the impacts of the COVID-19 pandemic. The decrease in employee-related expenses was primarily due to a decrease in employee travel related to the impacts of the COVID-19 pandemic. The decrease in professional service fees was primarily due to an overall reduction in external consultant-related fees in 2020, as compared to 2019.

The decrease in general and administrative expense was primarily due to a decrease in employee-related expenses of $14.1 million and a decrease in professional service fees of $4.0 million, partially offset by an increase in overhead costs of $9.5 million. The decrease in employee-related expenses was primarily due to a decrease in share-based compensation expense and in salaries and benefits, due to a decrease in general and administrative headcount of 2% from December 31, 2019 to December 31, 2020 and the impact of the Restructuring, and due to a decrease in employee travel related to the impacts of the COVID-19 pandemic. The decrease in professional service fees was primarily due to expense management measures taken in response to COVID-19-related disruptions to the business. The increase in overhead expenses was primarily related to the commencement of the 900 Winter Street Lease and an increase in insurance costs.

Amortization of Acquired Intangible Assets

(In millions)	Year Ended December 31, 2020	Year Ended December 31, 2019	Change 2020 - 2019
Amortization of acquired intangible assets	$ 39.5	$ 40.4	$ (0.9)

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, 2020 is expected to be approximately $40.0 million, $35.0 million, $35.0 million, $1.0 million and none in the years ending December 31, 2021 through 2025, respectively.

Restructuring

(In millions)	Year Ended December 31, 2020	2019	Change 2020 - 2019
Restructuring expense	$ —	$ 13.4	$ (13.4)

In the fourth quarter of 2019, our board of directors approved the Restructuring, which 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 were paid out by the end of 2020. We paid $8.7 million and $4.2 million of the total $13.4 million accrued for the Restructuring during the years ended December 31, 2020 and 2019, respectively.

Other Income (Expense), Net

(In millions)	Year Ended December 31, 2020	2019	Change 2020 - 2019
Interest income	$ 7.0	$ 14.0	$ (7.0)
Interest expense	(8.7)	(13.6)	4.9
Change in the fair value of contingent consideration	3.9	(22.8)	26.7
Other income, net	13.7	0.8	12.9
Total other income (expense), net	$ 15.9	$ (21.6)	$ 37.5

The decreases in interest income and interest expense in 2020, as compared to 2019, were primarily due to a decrease in interest rates. Interest income consists primarily of interest earned on our available-for-sale investments. Interest expense consists primarily of interest incurred on the 2023 Term Loans. The 2023 Term Loans bear interest at a LIBOR of our choosing (one, three or six months), plus 2.25% with a 0% LIBOR floor. During the years ended December 31, 2020 and 2019, the Company's average LIBOR rates were 0.51% and 2.27%, respectively.

In April 2015, we sold certain of our business assets to Recro Pharma, Inc. ("Recro") and Recro Gainesville LLC, which included as part of the purchase price 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 (such products, the "Meloxicam Products"), and milestone payments to be paid upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products (such transaction, the "Gainesville Transaction"). 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.

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, 2020 and 2019, we determined that the fair value of the contingent consideration increased by $3.9 million and decreased by $22.8 million, respectively. The increase in the fair value of the contingent consideration in 2020, as compared to 2019, was primarily due to the approval by the FDA of ANJESO in February 2020, partially offset by an increase in the discount rate due to an increase in the risk of non-payment. In Baudax's Quarterly Report on Form 10-Q for the period ended September 30, 2020, Baudax included disclosures around its ability to continue as a going concern.

The increase in other income, net in the year ended December 31, 2020, as compared to the year ended December 31, 2019, was primarily due to an $8.3 million gain on our equity method investment as a result of the sale of two of the companies within the Fountain Healthcare Partners II ("Fountain") portfolio. Our investment in Fountain is discussed in greater detail in Note 4, *Investments,* in the "Notes to Consolidated Financial Statements" in this Annual Report.

Provision (Benefit) for Income Taxes

(In millions)	Year Ended December 31, 2020	-2019	Change 2020 - 2019
Income tax provision (benefit)	$ 14.3	$ (0.4)	$ (14.7)

The income tax provision in 2020 and the income tax benefit in 2019 were primarily due to U.S. federal and state taxes. The unfavorable change in income taxes in 2020, as compared to 2019, was primarily due to a significant benefit recorded in 2019 related 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. Cumulative unremitted earnings of overseas subsidiaries totaled approximately $369.0 million at December 31, 2020. 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 $38.0 million of income taxes would be payable on the repatriation of the unremitted earnings to Ireland.

As of December 31, 2020, the Company had $1.6 billion of Irish NOL carryforwards, $33.3 million of U.S. federal NOL carryforwards, $43.2 million of state NOL carryforwards, $48.6 million of federal R&D credits and $23.0 million of state tax credits which will either expire on various dates through 2040 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 and 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, 2020 U.S.	Ireland	Total	December 31, 2019 U.S.	Ireland	Total
Cash and cash equivalents	$ 152.8	$ 120.2	$ 273.0	$ 63.3	$ 140.5	$ 203.8
Investments—short-term	293.5	68.5	362.0	285.3	45.9	331.2
Investments—long-term	23.2	1.6	24.8	40.3	39.1	79.4
Total cash and investments	$ 469.5	$ 190.3	$ 659.8	$ 388.9	$ 225.5	$ 614.4
Outstanding borrowings—short and long-term	$ 275.0	$ —	$ 275.0	$ 277.1	$ —	$ 277.1

At December 31, 2020, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Allowance for Credit Losses	Estimated Fair Value
Investments—short-term available-for-sale	$ 359.3	$ 1.9	$ —	$ (1.0)	$ 360.2
Investments—short-term held-to-maturity	1.7	0.1	—	—	1.8
Investments—long-term available-for-sale	23.0	—	—	—	23.0
Investments—long-term held-to-maturity	1.8	—	—	—	1.8
Total	$ 385.8	$ 2.0	$ —	$ (1.0)	$ 386.8

Sources and Uses of Cash

We generated $82.8 million and $72.0 million of cash from operating activities during the years ended December 31, 2020 and 2019, 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, 2020, 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, 2020 and 2019:

(In millions)	Year Ended December 31, 2020	2019
Cash and cash equivalents, beginning of period	$ 203.8	$ 266.8
Cash flows provided by operating activities	82.8	72.0
Cash flows used in investing activities	(11.5)	(141.8)
Cash flows (used in) provided by financing activities	(2.1)	6.8
Cash and cash equivalents, end of period	$ 273.0	$ 203.8

Operating Activities

The increase in cash flows provided by operating activities is primarily due to an increase in the cash provided from our net loss, net of adjustments to reconcile net loss to cash flows from operating activities. This was partially offset by a decrease in the cash provided from working capital, primarily due to increases in receivables and inventory, partially offset by an increase in accounts payable and accrued expenses.

Investing Activities

The decrease in cash used in investing activities was primarily due to the net sale of investments of $23.5 million in 2020 as compared to the net purchase of investments of $52.9 million in 2019. We also had a decrease in property, plant and equipment additions of $48.7 million in 2020 primarily due to a decrease in expenses related to leasehold improvements related to the 900 Winter Street Lease commencement in January 2020.

We expect to spend approximately $40.0 million during the year ended December 31, 2021 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 was 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, was included as an investing activity in the 2019 cash flow statement.

Financing Activities

The change in cash flows from financing activities was due to an $8.9 million decrease in the net cash provided from stock option exercises by our employees.

Borrowings

At December 31, 2020, our borrowings consisted of $276.4 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, 2020:

Contractual Obligations (In thousands)	Total	Less Than One Year (2021)	One to Three Years (2022 - 2023)	Three to Five Years (2024 - 2025)	More than Five Years (After 2025)
2023 Term Loans—Principal	$ 276,434	$ 2,843	$ 273,591	$ —	$ —
2023 Term Loans—Interest	23,700	10,602	13,098	—	—
Operating lease obligations	195,806	16,882	34,267	35,346	109,311
Purchase obligations(1)	208,743	208,743	—	—	—
Total contractual cash obligations	$ 704,683	$ 239,070	$ 320,956	$ 35,346	$ 109,311

(1) Purchase obligations represent open purchase orders for the acquisition of goods and services in the ordinary course of business and purchase orders for capital expenditures primarily related to certain planned capital spend. Our obligation to pay certain of these amounts may be reduced based on certain future events.

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 0.16% at December 31, 2020 and is the rate we were using at December 31, 2020 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, 2020, 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, 2020, we had $7.7 million of net liabilities associated with uncertain tax positions. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months.

Off-Balance Sheet Arrangements

At December 31, 2020, 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.

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 U.S. 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 U.S. 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 to individuals covered by Medicaid and rebates per unit under the Medicaid program and adjust our rebate accrual based on actual unit sales and rebates per unit and changes in trends in Medicaid utilization. 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 returns of product sold 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 reduction of sales. 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, 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
Provision:							
Current year	296.1	100.0	88.2	6.6	56.6	42.6	590.1
Prior year	(5.0)	—	—	(0.6)	—	—	(5.6)
Total	291.1	100.0	88.2	6.0	56.6	42.6	584.5
Actual:							
Current year	(125.6)	(96.4)	(69.7)	(6.9)	(39.8)	(33.4)	(371.8)
Prior year	(109.5)	(2.8)	(15.7)	—	(13.1)	(7.7)	(148.8)
Total	(235.1)	(99.2)	(85.4)	(6.9)	(52.9)	(41.1)	(520.6)
Balance, December 31, 2020	$ 182.0	$ 4.3	$ 14.4	$ 23.7	$ 12.9	$ 10.0	$ 247.3

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. Substantially all of our royalties 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.

