ALKERMES PUBLIC LIMITED COMPANY

DIRECTORS' REPORT AND CONSOLIDATED FINANCIAL STATEMENTS

For the Financial Year Ended December 31, 2022

Registered Company Number: 498284

ALKERMES PUBLIC LIMITED COMPANY
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DIRECTORS' REPORT

For the Financial Year Ended December 31, 2022

The directors present their report (this "Directors' Report") and the audited consolidated financial statements and related notes of Alkermes Public Limited Company ("Alkermes plc") for the year ended December 31, 2022. Irish law requires the directors to prepare financial statements for each financial year that give a true and fair view of the consolidated and parent company's assets, liabilities and financial position as at the end of the financial year and of the consolidated profit or loss of the Company for the financial year. Under that law, the directors have prepared the consolidated financial statements in accordance with United States ("U.S.") accounting standards, as defined in Section 279(1) of the Irish Companies Act 2014, as amended (the "Companies Act"), to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Act or of any regulations made thereunder and the parent company financial statements in accordance with generally accepted accounting practice in Ireland (accounting standards issued by the Financial Reporting Council of the UK, including Financial Reporting Standard 102, *The Financial Reporting Standard applicable in the UK and Republic of Ireland* and Irish law).

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

Use of terms such as "us," "we," "our," "Alkermes" or the "Company" in this Directors' 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 Directors' Report include our marketed products, marketed products using our proprietary technologies, our licensed products, our product candidates and product candidates using our proprietary technologies (b) references to the "biopharmaceutical industry" in this Directors' Report are intended to include reference to the "biotechnology industry" and/or the "pharmaceutical industry" and (c) references to "licensees" in this Directors' Report are used interchangeably with references to "partners."

NOTE REGARDING TRADEMARKS

We are the owner of various 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"); ANJESO®—Baudax Bio, Inc.; 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; BRIUMVI™—TG Therapeutics, Inc.; BUNAVAIL™—BioDelivery Sciences; CAMPRAL®—Merck Sante; CAPLYTA®—Intra-Cellular Therapies, Inc.; COPAXONE®—Teva Pharmaceutical Industries Ltd.; EXTAVIA®, GILENYA®, and MAYZENT®—Novartis AG; BYANNLI®, INVEGA®, INVEGA HAFYERA®, INVEGA SUSTENNA®, INVEGA TRINZA®, PONVORY®, RISPERDAL CONSTA®, TREVICTA® and XEPLION®—Johnson & Johnson or its affiliated companies; KEYTRUDA®—Merck Sharp & Dohme Corp.; 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); RYKINDO®—Luye Pharma Group; 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 Directors' Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Directors' 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.

CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This document contains and incorporates by reference "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. In some cases, these statements can be identified by the use of forward-looking terminology such as "may," "will," "could," "should," "would," "expect," "anticipate," "continue," "believe," "plan," "estimate," "intend," or other similar words. These 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 Directors' 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 expectations related to product development; regulatory filings, approvals and timelines; therapeutic and commercial value, scope and potential; and the costs and expenses related to such activities and expectations;
- 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 development programs, barriers to access or coverage of our products and potential changes in reimbursement of our products, and legislation, regulations, executive orders, guidance or other measures that may impact 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 collaborations, licensing arrangements and other significant agreements with third parties relating to our products and our development programs;
- our expectations regarding the impact of new legislation, rules and 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 expenditures for our operations and our ability to finance such capital requirements and expenditures;
- 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;
- our expectations regarding the potential separation of our neuroscience business and oncology business, including anticipated timing, effects, costs benefits and tax treatment; and
- other expectations discussed elsewhere in this Directors' 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 expectations discussed in this Directors' Report might not occur. You are cautioned not to place undue reliance on the forward-looking statements in this Directors' Report, which speak only as of the date of this Directors' Report. All subsequent written and oral forward-looking statements concerning the matters addressed in this Directors' 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 information about the risks, assumptions and uncertainties of our business, see the section entitled "Principal Risks" in this Directors' Report.

This Directors' Report may include 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. While we believe that any industry publications and third-party research, surveys and studies from which data is included in this Directors' Report are reliable, we have not independently verified any such data. This Directors' Report may also include data based on our own internal estimates and research. Our internal estimates and research have not been verified by any independent source and are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Principal Risks" in this Directors' Report. These and other factors could cause our results to differ materially from those expressed or implied in this Directors' Report.

Principal Activities

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 portfolio of proprietary commercial products focused on alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for neurological disorders and cancer. 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.