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 received a 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 license and collaboration agreement. Biogen paid a portion of the VUMERITY development costs we incurred in 2017 and, in January 2018, Biogen became responsible for all VUMERITY development costs we incurred, 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 payment 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.

We allocated the $150.0 milestone payment received in November 2019 to the relevant performance obligations as follows: $144.8 million was allocated to the delivery of the license; and $5.2 million 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 were recognized over the course of the development work and as clinical supply was delivered to Biogen in 2020.

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.

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 are 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 that portion 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 (the "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 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 will be allocated to each of the performance obligations using the standalone selling prices based on our 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 began performing under this commercial supply agreement in the first quarter of 2020.

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, 2020, is expected to be approximately $40.0 million, $35.0 million, $35.0 million, $1.0 million and none in the years ending December 31, 2021 through 2025, 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.

In the fourth quarter of 2020, we determined that an impairment triggering event occurred and evaluated certain of our long-lived assets for impairment under a held-and-used model. We concluded that the long-lived assets evaluated for impairment were recoverable based on an analysis of the undiscounted net cash flows to be generated from the use of these assets.

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, 2020, 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 Financial Accounting Standards Board that simplifies the test for goodwill impairment. This guidance removed Step 2 of the goodwill impairment test, which required a hypothetical purchase price allocation. A goodwill impairment charge is now 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, 2020, we elected to perform a quantitative impairment test and determined that the fair value of the reporting unit exceeded its carrying value.

Contingent Consideration

We record contingent consideration we receive related to the sale of a business 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, 2020, our contingent consideration related to consideration to be received as part of the Gainesville Transaction. 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 have received $13.8 million in milestone payments to date and are due to receive an additional $1.5 million in June 2021 related to the FDA approval in February 2020 of the NDA for ANJESO, the first Meloxicam Product, and $45.0 million in seven equal, annual installments beginning in February 2021, which is the first anniversary of such approval;
- We are entitled to receive future royalties on net sales of Meloxicam Products; and
- We are 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, we used a risk-adjusted expected growth rate based on Baudax's assessments of expected growth in net sales of the approved Meloxicam Product, adjusted by an appropriate factor capturing such assessment's respective correlation with the market.

In order to address the substantial doubt about Baudax's ability to continue as a going concern, we split our fair value analysis into two scenarios and applied an equal weighting to each. In the first scenario, the amounts above were all discounted using a rate of 13%, which we believe captures a market participant's view of the risk associated with the expected payments assuming Baudax is able to continue as a going concern. In the second scenario, we used the undiscounted values derived from the amounts summarized above and applied a recovery rate of 18%, based on an analysis performed by Moody's Investor Service regarding recoveries in a pandemic-driven default cycle.

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 "Risks Related to our Financial Condition and Tax Matters—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 expectations 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 27% of our investments at December 31, 2020 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, 2020, our borrowings consisted of $276.4 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 0.16% at December 31, 2020. 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, 2020 by approximately $0.4 million. At December 31, 2019, 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 $0.5 million. For a discussion about risks relating to LIBOR, see "Item 1A—Risk Factors" in this Annual Report and specifically the section entitled "Risks Related to our Financial Condition and Tax Matters—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, 2020, 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 $28.9 million, as compared to a reduction in revenues of approximately $26.5 million for the year ended December 31, 2019.

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, 2020, 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 $7.3 million, as compared to an increase in our expenses of approximately $7.1 million in the year ended December 31, 2019.

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, 2020					
REVENUES:					
Product sales, net	$ 129,726	$ 130,415	$ 142,658	$ 148,961	$ 551,760
Manufacturing and royalty revenues	116,251	116,505	120,351	130,893	484,000
Research and development revenue	243	609	953	141	1,946
License revenue	—	—	1,050	—	1,050
Total revenues	246,220	247,529	265,012	279,995	1,038,756
EXPENSES:					
Cost of goods manufactured and sold	47,211	45,054	43,129	42,922	178,316
Research and development	93,279	94,222	94,980	112,107	394,588
Selling, general and administrative	133,372	132,024	127,653	145,778	538,827
Amortization of acquired intangible assets	9,728	9,890	9,917	9,917	39,452
Total expenses	283,590	281,190	275,679	310,724	1,151,183
OPERATING LOSS	(37,370)	(33,661)	(10,667)	(30,729)	(112,427)
OTHER INCOME (EXPENSE), NET:	6,045	7,903	12,859	(10,917)	15,890
(LOSS) INCOME BEFORE INCOME TAXES	(31,325)	(25,758)	2,192	(41,646)	(96,537)
INCOME TAX PROVISION	7,329	3,673	2,326	996	14,324
NET LOSS	$ (38,654)	$ (29,431)	$ (134)	$ (42,642)	$ (110,861)
LOSS PER SHARE—BASIC AND DILUTED	$ (0.24)	$ (0.19)	$ (0.00)	$ (0.27)	$ (0.70)

	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)

(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, 2020. 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, 2020 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, 2020. 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, 2020, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2020 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 2021 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 2021Annual 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 2021 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 2021 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 2021 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
2.1.3	Third Amendment to Purchase and Sale Agreement, dated August 17, 2020, by and among Alkermes Pharma Ireland Limited, Daravita Limited, Alkermes US Holdings, Inc. (as successor in interest to Eagle Holdings USA, Inc.) and Baudax Bio, Inc. (as successor in interest to Recro Pharma, Inc. and Recro Gainesville LLC).	Exhibit 2.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 29, 2020
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

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
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
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
10.1.6	Sixth Amendment to Lease between Alkermes, Inc. and GI TC 850 Winter Street, LLC, dated as of July 24, 2020.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 29, 2020
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

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
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
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

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
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
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

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
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
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.	Exhibit 10.10.3 of the Alkermes plc Annual Report on Form 10-K (File No. 011-35299)	February 13, 2020
10.11	Cooperation Agreement, dated as of December 10, 2020, by and among Alkermes plc and Elliott Investment Management L.P., Elliott Associates, L.P., Elliott Advisors (UK) Limited and Elliott International, L.P.	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299)	December 10, 2020
10.12	Lease, dated March 23, 2018, by and between Alkermes, Inc. and PDM 900 Unit, LLC.	Exhibit 10.4 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	April 26, 2018
10.12.1	First Amendment to Lease, dated June 21, 2018, by and between Alkermes, Inc. and PDM 900 Unit, LLC.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 26, 2018
10.12.2	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
10.13 †	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
10.13.1 †	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
10.13.2 †	Amendment No. 2 to Employment Agreement, dated as of September 10, 2009 by and between Richard F. Pops and Alkermes, Inc.	Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	September 11, 2009
10.14 †	Form of Employment Agreement, as amended by the Form of Amendment to Employment Agreement set forth in 10.14.1, entered into by and between Alkermes, Inc. and each of James M. Frates, Blair C. Jackson and Michael J. Landine.	Exhibit 10.3 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 11, 2008
10.14.1 †	Form of Amendment to Employment Agreement with Alkermes, Inc.	Exhibit 10.7 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	October 7, 2008
10.15 †	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
10.16 †	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 Christian Todd Nichols.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	November 2, 2016

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.17.1†	Offer Letter by and 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, dated March 29, 2019, by and between Alkermes, Inc. and Christian Todd Nichols.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 29, 2020
10.18 †	Form of Indemnification Agreement entered into by and between Alkermes, Inc. and each of its Directors and Secretaries of Alkermes plc and its Irish subsidiaries.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	April 29, 2020
10.19 †	Form of Deed of Indemnification entered into by and between each of the Directors, Secretaries and executive officers of Alkermes plc and its subsidiaries.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	April 29, 2020
10.20†	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
10.20.1 †	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
10.20.2 †	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
10.20.3 †	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
10.20.4 †	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
10.20.5 †	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
10.20.6 †	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
10.20.7 †	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
10.21†	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

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.21.1 †	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
10.21.2 †	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
10.21.3 †	Form of Restricted Stock Unit (Time-Vesting) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.3 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.21.4 †	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
10.21.5 †	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
10.22 †	Alkermes plc 2018 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 20, 2020
10.22.1 †	Form of Incentive Stock Option Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan, as amended.	Exhibit 10.6 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.22.2 †	Form of Non-Qualified Stock Option (Employee) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan, as amended.	Exhibit 10.7 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.22.3 †	Form of Restricted Stock Unit (Time-Vesting) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan, as amended.	Exhibit 10.8 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23 ,2018
10.22.4 †	Form of Restricted Stock Unit (Performance-Vesting) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan, as amended.	Exhibit 10.6 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 29, 2020
10.22.5 †	Form of Non-Qualified Stock Option (Non-Employee Director) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan, as amended.	Exhibit 10.4 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 29, 2020
10.23.6 †	Form of Non-Employee Director Restricted Stock Unit (Time-Vesting) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan, as amended.	Exhibit 10.5 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 29, 2020
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.		

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
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 11, 2021

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 Iain M. Brown, 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 11, 2021
/s/ Iain M. Brown Iain M. Brown	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 11, 2021
/s/ David W. Anstice David W. Anstice	Director	February 11, 2021
/s/ Robert A. Breyer Robert A. Breyer	Director	February 11, 2021
/s/ Shane Cooke Shane Cooke	Director	February 11, 2021
/s/ David A. Daglio, Jr. David A. Daglio, Jr.	Director	February 11, 2021
/s/ Richard Gaynor Richard Gaynor	Director	February 11, 2021
/s/ Wendy L. Dixon Wendy L. Dixon	Director	February 11, 2021
/s/ Brian P. McKeon Brian P. McKeon	Director	February 11, 2021
/s/ Paul J. Mitchell Paul J. Mitchell	Director	February 11, 2021
/s/ Nancy L. Snyderman Nancy L. Snyderman	Director	February 11, 2021
/s/ Frank Anders Wilson Frank Anders Wilson	Director	February 11, 2021
/s/ Nancy J. Wysenski Nancy J. Wysenski	Director	February 11, 2021

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, 2020 and 2019, 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, 2020, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 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, 2020, 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 and the manner in which it accounts for revenue from contracts with customers in 2018.

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.

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. The Company records accruals for rebates to U.S. 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. As of December 31, 2020, total accrued sales discounts, allowances and reserves were $218.9 million, of which a significant amount related to Medicaid rebates. The Company rebates individual U.S. 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 to individuals covered by Medicaid and rebates per unit under the Medicaid program and adjusts its rebate accrual based on actual unit sales and rebates per unit and changes in trends in Medicaid utilization.

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 (i) the significant judgment by management due to significant measurement uncertainty involved in developing the reserves, as the reserves are based on assumptions developed using historical experience, current contractual requirements, specific known market events and payment patterns and (ii) a high degree of auditor judgment, effort, and subjectivity in applying procedures related to these assumptions.

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) developing an independent estimate of the rebate accruals by utilizing third-party data related to product sales, the historical trend of actual rebate claims paid and consideration of contractual requirement changes and market events; (ii) comparing the independent estimate to management's estimate; and (iii) testing rebate claims processed by the Company.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
February 11, 2021

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

ALKERMES PLC AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2020 and 2019

	December 31, 2020	December 31, 2019
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 272,961	$ 203,771
Investments—short-term	362,066	331,208
Receivables, net	275,143	257,086
Contract assets	14,401	8,386
Inventory	125,738	101,803
Prepaid expenses and other current assets	60,662	59,716
Total current assets	1,110,971	961,970
PROPERTY, PLANT AND EQUIPMENT, NET	350,003	362,168
RIGHT-OF-USE ASSETS	131,718	12,379
INTANGIBLE ASSETS, NET	111,191	150,643
GOODWILL	92,873	92,873
DEFERRED TAX ASSETS	86,228	96,558
INVESTMENTS—LONG-TERM	24,780	79,391
CONTINGENT CONSIDERATION	24,651	32,400
OTHER ASSETS	17,315	17,021
TOTAL ASSETS	$ 1,949,730	$ 1,805,403
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 412,171	$ 373,037
Operating lease liabilities—short-term	15,732	8,466
Contract liabilities—short-term	7,512	6,766
Current portion of long-term debt	2,843	2,843
Total current liabilities	438,258	391,112
LONG-TERM DEBT	272,118	274,295
OPERATING LEASE LIABILITIES—LONG-TERM	119,464	5,342
CONTRACT LIABILITIES—LONG-TERM	16,397	22,068
OTHER LONG-TERM LIABILITIES	36,511	27,144
Total liabilities	882,748	719,961
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, 2020 and 2019, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 162,269,220 and 160,489,888 shares issued; 159,161,141 and 157,779,002 shares outstanding at December 31, 2020 and 2019, respectively	1,620	1,602
Treasury shares, at cost (3,108,079 and 2,710,886 shares at December 31, 2020 and 2019, respectively)	(126,087)	(118,386)
Additional paid-in capital	2,685,647	2,586,030
Accumulated other comprehensive loss	(1,349)	(1,816)
Accumulated deficit	(1,492,849)	(1,381,988)
Total shareholders' equity	1,066,982	1,085,442
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 1,949,730	$ 1,805,403

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, 2020, 2019 and 2018

	Year Ended December 31,		
	2020	2019	2018
	(In thousands, except per share amounts)		
REVENUES:			
Product sales, net	$ 551,760	$ 524,499	$ 450,334
Manufacturing and royalty revenues	484,000	447,882	526,675
Research and development revenue	1,946	52,816	68,895
License revenue	1,050	145,750	48,370
Total revenues	1,038,756	1,170,947	1,094,274
EXPENSES:			
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	178,316	180,385	176,420
Research and development	394,588	512,833	425,406
Selling, general and administrative	538,827	599,449	526,408
Amortization of acquired intangible assets	39,452	40,358	65,168
Restructuring expense	—	13,401	—
Total expenses	1,151,183	1,346,426	1,193,402
OPERATING LOSS	(112,427)	(175,479)	(99,128)
OTHER INCOME (EXPENSE), NET:			
Interest income	6,960	13,976	9,238
Interest expense	(8,659)	(13,601)	(15,437)
Change in the fair value of contingent consideration	3,945	(22,800)	(19,600)
Other income (expense), net	13,644	848	(2,040)
Total other income (expense), net	15,890	(21,577)	(27,839)
LOSS BEFORE INCOME TAXES	(96,537)	(197,056)	(126,967)
INCOME TAX PROVISION (BENEFIT)	14,324	(436)	12,344
NET LOSS	$ (110,861)	$ (196,620)	$ (139,311)
LOSS PER ORDINARY SHARE:			
Basic and diluted	$ (0.70)	$ (1.25)	$ (0.90)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:			
Basic and diluted	158,803	157,051	155,112
COMPREHENSIVE LOSS:			
Net loss	$ (110,861)	$ (196,620)	$ (139,311)
Holding gain, net of a tax provision of $130, $426, $159, respectively	467	1,464	512
COMPREHENSIVE LOSS	$ (110,394)	$ (195,156)	$ (138,799)

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, 2020, 2019 and 2018

	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, 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 gain 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 gain 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
Issuance of ordinary shares under employee stock plans	682,122	7	8,366	—	—	—	—	8,373
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	1,097,210	11	(11)	—	—	(397,193)	(7,701)	(7,701)
Share-based compensation expense	—	—	91,262	—	—	—	—	91,262
Unrealized gain on marketable securities, net of tax provision of $130	—	—	—	467	—	—	—	467
Net loss	—	—	—	—	(110,861)	—	—	(110,861)
BALANCE — December 31, 2020	162,269,220	$ 1,620	$ 2,685,647	$ (1,349)	$ (1,492,849)	(3,108,079)	$ (126,087)	$ 1,066,982

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, 2020, 2019 and 2018

	Year Ended December 31,		
	2020	2019	2018
	(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (110,861)	$ (196,620)	$ (139,311)
Adjustments to reconcile net loss to cash flows from operating activities:			
Share-based compensation expense	90,164	100,977	105,357
Depreciation and amortization	81,854	80,413	103,660
Deferred income taxes	9,985	(319)	10,623
Change in the fair value of contingent consideration	(3,945)	22,800	19,600
Loss on debt refinancing	—	—	2,298
Payment made for debt refinancing	—	—	(2,251)
Impairment of property, plant and equipment	—	—	5,746
Other non-cash charges	2,514	(580)	979
Changes in assets and liabilities, excluding the effect of acquisitions:			
Receivables	(18,050)	35,136	(58,632)
Contract assets	(6,015)	(5,156)	880
Inventory	(22,933)	(13,077)	(2,665)
Prepaid expenses and other assets	4,022	(1,784)	(5,990)
Right-of-use assets	17,336	8,399	—
Accounts payable and accrued expenses	50,600	34,847	46,739
Contract liabilities	(4,924)	16,140	3,252
Operating lease liabilities	(16,273)	(9,117)	—
Other long-term liabilities	9,368	18	8,996
Cash flows provided by operating activities	82,842	72,077	99,281
CASH FLOWS FROM INVESTING ACTIVITIES:			
Additions of property, plant and equipment	(42,219)	(90,942)	(69,431)
Proceeds from the sale of equipment	643	900	507
Proceeds from contingent consideration	3,886	10,000	—
Return of Fountain Healthcare Partners II, L.P. investment	2,751	—	—
Purchases of investments	(229,543)	(277,518)	(397,727)
Sales and maturities of investments	253,001	224,602	444,456
Acquisition of Rodin Therapeutics, Inc.'s net assets, net of cash acquired	—	(8,875)	—
Cash flows used in investing activities	(11,481)	(141,833)	(22,195)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	8,373	18,925	20,877
Employee taxes paid related to net share settlement of equity awards	(7,701)	(9,317)	(19,622)
Principal payments of long-term debt	(2,843)	(2,843)	(743)
Payment made for debt refinancing	—	—	(2,132)
Cash flows (used in) provided by financing activities	(2,171)	6,765	(1,620)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	69,190	(62,991)	75,466
CASH AND CASH EQUIVALENTS—Beginning of period	203,771	266,762	191,296
CASH AND CASH EQUIVALENTS—End of period	$ 272,961	$ 203,771	$ 266,762
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest	$ 8,288	$ 13,254	$ 12,526
Cash paid for taxes	$ 620	$ 2,508	$ 754
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	$ 2,420	$ 13,789	$ 11,720

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. Intercompany accounts and transactions have been eliminated.

During the year ended December 31, 2020, Alkermes Finance S.à r.l, an indirect subsidiary of Alkermes plc, was liquidated and its net assets were transferred to its parent company, Alkermes Pharma Ireland Limited.

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 cash equivalents only those investments that 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.

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, 2020, 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, 2020, 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, 2020 included U.S. treasury securities, marketable securities classified as cash equivalents and a fixed term deposit account;
- *Level 2*–these valuations are based on quoted prices for identical or similar assets in active markets or other market observable inputs such as interest rates, yield curves, foreign currency spot rates and option pricing valuation models. Assets utilizing Level 2 inputs at December 31, 2020 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, 2020, 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 preclinical 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.