COVID-19 Update

The COVID-19 pandemic has impacted, and may continue to impact, many aspects of society, including the operation of healthcare systems, global travel, supply and labor markets and other business and economic activity worldwide. A number of the marketed products from which we derive revenue, including manufacturing and royalty revenue, are injectable medications administered by healthcare professionals, which have been, and may continue to be, adversely impacted to varying degrees as a result of COVID-19 related closures, restrictions, labor shortages and other disruptions that have transpired, and may continue to transpire, while the pandemic persists.

The COVID-19 pandemic has caused, and may continue to cause, varying degrees of disruption to our employees and our business operations. While we have continued to operate our manufacturing facilities and supply our medicines throughout the pandemic, we have at times during the pandemic experienced labor or supply chain disruptions at our manufacturing facilities and may continue to experience such disruptions while the pandemic persists, which could impact our ability to manufacture our products and the third-party products from which we receive revenue in a timely matter or at all. In addition, while we have continued to conduct R&D activities, including our ongoing clinical trials, the COVID-19 pandemic has at times impacted the timelines of certain of our early-stage discovery efforts and clinical trials, and may continue to impact such timelines while the pandemic persists. We work 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.

The degree to which the COVID-19 pandemic may continue to impact our employees, business, financial condition and results of operations will depend on the ultimate severity and duration of the pandemic and the manner in which it continues to evolve, including the emergence, prevalence and severity of new COVID-19 variants, and future developments in response thereto. Due to these and numerous other uncertainties surrounding the ongoing COVID-19 pandemic, the actual impact of the pandemic on our financial condition and operating results may differ from our current projections. 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 "Principal Risks" in this Directors' Report and specifically the section entitled "Our business, financial condition and results of operations have been, and may continue to be, adversely affected by the ongoing COVID-19 pandemic or other similar outbreaks of contagious diseases."

Business Overview

Marketed Products

The key marketed products discussed below have generated, or are expected to generate, significant revenues for us. See the "Patents and Proprietary Rights" section in this Directors' 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:

Proprietary Products

Product	Indication(s)	Territory
ARISTADA INITIO	Initiation or re-initiation of ARISTADA for the treatment of Schizophrenia	U.S.
ARISTADA	Schizophrenia	U.S.
LYBALVI	Schizophrenia; Bipolar I disorder	U.S.
VIVITROL	Alcohol dependence; Opioid dependence	U.S.

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

Key Third-Party Products Using Our Proprietary Technologies

Product	Indication(s)	Licensee	Licensed Territory
RISPERDAL CONSTA	Schizophrenia; Bipolar I disorder	Janssen Pharmaceuticals, Inc. ("Janssen, Inc.") and Janssen Pharmaceutica International, a division of Cilag International AG ("Janssen International")	Worldwide
INVEGA SUSTENNA / XEPLION*	INVEGA SUSTENNA: Schizophrenia; 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
INVEGA HAFYERA / BYANNLI*	Schizophrenia	Janssen	Worldwide

* Janssen partially terminated its license agreement related to these products, effective February 2022. See the section entitled "Products Using Our Proprietary Technologies" below and Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report for more information with respect to this partial termination and the arbitration proceedings related to this partial termination and other matters in respect of these products.

Our Key Licensed Product

Product	Indication(s)	Licensee	Licensed Territory
VUMERITY	Multiple sclerosis	Biogen	Worldwide

Proprietary Products

We have developed and now commercialize products designed to help address the unmet needs of people living with opioid dependence, alcohol dependence, schizophrenia and bipolar I disorder. See the "Patents and Proprietary Rights" section in this Directors' 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 utilizes 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 syringe product format. We exclusively manufacture and commercialize ARISTADA in the U.S.

ARISTADA INITIO

ARISTADA INITIO (aripiprazole lauroxil) leverages our proprietary LinkeRx and NanoCrystal technologies 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 exclusively manufacture and commercialize ARISTADA INITIO in the U.S.

In December 2022, U.S. Patent No. 11,518,745 relating to ARISTADA and ARISTADA INITIO was granted. The patent has claims to the synthesis of aripiprazole lauroxil and expires in 2030.

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). Schizophrenia affects approximately 1.1% of the U.S. population.

LYBALVI

LYBALVI (olanzapine and samidorphan) is a once-daily, oral atypical antipsychotic drug approved in the U.S. for the treatment of adults with schizophrenia and for the treatment of adults with bipolar I disorder, as a maintenance monotherapy or for the acute treatment of manic or mixed episodes, as monotherapy or an adjunct to lithium or valproate. LYBALVI is composed of olanzapine, an established antipsychotic agent, co-formulated with samidorphan, a new chemical entity, in a single bilayer tablet. LYBALVI was launched commercially in October 2021 and is available in fixed dosage strengths composed of 10 mg of samidorphan and 5 mg, 10 mg, 15 mg or 20 mg of olanzapine. We exclusively manufacture and commercialize LYBALVI in the U.S.