The Company capitalizes inventory costs associated with its products prior to regulatory approval when, based on management's judgment, future commercialization of the product is considered probable and future economic benefit from such product is expected to be realized. The Company assesses the regulatory approval process and where the particular product stands in relation to that approval process, including any known safety, efficacy or quality concerns, potential labeling restrictions and other potential impediments to approval. The Company also considers the shelf life of the product in relation to the expected timeline for approval and considers issues that may prevent or delay commercialization, including issues that may arise in relation to the manufacturing of the product. The Company expenses previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or significant delay of approval by relevant regulatory agencies or other issues that may make the pre-approval inventory batches less likely or unlikely to be commercialized and to result in future economic benefit.

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 likelihood of achievement of milestones and of receipt of the 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, changes in the assumed probability associated with regulatory approvals and creditworthiness of the counterparty.

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; a significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset; an accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of a long-lived asset; a current-period operating or cash flow loss combined with a history of operating or cash-flow losses or a projection or forecast that demonstrates continuing losses associated with the use of a long-lived asset; or a current expectation that, more likely than not, a long-lived asset will be sold or otherwise disposed of significantly before the end of its previously estimated useful life. 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.

In the fourth quarter of 2020, the Company determined that an impairment triggering event occurred and evaluated certain of its long-lived assets for impairment under a held-and-used model. The Company concluded that the long-lived assets evaluated for impairment were recoverable based on an analysis of the undiscounted net cash flows to be generated from the use of these assets.

Revenue from Contracts with Customers

The Company recognizes revenue in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("Topic 606"). 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.

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 U.S. 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 U.S. 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 to individuals covered by Medicaid and rebates per unit under the Medicaid program and adjusts its rebate accrual based on actual unit sales and rebates per unit and changes in trends in Medicaid utilization. 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 returns of product sold 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 reduction of sales. 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, among others, 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®. 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. Substantially all of the Company's royalties 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.

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, preclinical 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 amounts unbilled but currently unconditionally due from customers. The amounts due are stated at their net estimated realizable value. The Company's unbilled receivable balance was $110.9 million and $89.7 million at December 31, 2020 and 2019, respectively, and related primarily to royalty revenues. 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 approximately $0.1 million and $0.2 million at December 31, 2020 and 2019, respectively.

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 two years, and is included in "Other assets" in the accompanying consolidated balance sheets. The manufacturing-related amounts included in the contract assets table below are classified as "Current assets" in the accompanying consolidated balance sheets, as they related to manufacturing processes that are completed in ten days to eight weeks.

Contract assets consisted of the following:

(In thousands)	Contract Assets
Contract assets at January 1, 2019	$ 8,230
Additions	37,911
Transferred to receivables, net	(32,755)
Contract assets at December 31, 2019	13,386
Additions	46,325
Transferred to receivables, net	(40,310)
Contract assets at December 31, 2020	$ 19,401

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, 2019	$ 12,694
Additions	18,677
Amounts recognized into revenue	(2,537)
Contract liabilities at December 31, 2019	28,834
Additions	—
Amounts recognized into revenue	(4,925)
Contract liabilities at December 31, 2020	$ 23,909

Foreign Currency

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within "Other income (expense), net" in the accompanying consolidated statements of operations and comprehensive loss. During the years ended December 31, 2020, 2019 and 2018, the Company recorded a gain (loss) on foreign currency translation of $2.4 million, $(0.9) million and $(2.3) 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, 2020, 2019 and 2018:

	Year Ended December 31,					
	2020		2019		2018	
Customer	Receivables	Revenue	Receivables	Revenue	Receivables	Revenue
Janssen	30%	33%	29%	28%	27%	29%
Biogen	*	*	*	17%	*	10%
Cardinal Health	16%	21%	12%	*	*	13%
AmerisourceBergen	11%	10%	10%	*	*	*
McKesson	*	14%	*	*	*	*
Acorda	*	*	*	*	15%	10%

* Indicates the revenues or receivables for the customer did not exceed 10% of the Company's total in each category as of or for the years ended December 31, 2020, 2019 and 2018, 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 ensure 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, 2020	2019	2018
Revenue by region:			
U.S.	$ 838,995	$ 966,929	$ 884,600
Ireland	3,233	3,195	4,915
Rest of world	196,528	200,823	204,759
Assets by region:			
Current assets:			
U.S.	$ 662,615	$ 551,799	$ 546,533
Ireland	448,356	407,791	433,837
Rest of world	—	2,381	2,882
Long-term assets:			
U.S.:			
Other	$ 472,999	$ 382,029	$ 312,243
Ireland:			
Intangible assets	$ 111,191	$ 150,643	$ 191,001
Goodwill	92,873	92,873	92,873
Other	161,696	217,887	245,638

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 selling and marketing, finance, human resources, legal, information technology and other administrative personnel, outside marketing, advertising, financial and legal expenses and other general and administrative costs.

Advertising costs are expensed as incurred. During the years ended December 31, 2020, 2019 and 2018, advertising costs totaled $25.5 million, $31.1 million and $54.7 million, respectively.

Share-Based Compensation

The Company's share-based compensation programs grant awards in the form of stock options and restricted stock unit awards ("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 options or the vesting of RSUs. Under the terms of the Company's stock option plans (the "Plans"), certain of the Company's employees may, at the discretion of the plan administrator, 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 would be expensed in full on the grant date or upon meeting the retirement eligibility criteria, whichever is later.

Time-Based Stock Options

Except as otherwise provided in the applicable Plan, stock option grants to employees expire ten years from the grant date and generally vest in four equal annual installments, commencing on the first anniversary of the date of grant, provided the employee remains continuously employed with the Company during the applicable vesting period. 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. 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.

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 stock 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 of 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 weekly price changes of the Company's ordinary shares. The risk-free interest rate for periods commensurate with the expected term of the stock 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 dividends, and does not expect to pay dividends in the near future. 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,		
	2020	2019	2018
Expected option term	5 - 7 years	5 - 7 years	5 - 8 years
Expected stock volatility	47 % - 54 %	46 % - 50 %	44 % - 49 %
Risk-free interest rate	0.24 % - 1.69 %	1.34 % - 2.59 %	2.25 % - 3.10 %
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 Unit Awards

Except as otherwise provided in the applicable Plan, time-based RSUs awarded to employees generally vest in four equal annual installments, commencing on the first anniversary of the date of grant, provided the employee remains continuously employed with the Company during the applicable vesting period. Shares subject to these RSUs are delivered to the employee upon vesting, subject to payment of applicable withholding taxes. The fair value of time-based 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 Unit Awards

Performance-based RSUs awarded to employees vest upon the achievement of certain performance criteria, typically during or at the end of a specified performance period. The estimated fair value of these RSUs are generally based on the closing price of the Company's ordinary shares traded on the Nasdaq Global Select Market on the date of grant, unless the RSU is also subject to a market condition. In that case, the fair value of the RSU is based on a Monte Carlo simulation model. Compensation expense for performance-based RSUs is recognized from the date the Company determines the performance criteria probable of being achieved to the date the award, or relevant portion of the award, is expected to vest. Cumulative adjustments are recorded on a quarterly basis to reflect subsequent changes to the estimated outcome of the performance criteria 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 and 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 address unmet medical needs of patients in major therapeutic areas. 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, 2020, 2019 and 2018, the Company contributed $14.7 million, $14.8 million and $12.1 million, respectively, to match employee deferrals under the 401(k) Plan.

Defined Contribution Plan

The Company maintains a defined contribution plan for its Ireland-based employees (the "Defined Contribution Plan"). The Defined Contribution Plan provides for eligible employees to contribute up to 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, 2020, 2019 and 2018, the Company contributed $4.4 million, $4.1 million and $4.0 million, respectively, in contributions to the Defined Contribution Plan.

Risks and Uncertainties

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization. To date, COVID-19 has surfaced in nearly all regions around the world and resulted in travel restrictions and business slowdowns and/or shutdowns in affected areas. All U.S. states, and many local jurisdictions and countries around the world, including Ireland, have, at times during the pandemic, issued "shelter-in-place" orders, quarantines, executive orders and similar government orders, restrictions, and recommendations for their residents to control the spread of COVID-19. Such orders, restrictions and/or recommendations, and/or the perception that additional orders, restrictions or recommendations could occur, have resulted in widespread closures of businesses, including healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia, work stoppages, slowdowns and/or delays, work-from-home policies and travel restrictions, among other effects.

The Company continues to closely monitor and rapidly respond to the ongoing impact of COVID-19 on its employees, communities and business operations. Due to numerous uncertainties surrounding the ongoing COVID-19 pandemic, the actual impact on the Company's financial condition and operating results resulting from the pandemic may differ from current projections. These

uncertainties include, among other things, the ultimate severity and duration of the pandemic; governmental, business or other actions that have been, are being or will be, taken in response to the pandemic, including restrictions on travel and mobility, business closures and operating restrictions, and imposition of social distancing measures; impacts of the pandemic on the Company's employees, the vendors or distribution channels in the Company's supply chain and on the Company's ability to continue to manufacture its products; impacts of the pandemic on the conduct of the Company's clinical trials, including with respect to enrollment rates, availability of investigators and clinical trial sites, and monitoring of data; impacts of the pandemic on healthcare systems that serve people living with opioid dependence, alcohol dependence and schizophrenia; impacts of the pandemic on the regulatory agencies with which the Company interacts in the development, review, approval and commercialization of its medicines; impacts of the pandemic on reimbursement for the Company's products, including the Company's Medicaid rebate liability, and for services related to the use of its products; and impacts of the pandemic on the U.S., Irish and global economies more broadly.

The Company relies upon third parties for many aspects of its business, including the provision of goods and services related to the manufacture of its clinical products and its and its partners' marketed products, the conduct of its clinical trials, and the sale of marketed products from which the Company receives manufacturing and royalty revenue. Any prolonged material disruption to the third parties on which the Company relies could negatively impact the Company's ability to conduct business in the manner and on the timelines presently planned, which could have a material adverse impact on the Company's business, results of operations and financial condition.

The marketed products from which the Company derives revenue, including manufacturing and royalty revenue, are primarily injectable medications administered by healthcare professionals. Given developments that have transpired to date, and may continue to transpire, in response to the pandemic, including the implementation of "shelter-in-place" policies, social distancing requirements and other restrictive measures, commercial sales of these marketed products have been adversely impacted to varying degrees and the Company expects commercial sales of these marketed products to continue to be adversely impacted while the pandemic persists.

As it relates to the Company's proprietary marketed products, during the three months ended December 31, 2020, the Company saw a decrease of 5% in the number of VIVITROL units sold compared to the three months ended September 30, 2020. ARISTADA units sold during the three months ended December 31, 2020 increased 12% compared to the three months ended September 30, 2020. During the three months ended December 31, 2020, the Company continued to take actions to support uninterrupted access to its proprietary marketed products. However, the Company currently expects commercial sales of its marketed products, particularly VIVITROL, to continue to be impacted by the COVID-19 pandemic over the next few quarters. These items are discussed in greater detail in the "Results of Operations" section in "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report.

The Company continues to operate its manufacturing facilities and supply its medicines. While the Company continues to conduct R&D activities, including its ongoing clinical trials, the COVID-19 pandemic has impacted, and may continue to impact, the timelines of certain of its early-stage discovery efforts and clinical trials. The Company is working with its internal teams, its clinical investigators, R&D vendors and critical supply chain vendors to continually assess, and mitigate, any potential adverse impacts of COVID-19 on its manufacturing operations and R&D activities.

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.

Recently Adopted Accounting Pronouncements

The Company adopted ASU 2014-09, Topic 606, as of January 1, 2018, using the modified retrospective method for all contracts not completed as of the date of adoption.

The Company adopted ASU 2016-02, *Leases* ("Topic 842"), as of January 1, 2019, using the optional transition method that allows for a cumulative-effect adjustment in the period of adoption and did not restate prior periods.

In June 2016, the FASB issued Accounting Standards Update ("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 was adopted by the Company in the year ended 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, certain lease receivables, reinsurance receivables, financial guarantee contracts and loan commitments. Available-for-sale debt securities are largely 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. 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 was adopted by the Company in the year ended December 31, 2020 and did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This ASU also requires the entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement, which includes reasonably certain renewals. This ASU was adopted by the Company in the year ended December 31, 2020, using the prospective transition method, whereby it applied the requirements to any eligible costs incurred after adoption. The adoption of this ASU did not have an impact on 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 was adopted by the Company in the year ended December 31, 2020 and after review of its collaborative arrangements, the Company 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. Depending on the amendment, adoption may be applied on a retrospective, modified retrospective or prospective basis. This ASU was adopted by the Company in the year ended December 31, 2020 and the adoption of this ASU did not have a material impact on the Company's consolidated financial statements.

New Accounting Pronouncements not Adopted

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform*, which provides optional guidance for a limited period of time to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting. This amendment applies to all entities, subject to meeting certain criteria, that have contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. This ASU became effective immediately and may be applied prospectively to contract modifications made and hedging relationships entered into or evaluated on or before December 31, 2022. The Company is currently assessing the impact that this ASU may have on its consolidated financial statements.

3. REVENUE FROM CONTRACTS WITH CUSTOMERS

During the years ended December 31, 2020, 2019 and 2018, the Company recorded product sales, net, as follows:

	Year Ended December 31,		
(In thousands)	**2020**	**2019**	**2018**
VIVITROL	$ 310,722	$ 335,365	$ 302,609
ARISTADA and ARISTADA INITIO	241,038	189,134	147,725
Total product sales, net	$ 551,760	$ 524,499	$ 450,334

During the years ended December 31, 2020, 2019 and 2018, the Company recorded manufacturing and royalty revenues from its collaboration arrangements as follows:

	Year Ended December 31, 2020		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$ —	$ 274,200	$ 274,200
RISPERDAL CONSTA	56,893	14,468	71,361
AMPYRA/FAMPYRA	26,909	20,984	47,893
Other	35,232	55,314	90,546
	$ 119,034	$ 364,966	$ 484,000

	Year Ended December 31, 2019		
(In thousands)	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

	Year Ended December 31, 2018		
(In thousands)	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

The research and development revenue and license revenue recorded during the years ended December 31, 2020, 2019 and 2018 primarily related to revenue earned under the Company's license and collaboration agreement with Biogen for VUMERITY. In addition to the research and development revenue and license revenue, during the year ended December 31, 2020, 2019 and 2018 the Company recognized $22.5 million. $1.0 million and none, respectively, of manufacturing and royalty revenue related to 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 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 received an additional payment of $150.0 million following the U.S. Food and Drug Administration's ("FDA") approval of the New Drug Application ("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 license and collaboration agreement. Biogen paid a portion of the VUMERITY development costs the Company incurred in 2017 and, in January 2018, Biogen became responsible for all VUMERITY development costs that the Company incurred, 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.

The Company allocated the $150.0 million milestone payment received in November 2019 to the relevant performance obligations as follows: $144.8 million to the delivery of the license; and $5.2 million 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 were recognized over the course of the development work and as clinical supply was delivered to Biogen in 2020.

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.

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 are 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 that portion 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 VUMERITY (the "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 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 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 began performing under this commercial supply agreement in 2020.

4. INVESTMENTS

Investments consist of the following:

December 31, 2020	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses Less than One Year	Gross Unrealized Losses Greater than One Year	Allowance for Credit Losses	Estimated Fair Value
Short-term investments:						
Available-for-sale securities:						
Corporate debt securities	$ 176,937	$ 1,105	$ (7)	$ —	$ (977)	$ 177,058
U.S. government and agency debt securities	103,011	336	(2)	—	—	103,345
International government agency debt securities	79,346	469	(6)	—	—	79,809
	359,294	1,910	(15)	—	(977)	360,212
Held-to-maturity securities:						
Fixed term deposit account	1,667	187	—	—	—	1,854
Total short-term investments	360,961	2,097	(15)	—	(977)	362,066
Long-term investments:						
Available-for-sale securities:						
Corporate debt securities	7,908	—	(10)	—	—	7,898
International government agency debt securities	15,077	—	(15)	—	—	15,062
	22,985	—	(25)	—	—	$ 22,960
Held-to-maturity securities:						
Certificates of deposit	1,820	—	—	—	—	1,820
Total long-term investments	24,805	—	(25)	—	—	24,780
Total investments	$ 385,766	$ 2,097	$ (40)	$ —	$ (977)	$ 386,846
December 31, 2019						
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

At December 31, 2020, the Company reviewed its investment portfolio to assess whether the unrealized losses on its available-for-sale investments were other-than-temporary. Investments with unrealized losses consisted primarily of corporate debt securities and debt securities issued by foreign agencies and backed by foreign governments. In making the determination whether the decline in fair value of these securities was other-than-temporary, the Company evaluated whether it intended to sell the security and whether it was more likely than not that the Company would be required to sell the security before recovering its amortized cost basis.

If the Company intends to sell a security, or it is more likely than not that the Company would be required to sell a security prior to recovering its amortized cost basis, an other-than-temporary impairment is deemed to have occurred. The amount of an other-than-temporary impairment related to a credit loss, or investments that the Company intends to sell before recovery, is recognized in earnings. The amount of an other-than-temporary impairment on available-for-sale investments related to other factors is recorded as a component of accumulated other comprehensive income.

In September 2019, the Company purchased $1.9 million of convertible promissory notes from Synchronicity Pharma, Inc. ("Synchronicity"), a related party. The notes mature on the earlier of June 30, 2021 or the closing of a preferred equity financing or closing of a merger, business combination or sale of stock resulting in Synchronicity's stockholders owning less than 50% of the surviving entity. The note is classified as a corporate debt instrument and is classified as available-for-sale. During the year ended December 31, 2020, the Company recorded an other-than-temporary credit loss of $1.0 million against the value of this investment. The loss was recorded within "Other income (expense), net" in the accompanying consolidated statements of operations and comprehensive loss.

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, 2020, the Company's total contribution in Fountain was equal to €7.0 million, and its commitment represented approximately 7% of the partnership's total funding. The Company is accounting for its investment in Fountain under the equity method.

During the year ended December 31, 2020, two of the companies within the Fountain portfolio were acquired by third parties. The Company's proportional share of the proceeds from these transactions was $11.1 million, of which $10.4 million was received in September 2020 and $0.7 million is being held in escrow. The Company expects to collect the funds in escrow in 2021. The transactions were accounted for under the cumulative earnings approach whereby the return on investment of $8.3 million was recorded as a gain within "Other income (expense), net" in the accompanying consolidated statements of operations and comprehensive loss and the return of investment of $2.8 million was recorded as a reduction in the Company's net investment in Fountain. The Company's net investment in Fountain was $6.2 million and $5.9 million at December 31, 2020 and 2019, respectively, and was included within "Other assets" in the accompanying consolidated balance sheets.

During the years ended December 31, 2020, 2019 and 2018, the Company recorded an increase in its investment in Fountain of $0.3 million, a reduction of $0.4 million and an increase of $0.5 million, respectively, which represented the Company's proportional share of Fountain's net gains or losses for such periods.