What is bipolar I disorder?

Bipolar I disorder is a brain disorder that is marked by extreme changes in a person's mood, energy and ability to function. Individuals with this brain disorder may experience debilitating changes in mood from extreme highs (mania) to extreme lows (depression). Bipolar I disorder is characterized by the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode, and affects approximately 1% of the American adult population in any given year.

VIVITROL

VIVITROL (naltrexone for extended-release injectable suspension) is a once-monthly, non-narcotic, injectable medication approved in the U.S. for the treatment of alcohol dependence in patients able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL 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 exclusively manufacture and 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 Directors' Report, and for information about risks relating to such legal proceedings, see the section entitled "Principal Risks" in this Directors' 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 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 2020 U.S. National Survey on Drug Use and Health, an estimated 2.6 million people aged 18 or older in the U.S. had an opioid use disorder in the prior 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 2020 U.S. National Survey on Drug Use and Health, an estimated 27.8 million people aged 18 or older in the U.S. had an alcohol use disorder in the prior 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 indications of VIVITROL, were subsumed under a new 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. In determining the applicability of treatments for DSM-IV conditions to persons diagnosed according to DSM-5, one study found agreement between the DSM-IV diagnoses of alcohol dependence and opioid dependence and moderate to severe alcohol use disorder and opioid use disorder, respectively, under DSM-5.

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 the "Proprietary Technology Platforms" and "Patents and Proprietary Rights" sections in this Directors' Report for information with respect to our proprietary technologies and the IP protection for these products. We receive royalties and/or manufacturing and other revenues from the commercialization of these products under our collaborative arrangements with these third parties. Such arrangements include the following:

Products Using Our Proprietary Technologies

INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and INVEGA HAFYERA/BYANNLI

In November 2021, we received notice of partial termination of an exclusive license agreement with Janssen. Under this license agreement, we provided Janssen with rights to, and know-how, training and technical assistance in respect of, our small particle pharmaceutical compound technology, known as NanoCrystal technology, which was used to develop INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, and INVEGA HAFYERA/BYANNLI. When the partial termination became effective in February 2022, Janssen ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. In April 2022, we commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of this license agreement and Janssen's royalty and other obligations under the agreement. On December 21, 2022, we received an interim award (the "Interim Award") in these proceedings from the arbitral tribunal (the "Tribunal"), in which the Tribunal agreed with our position that, while Janssen may terminate the agreement, it may not continue to sell Products (as defined in the agreement) developed during the term of the agreement without paying royalties pursuant to the terms of the agreement. This award is not yet final. We will engage with Janssen and the Tribunal in additional proceedings prior to the Tribunal's issuance of a final award. For additional information about these proceedings, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report and for information about risks relating to this notice of partial termination and our collaborative arrangements more broadly, see the section entitled "Principal Risks" in this Directors' Report and specifically that section entitled "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, or if disputes arise in respect of our contractual arrangements, our revenues could be materially adversely affected."

INVEGA SUSTENNA/XEPLION (paliperidone palmitate), INVEGA TRINZA/TREVICTA (paliperidone palmitate) and INVEGA HAFYERA/BYANNLI (paliperidone palmitate) (collectively, the "long-acting INVEGA products") are long-acting atypical antipsychotics owned and commercialized worldwide by Janssen. We believe that these products incorporate, our 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 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 manufactured by Janssen.

INVEGA HAFYERA 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 or INVEGA TRINZA for at least three months. BYANNLI is approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION or TREVICTA. INVEGA HAFYERA/BYANNLI is manufactured by Janssen.

For a discussion of legal proceedings related to certain of the patents covering INVEGA SUSTENNA and INVEGA TRINZA, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report and for information about risks relating to such legal proceedings, see the section entitled "Principal Risks" in this Directors' 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 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.

RISPERDAL CONSTA

RISPERDAL CONSTA (risperidone long-acting injection) is a long-acting atypical antipsychotic owned and commercialized worldwide by Janssen that incorporates our proprietary technologies. 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.

Licensed Product

VUMERITY

VUMERITY (diroximel fumarate) is a novel, oral fumarate with a distinct chemical structure that is approved in the U.S., the EU and several other countries 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 this Directors' 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 Program

Our R&D is focused on the development of innovative medicines in the fields of neuroscience and oncology that are designed to address unmet patient needs. 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 development program. 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 the section entitled "Principal Risks" in this Directors' Report. See the section entitled "Patents and Proprietary Rights" in this Directors' Report for information with respect to the IP protection for our key development program.

nemvaleukin alfa

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 preferentially expand tumor-killing immune cells while avoiding the activation of immunosuppressive cells by selectively binding to the intermediate-affinity IL-2 receptor complex. The selectivity of nemvaleukin is designed to leverage the proven anti-tumor effects of existing IL-2 therapy while mitigating certain limitations.