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

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Proceeds from the sales and maturities of marketable securities	$ 253,001	$ 224,602	$ 444,456
Realized gains	$ 76	$ 997	$ 4
Realized losses	$ 977	$ 497	$ 268

The Company's available-for-sale and held-to-maturity securities at December 31, 2020 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	$ 242,605	$ 242,365	$ 3,487	$ 3,674
After 1 year through 5 years	139,674	140,807	—	—
Total	$ 382,279	$ 383,172	$ 3,487	$ 3,674

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, 2020	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 41,849	$ 41,849	$ —	$ —
U.S. government and agency debt securities	103,345	73,451	29,894	—
Corporate debt securities	184,956	—	183,979	977
International government agency debt securities	94,871	—	94,871	—
Contingent consideration	32,451	—	—	32,451
Total	$ 457,472	$ 115,300	$ 308,744	$ 33,428

	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

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 between levels during the year ended December 31, 2020. 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, 2020:

(In thousands)	Fair Value
Balance, January 1, 2020	$ 34,353
Change in the fair value of contingent consideration	3,945
Milestone and royalty payments received by the Company related to contingent consideration	(3,886)
Royalty payments due to the Company related to contingent consideration	(7)
Impairment of corporate debt security	(977)
Balance, December 31, 2020	$ 33,428

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 sold 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 to Recro Pharma, Inc. ("Recro") and Recro Gainesville LLC (such transaction the "Gainesville Transaction"). The Gainesville Transaction included in the purchase price 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 the Company's IP to which Recro was provided a right of use, through license or transfer, pursuant to the Gainesville Transaction (such products, the "Meloxicam Products"), and milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products.

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.

In Baudax's Quarterly Report on Form 10-Q for the period ended September 30, 2020, Baudax included disclosures around its ability to continue as a going concern. At December 31, 2020, the Company determined the fair value of the contingent consideration to be received as follows:

- The Company received $3.8 million and $10.0 million in milestone payments during 2020 and 2019, respectively, and is due to receive an additional $1.5 million in June 2021 related to the FDA approval in February 2020 of the NDA for ANJESO, the first Meloxicam Product, and $45.0 million in seven equal, annual installments beginning in February 2021, which is the first anniversary of such approval;
- The Company is entitled to receive future royalties on net sales of Meloxicam Products; 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.

In order to address the substantial doubt about Baudax's ability to continue as a going concern, the Company split its fair value analysis into two scenarios and applied an equal weighting to each. In the first scenario, the amounts above were all discounted using a rate of 13%, which the Company believes captures a market participant's view of the risk associated with the expected payments assuming Baudax is able to continue as a going concern. In the second scenario, the Company used the undiscounted values derived from the amounts summarized above and applied a recovery rate of 18%, based on an analysis performed by Moody's Investor Service regarding recoveries in a pandemic-driven default cycle.

At December 31, 2020 and 2019, the Company determined that the fair value of the contingent consideration was $32.5 million and $32.4 million, respectively. At December 31, 2020 and 2019, $7.8 million and none, respectively, of the fair value of the contingent consideration was included within "Prepaid expenses and other current assets" in the accompanying consolidated balance sheets, and $24.7 million and $32.4 million, respectively, of the fair value of the contingent consideration was included within "Contingent consideration" in the accompanying consolidated balance sheets. The Company recorded an increase of $3.9 million, and decreases of $22.8 million and $19.6 million during the years ended December 31, 2020, 2019 and 2018, respectively, within "Change in the fair value of contingent consideration" in the accompanying consolidated statements of operations and comprehensive loss.

The carrying amounts reflected in the accompanying 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 $275.1 million and $277.9 million at December 31, 2020 and 2019, 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, 2020	December 31, 2019
Raw materials	$ 44,944	$ 34,577
Work in process	53,243	54,061
Finished goods(1)	27,551	13,165
Total inventory	$ 125,738	$ 101,803

(1) At December 31, 2020 and 2019, the Company had $26.5 million and $7.6 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

In November 2020, the Company received a complete response letter, which included a request for information, from the FDA regarding the LYBALVI (formerly referred to as ALKS 3831) NDA, following the FDA's remote review of manufacturing records to the manufacture of LYBALVI at the Company's Wilmington, Ohio facility. The NDA was resubmitted in December 2020 and the assigned the NDA a Prescription Drug User Fee Act target action date of June 1, 2021.

In the third quarter of 2020, the Company capitalized a total of $15.3 million of LYBALVI inventory in advance of regulatory approval, of which $6.3 million was subsequently expensed in the fourth quarter of 2020 as the Company determined that certain lots were no longer probable of being sold commercially. As of December 31, 2020 and 2019, the carrying value of inventory included $13.8 million and none, respectively, associated with LYBALVI, which was capitalized in advance of regulatory approval.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following:

(In thousands)	December 31, 2020	December 31, 2019
Land	$ 6,560	$ 6,560
Building and improvements	178,194	177,087
Furniture, fixtures and equipment	366,051	340,146
Leasehold improvements	52,508	20,737
Construction in progress	102,833	134,683
Subtotal	706,146	679,213
Less: accumulated depreciation	(356,143)	(317,045)
Total property, plant and equipment, net	$ 350,003	$ 362,168

Depreciation expense was $42.4 million, $40.1 million and $38.5 million for the years ended December 31, 2020, 2019 and 2018, respectively. Also, during the years ended December 31, 2020, 2019 and 2018, the Company wrote off furniture, fixtures and equipment that had an approximate carrying value of less than $0.1 million, $0.9 million and $0.5 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. Approximately $24.2 million of the construction in progress balance at December 31, 2020 relates to certain building and equipment that the Company would place into service upon approval by the FDA of the NDA for LYBALVI. 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, 2020 Gross Carrying Amount	December 31, 2020 Accumulated Amortization	December 31, 2020 Net Carrying Amount	December 31, 2019 Gross Carrying Amount	December 31, 2019 Accumulated Amortization	December 31, 2019 Net Carrying Amount
Goodwill		$ 92,873	$ —	$ 92,873	$ 92,873	$ —	$ 92,873
Finite-lived intangible assets:							
Collaboration agreements	12	$ 465,590	$ (377,727)	$ 87,863	$ 465,590	$ (348,595)	$ 116,995
NanoCrystal technology	13	74,600	(54,391)	20,209	74,600	(46,773)	27,827
OCR(1) technologies	12	42,560	(39,441)	3,119	42,560	(36,739)	5,821
Total		$ 582,750	$ (471,559)	$ 111,191	$ 582,750	$ (432,107)	$ 150,643

(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 $39.5 million, $40.4 million and $65.2 million of amortization expense related to its finite-lived intangible assets during the years ended December 31, 2020, 2019 and 2018, respectively. Based on the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheets at December 31, 2020 is expected to be approximately $40.0 million, $35.0 million, $35.0 million, $1.0 million and none in the years ending

December 31, 2021 through 2025, 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, 2020. The Company elected to perform a quantitative impairment test and determined that the fair value of the reporting unit exceeded its carrying value.

9. LEASES

Leases are recorded in accordance with FASB Topic 842, which the Company adopted on January 1, 2019 under the modified retrospective transition method. The Company determines if an arrangement includes a lease at the inception of the agreement. For each of the Company's lease arrangements, a right-of-use asset representing its right to use an underlying asset for the lease term and a lease liability representing its obligation to make lease payments are recorded. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the net present value of lease payments over the term of the lease. See "Item 2—Properties" in this Annual Report for a description of the significant operating leases of offices and laboratory space the Company had as of December 31, 2020. The Company did not assume lease extension options would be exercised in its right-of-use asset and lease liability amounts. The Company has three additional operating leases that are included in its lease accounting but are not considered significant.

The Company determined that the identified operating leases did not contain non-lease components and required 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, 2020, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 5.25% and 12.6 years, respectively.

In July 2020, the Company entered into an amendment to its existing lease at 852 Winter Street, Waltham, Massachusetts (as amended, the "852 Winter Street Lease"). The amendment became effective on October 7, 2020. The 852 Winter Street Lease governs approximately 180,000 square feet of corporate office space, administrative areas and laboratories. The amendment served to, among other things, extend the term of the 852 Winter Street Lease for a period of approximately five years, to commence in March 2021 and expire in April 2026 with respect to approximately 163,000 square feet of the 852 Winter Street Lease premises (the "Base Premises") and to commence in September 2021 and expire in October 2026 with respect to approximately 17,000 square feet of the 852 Winter Street Lease premises (the "Additional Premises"). The Company expects to make annual lease payments of approximately $5.7 million for the Base Premises and $0.5 million for the Additional Premises, subject to annual increases. Under the terms of the 852 Winter Street Lease, the Company will have the option to extend the term for an additional five-year period. The Company determined that the amendment did not grant an additional right-of-use and therefore was not deemed to be a separate new lease and that the 852 Winter Street Lease should be reassessed and remeasured as of the effective date of the amendment. The Company accounted for the amendment prospectively.

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 that was to be built at 900 Winter Street, Waltham, Massachusetts (the "900 Winter Street Lease"). The initial term of the lease commenced on January 20, 2020 (the "Commencement Date") and includes an option to extend the term for an additional ten-year period. As the lease had not commenced as of December 31, 2019 and 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, the partially constructed assets could have potentially been leased to another tenant; and (c) did not legally own or control the land on which the property improvements were being constructed, the lease assets were not included as right-of-use assets at December 31, 2019. The future lease payments outlined below do not include the 900 Winter Street Lease payments as of December 31, 2019 under Topic 842.

As of December 31, 2020 and 2019, right-of-use assets arising from operating leases were $131.7 million and $12.4 million, respectively, and right-of-use liabilities arising from operating leases were $135.2 million and $13.8 million, respectively. During the year ended December 31, 2020 and 2019, cash paid for amounts included for the measurement of lease liabilities was $17.3 million and $9.1 million, respectively. The Company recorded operating lease expense of $16.3 million, $8.1 million and $10.8 million for the years ended December 31, 2020, 2019 and 2018, respectively.

Future lease payments under non-cancelable leases as of December 31, 2020 consisted of the following:

(In thousands)	December 31, 2020
2021	$ 16,882
2022	17,001
2023	17,266
2024	17,536
2025	17,810
Thereafter	109,311
Total lease payments	$ 195,806
Less: imputed interest	(60,610)
Total operating lease liabilities	$ 135,196

For comparable purposes, 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

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

(In thousands)	December 31, 2020	December 31, 2019
Accounts payable	$ 46,034	$ 54,261
Accrued compensation	71,178	72,072
Accrued sales discounts, allowances and reserves	218,877	153,902
Accrued other	76,082	92,802
Total accounts payable and accrued expenses	$ 412,171	$ 373,037

11. LONG-TERM DEBT

Long-term debt consists of the following:

(In thousands)	December 31, 2020	December 31, 2019
2023 Term Loans, due March 26, 2023	$ 274,961	$ 277,138
Less: current portion	(2,843)	(2,843)
Long-term debt	$ 272,118	$ 274,295

2023 Term Loans

In March 2018, the Company amended and refinanced its existing term loan, previously 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:		
2021	$	2,843
2022		2,843
2023		270,747
2024		—
2025		—
Total	$	276,433

The Company is subject to mandatory prepayments of principal if certain excess cash flow thresholds, as defined in the 2023 Term Loans, are 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, 2020.

At December 31, 2020, the Company's balance of unamortized deferred financing costs and unamortized original issue discount costs were $0.4 million and $1.0 million, respectively. These costs are being amortized to interest expense over the estimated repayment period of the 2023 Term Loans using the effective interest method. During each of the years ended December 31, 2020, 2019 and 2018, the Company had amortization expense of $0.7 million 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, 2020, 2019 and 2018, 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 had an anti-dilutive effect on loss per share.

The following potential ordinary share equivalents 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)	**2020**	**2019**	**2018**
Stock options	15,274	13,814	11,331
Restricted stock units	3,279	3,177	2,592
Total	18,553	16,991	13,923

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, 2020, 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, 2020 and 2019, 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)	2020	2019	2018
Cost of goods manufactured and sold	$ 8,430	$ 9,948	$ 9,174
Research and development	26,408	29,924	32,943
Selling, general and administrative	55,326	61,105	63,240
Total share-based compensation expense	$ 90,164	$ 100,977	$ 105,357

During the years ended December 31, 2020, 2019 and 2018, $2.6 million, $1.5 million and $2.7 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 one share-based compensation plan pursuant to which awards are currently being made: the 2018 Stock Option and Incentive Plan, as amended (the "2018 Plan"). The Company has two share-based compensation plans pursuant to which outstanding awards have been made, but from which no further awards can or will be made: the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended, (the "2008 Plan") and the Alkermes plc 2011 Stock Option and Incentive Plan, as amended (the "2011 Plan"). Effective May 20, 2020, the 2018 Plan was amended such that any shares underlying any outstanding awards granted under the 2011 Plan or the 2008 Plan that are forfeited, canceled, repurchased or otherwise terminated (other than by exercise) from and after such date will become available for issuance pursuant to the 2018 Plan, notwithstanding anything to the contrary in the terms of the 2011 Plan or the 2008 Plan.

The 2018 Plan allows 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, as applicable.

At December 31, 2020, there were 13.9 million ordinary shares available for issuance in the aggregate under the 2018 Plan. The 2018 Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 1.8-to-1 ratio.

Stock Options

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

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 2020	15,235,845	$ 40.34
Granted	3,799,952	$ 20.20
Exercised	(682,122)	$ 12.27
Expired	(1,266,999)	$ 49.81
Forfeited	(974,487)	$ 36.28
Outstanding, December 31, 2020	16,112,189	$ 36.27
Exercisable, December 31, 2020	9,842,531	$ 40.08

The weighted average grant date fair value of stock options granted during the years ended December 31, 2020, 2019 and 2018 was $9.52, $15.57 and $30.47, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2020, 2019 and 2018 was $2.0 million, $21.3 million and $35.5 million, respectively.

At December 31, 2020, there were 6.1 million stock options expected to vest with a weighted average exercise price of $30.46 per share, a weighted average contractual remaining life of 8.5 years with an aggregate intrinsic value of $0.2 million. At December 31, 2020, the aggregate intrinsic value of stock options exercisable was $6.9 million with a weighted average remaining contractual term of 4.3 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, 2020, there was $34.6 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of 1.8 years. Included within the outstanding stock option balances at December 31, 2020 was 0.4 million performance-based stock options that were granted in 2019 and valued using a Monte Carlo simulation model. The weighted average grant date fair value of such performance-based stock options was $16.78. The unrecognized compensation cost related to these performance-based stock options was $1.9 million at December 31, 2020 and is included in the unrecognized compensation cost noted above. Cash received from option exercises under the Company's award plans during the years ended December 31, 2020, 2019 and 2018 was $8.4 million, $18.9 million and $20.9 million, respectively.

Time-Based Restricted Stock Unit Awards

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, 2020	3,744,800	$ 38.99
Granted	3,494,759	$ 20.22
Vested	(1,097,210)	$ 41.84
Forfeited	(587,087)	$ 31.16
Unvested, December 31, 2020	5,555,262	$ 27.45

The weighted average grant date fair value of time-vested RSUs granted during the years ended December 31, 2020, 2019 and 2018 were $20.22, $30.47 and $63.01, respectively. The total fair value of time-vested RSUs that vested during the years ended December 31, 2020, 2019 and 2018, was $45.9 million, $42.4 million and $34.5 million, respectively.

At December 31, 2020, there was $61.0 million of total unrecognized compensation cost related to unvested time-vested RSUs, which will be recognized over a weighted average remaining contractual term of 1.8 years.

Performance-Based Restricted Stock Unit Awards

In February 2020, the compensation committee of the Company's board of directors approved awards of performance-based RSUs to employees of the Company at the Senior Vice President level and above, in each case subject to vesting on the achievement of certain commercial and R&D performance criteria to be assessed over a performance period of three years from the date of the grant, and subject, at the end of such three-year performance period, to upward or downward adjustment based on a market condition tied to relative share price performance over the three-year performance period.

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, 2020	543,554	$ 54.75
Granted	529,578	$ 23.43
Forfeited	(574,148)	$ 53.08
Vested	—	$ —
Unvested, December 31, 2020	498,984	$ 23.43

As the performance-based RSUs granted in February 2020 are subject to a market condition, the grant date fair value for such RSUs was based on a Monte Carlo simulation model. At December 31, 2020, the Company believed it probable that commercial performance criteria underlying the RSUs will be met and, accordingly, has recognized share-based compensation expense related to this portion of the performance-based RSUs. At December 31, 2020, the Company did not consider it probable that the performance criteria related to the R&D portion of the awards will be met and has not recognized any additional share-based compensation expense

related to this portion of the performance-based RSUs. At December 31, 2020, there was $10.4 million of unrecognized compensation cost related to the R&D portion of the performance-based RSUs, which would be recognized in accordance with the terms of the award when the Company deems it probable that the performance criteria will be met. The unvested awards will expire if it is determined that the performance criteria have not been met on or before December 31, 2022.

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 certain performance criteria which were to be assessed over a performance period of three years from the date of the grant (the "2017 Performance Awards"). The grant date fair value of the 2017 Performance Awards was equal to the closing price of the Company's stock on the Nasdaq Global Select Market on the dates of grant.

In December 2018, the Company achieved one such performance criteria, resulting in the vesting of a portion of the 2017 Performance Awards. Prior to December 2018, the Company did not consider it probable that the performance criteria related to the awards would be met and had not recognized any share-based compensation expense related to the 2017 Performance Awards. Once it was deemed probable that certain performance conditions would be achieved, the Company recognized $17.1 million in share-based compensation expense related to such 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 determined the two remaining performance criteria of the 2017 Performance Awards were not achieved. The unvested portion of the 2017 Performance Awards expired as 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 resulted in cash expenditures and substantially all of which were paid out by December 31, 2020. Restructuring activity during the year ended December 31, 2020 was as follows:

(In thousands)	
Balance, January 1, 2020	$ 9,201
Amounts paid during the period:	
Severance	(7,354)
Outplacement services	(108)
Benefits	(1,277)
Balance, December 31, 2020	$ 462

At December 31, 2020 and 2019, $0.5 million and $9.0 million of the restructuring accrual were included within "Accounts payable and accrued expenses" in the accompanying consolidated balance sheets, respectively, and none and $0.2 million of the restructuring accrual were included within "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 Therapeutics, Inc. ("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 former 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 was largely in the preclinical 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 were considered probable of occurring at December 31, 2020 and 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, 2020, 2019 and 2018 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%.

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: (i) initiation of a phase 3 clinical trial: $1.0 million; (ii) acceptance of an NDA by the FDA: $1.0 million; (iii) approval of the NDA by the FDA: $1.5 million; and (iv) the first commercial sale: $1.5 million.

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. Biogen has elected to initiate a technology transfer and, following a transition period, assume responsibility 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 that portion 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.

18. INCOME TAXES

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

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Current income tax provision (benefit):			
U.S. federal	$ 2,943	$ (471)	$ (53)
U.S. state	1,396	354	1,774
Rest of world	—	—	—
Deferred income tax provision (benefit):			
U.S. federal	9,876	(1,503)	10,624
U.S. state	109	881	62
Ireland	—	303	(63)
Total tax provision (benefit)	$ 14,324	$ (436)	$ 12,344

The income tax provision in 2020, the income tax benefit in 2019 and the income tax provision in 2018 were primarily due to U.S. federal and state taxes. The unfavorable change in income taxes in 2020, as compared to 2019, and the favorable change in income taxes in 2019, as compared to 2018 was primarily due to a significant benefit recorded in 2019 relating 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.

On March 27, 2020 the Coronavirus Aid, Relief and Economic Security ("CARES") Act was passed by the U.S. Congress and signed into law by the President of the United States. The CARES Act, among other things, includes certain income tax provisions for individuals and corporations; however, these benefits have limited impact on the Company's income tax provision.

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. Cumulative unremitted earnings of overseas subsidiaries totaled approximately $369.0 million at December 31, 2020. 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 $38.0 million of income taxes would be payable on the repatriation of the unremitted earnings to Ireland.

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

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Ireland	$ (138,070)	$ (141,869)	$ (180,195)
U.S.	41,599	(55,102)	53,287
Rest of world	(66)	(85)	(59)
Loss before provision (benefit) for income taxes	$ (96,537)	$ (197,056)	$ (126,967)

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

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

(In thousands)	December 31, 2020	December 31, 2019
Deferred tax assets:		
NOL carryforwards	$ 233,755	$ 227,872
Tax credits	59,098	57,385
Accrued expenses and reserves	49,730	20,337
Share-based compensation	44,480	45,214
Other	6,651	8,756
Less: valuation allowance	(253,649)	(242,059)
Total deferred tax assets	140,065	117,505
Deferred tax liabilities:		
Property, plant and equipment	(52,707)	(19,926)
Other	(1,697)	(1,590)
Total deferred tax liabilities	(54,404)	(21,516)
Net deferred tax assets	$ 85,661	$ 95,989

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, 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)
Deferred tax asset valuation allowance for the year ended December 31, 2020	$ (242,059)	$ (11,590)	$ (253,649)

(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, 2020, the Company maintained a valuation allowance of $20.9 million against certain U.S. state deferred tax assets and $232.8 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, 2020, the Company had $1.6 billion of Irish NOL carryforwards, $33.3 million of U.S. federal NOL carryforwards, $43.2 million of state NOL carryforwards, $48.6 million of federal R&D credits and $23.0 million of state tax credits which will either expire on various dates through 2040 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 $51.3 million of U.S. federal NOL carryforwards, $43.2 million of state NOL carryforwards, $0.7 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.

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

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

(In thousands, except percentage amounts)	Year Ended December 31, 2020	2019	2018
Statutory tax rate	12.5 %	12.5 %	12.5 %
Loss before income taxes at statutory rate	$ (12,067)	$ (24,632)	$ (15,871)
Change in valuation allowance	11,590	19,882	28,371
Share-based compensation	8,972	6,287	1,163
Foreign rate differential(1)	7,798	5,390	5,405
Intercompany amounts(2)	6,234	(1,125)	(751)
U.S. state income taxes, net of U.S. federal benefit	1,298	1,051	1,732
Irish rate differential(3)	2,511	(146)	(2,350)
Uncertain tax positions	811	776	563
Non deductible lobbying expenses	683	736	661
Federal tax law change(4)	248	(8,111)	—
In-process R&D(5)	84	10,824	—
Foreign derived intangible income	(3,125)	(3,450)	—
R&D credit	(11,198)	(8,846)	(7,698)
Other permanent items(6)	485	928	1,119
Income tax provision (benefit)	$ 14,324	$ (436)	$ 12,344
Effective tax rate	(14.8) %	0.2 %	(9.7) %

(1) Represents income or losses of non-Irish subsidiaries, including U.S. subsidiaries, subject to tax at a rate other than the Irish statutory rate.
(2) 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.
(3) Represents income or losses of Irish companies subject to tax at a rate other than the Irish statutory rate.
(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.
(5) Represents the tax effect of the research and development expense recorded on the acquisition of Rodin.
(6) Other permanent items include, but are not limited to, non-deductible meals and entertainment expenses and non-deductible compensation of senior officers of the Company.

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

(In thousands)	Unrecognized Tax Benefits
Balance, December 31, 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
Additions based on tax positions related to prior periods	15
Additions based on tax positions related to the current period	796
Balance, December 31, 2020	$ 7,668

The unrecognized tax benefits at December 31, 2020, 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, 2020, 2019 and 2018, 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 2017 through 2020 fiscal years remain subject to examination by the respective tax authorities.

In Ireland, the years 2016 to 2020 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 Finance S.a.r.l are currently under examination by the Tax Authorities in Luxembourg. There are no uncertain tax positions or adjustments associated with the audit 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, utilizing all 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, 2020, 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

Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated patent infringement lawsuits in the U.S. District Court for the District of New Jersey (the "NJ District Court") in January 2018 against Teva Pharmaceuticals USA, Inc. ("Teva") and Teva Pharmaceuticals Industries, Ltd. ("Teva PI"), in August 2019 against Mylan Laboratories Limited ("Mylan Labs"), Mylan Pharmaceuticals Inc. ("Mylan"), and Mylan Institutional LLC and in December 2019 against Pharmascience, Inc. ("Pharmascience"), Mallinckrodt plc, and SpecGX LLC, following the respective filings by each of Teva, Mylan Labs, and Pharmascience of an Abbreviated New Drug Application ("ANDA") seeking approval from the FDA to market a generic version of INVEGA SUSTENNA before the expiration of U.S. Patent No. 9,439,906. In October 2020, a trial was held in the lawsuit between the Janssen entities and the Teva entities. Requested judicial remedies in each of the lawsuits included recovery of litigation costs and injunctive relief. The Company is not a party to any of these proceedings.

INVEGA TRINZA ANDA Litigation

In September 2020, Janssen Pharmaceuticals NV, Janssen Pharmaceuticals, Inc., and Janssen Research & Development, LLC, initiated a patent infringement lawsuit in the NJ District Court against Mylan Labs, Mylan, and Mylan Institutional LLC following the filing by Mylan Labs of an ANDA seeking approval from the FDA to market a generic version of INVEGA TRINZA before the expiration of U.S. Patent No. 10,143,693. Requested judicial remedies include recovery of litigation costs and injunctive relief. The Company is not a party to this proceeding.

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 and Nanjing Luye Pharmaceutical Co Ltd. and Teva Pharmaceutical Industries Ltd. submitted replies on December 20, 2019. The Company will continue to vigorously defend the EP '577 Patent.

VIVITROL ANDA Litigation

In September 2020, Alkermes, Inc. and Alkermes Pharma Ireland Limited filed a patent infringement lawsuit in the NJ District Court against Teva and Teva PI following the filing by Teva of an ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a generic version of VIVITROL (naltrexone for extended-release injectable suspension) before the expiration of the Company's U.S. Patent No. 7,919,499. Teva filed its Answer on November 16, 2020, which included counterclaims against the Company. The Company filed its Reply to Teva's counterclaims on December 7, 2020. The Company intends to vigorously defend its intellectual property. The filing of the lawsuit triggered a stay of FDA approval of the ANDA for up to 30 months in accordance with the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act).

Government Matters

The Company has received a subpoena and civil investigative demands from U.S. state and Federal governmental authorities for documents related to VIVITROL. The Company is cooperating with the investigations.

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 U.S. 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.

Product Liability and Other Legal Proceedings

The Company is also involved in product liability cases and other legal proceedings incidental to its normal business activities, including product liability cases alleging that the FDA-approved VIVITROL labeling was inadequate and caused the users of the product to suffer from opioid overdose and death. The Company intends to vigorously defend itself in these matters. While the outcome of any of these proceedings cannot be accurately predicted, the Company does not believe the ultimate resolution of any of these existing matters would have a material adverse effect on the Company's business or financial condition.

Purchase Commitments

The Company has open purchase orders for plant and equipment as part of the normal course of business. At December 31, 2020, the Company's open purchase orders were $3.5 million for capital commitments.

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 any 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: (i) our undenominated capital; (ii) 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; and (iii) any other reserve we are prohibited, at law, from distributing.

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-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, a subsidiary may purchase our shares either on-market (an overseas market purchase) 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 overseas 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, 2020, 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 authorization of the Board to approve the remuneration of the statutory auditors; and (iv) the election and/or re-election of members of the Board in accordance with our Constitution. 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 on the requisition of 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 s/he 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 Constitution;

b) approving a change of our name;

c) 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;

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

e) creating a new class of shares;

f) our re-registration from a public limited company to a private company;

g) variation of class rights attaching to classes of shares (where the Constitution do not provide otherwise);

h) purchase of our own shares off-market;

i) reduction of issued share capital;

j) sanctioning a compromise/scheme of arrangement;

k) resolving that we be wound up by the Irish courts;

l) resolving in favor of a shareholders' voluntary winding-up;

m) re-designation of shares into different share classes; and

n) 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

Irish law generally does not provide for "appraisal rights". However, it does provide for dissenters' rights in certain situations, as described below.

Under a tender or takeover offer, the bidder may require any remaining shareholders to transfer their shares on the terms of the offer (i.e., a "squeeze out") if it has acquired, pursuant to the offer, not less than 80% of the target shares to which the offer relates (in the case of a company that is not listed on an EEA regulated market). Dissenting shareholders have the right to apply to the Irish High Court for relief.

A scheme of arrangement which has been approved by the requisite shareholder majority and sanctioned by the Irish High Court will be binding on all shareholders. Dissenting shareholders have the right to appear at the Irish High Court hearing and make representations in objection to the scheme.

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.

Similar rights apply in the case of a merger of an Irish public limited company into another company to which the provisions of the Companies Act apply.

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 it 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 that 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 contains 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 provides 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 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 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, 333-232831 and 333-240170) of Alkermes plc of our report dated February 11, 2021 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 11, 2021

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 11, 2021

Exhibit 31.2

CERTIFICATIONS

I, Iain M. Brown, 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/ Iain M. Brown
Senior Vice President, Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Date: February 11, 2021

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, 2020 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 Iain M. Brown, 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/ Iain M. Brown
Iain M. Brown
Senior Vice President, Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Date: February 11, 2021