ARTISTRY is our clinical development program evaluating nemvaleukin as a potential immunotherapy for cancer. The ARTISTRY program is comprised of multiple clinical trials evaluating intravenous ("IV") and subcutaneous ("SC") dosing of nemvaleukin, both as a monotherapy and in combination with the anti-PD-1 therapy KEYTRUDA (pembrolizumab) in patients with advanced solid tumors. ARTISTRY-6 is an ongoing phase 2 study evaluating the anti-tumor activity, safety and

tolerability of IV nemvaleukin monotherapy in patients with mucosal melanoma and SC nemvaleukin monotherapy in patients with advanced cutaneous melanoma. ARTISTRY-7 is an ongoing phase 3 study evaluating the efficacy, safety and tolerability of IV nemvaleukin as monotherapy and in combination with pembrolizumab compared to investigator's choice chemotherapy in patients with platinum-resistant ovarian cancer.

In March 2021 and August 2021, we announced that the U.S. Food and Drug Administration (the "FDA") granted Orphan Drug Designation and Fast Track designation, respectively, to nemvaleukin for the treatment of mucosal melanoma. In October 2021, we announced that the FDA granted Fast Track designation to nemvaleukin in combination with pembrolizumab for the treatment of platinum-resistant ovarian cancer. In January 2023, we announced that the Medicines and Healthcare products Regulatory Agency (MHRA), the regulatory body of the United Kingdom (UK), granted nemvaleukin an Innovation Passport for the treatment of mucosal melanoma under the Innovative Licensing and Access Pathway (ILAP).

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, INVEGA TRINZA/TREVICTA and INVEGA HAFYERA/BYANNLI

In November 2021, we received notice of partial termination of an exclusive license agreement with Janssen. Under this license agreement, we provided Janssen with rights to, and know-how, training and technical assistance in respect of, our small particle pharmaceutical compound technology, known as NanoCrystal technology, which was used to develop INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, and INVEGA HAFYERA/BYANNLI. When the partial termination became effective in February 2022, Janssen ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. and we stopped recognizing royalty revenue related to net sales of these products. In April 2022, we commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of this license agreement and Janssen's royalty and other obligations under the agreement. On December 21, 2022, we received the Interim Award in these proceedings from the Tribunal, in which the Tribunal agreed with our position that, while Janssen may terminate the agreement, it may not continue to sell Products (as defined in the agreement) developed during the term of the agreement without paying royalties pursuant to the terms of the agreement. This award is not yet final. We will engage with Janssen and the Tribunal in additional proceedings prior to the Tribunal's issuance of a final award. For additional information about these proceedings, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report and for information about risks relating to this notice of partial termination and our collaborative arrangements more broadly, see the section entitled "Principal Risks" in this Directors' Report and specifically those sections entitled "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, or if disputes arise in respect of our contractual arrangements, our revenues could be materially adversely affected."

Under this license agreement, we granted Janssen a worldwide exclusive license under our NanoCrystal technology to develop, commercialize and manufacture injectable pharmaceutical products containing paliperidone palmitate, which include the long-acting INVEGA products, and we received milestone payments from Janssen upon the achievement of certain development goals; there are no further milestones to be earned under this agreement. The agreement also provides for tiered royalty payments between 3.5% and 9% of net sales of products subject to the agreement 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 royalty-bearing 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 expiry of the 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, unless earlier terminated, terminates 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 subject to certain surviving obligations.

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 15% and 30% of our consolidated revenues for the years ended December 31, 2022 and 2021, respectively.

Biogen

Under a license and collaboration agreement with Biogen, 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 and milestone payments related to the achievement of certain milestones, including FDA approval of the NDA for VUMERITY and amendment of the license and collaboration agreement. 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 increases for VUMERITY manufactured and/or packaged by Biogen or its designees, and 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 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 license and collaboration agreement with Biogen, pursuant to which Biogen has elected to conduct a technology transfer and, subject to agreement in respect of a manufacturing 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.

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 10% and 7% of our consolidated revenues for the years ended December 31, 2022 and 2021, 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

Our 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, 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 ingredient ("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 related 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 for such materials and related services 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 or long-term provision of related services.

Our supply chain includes an 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 the section entitled "Principal Risks" in this Directors' 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, ARISTADA INITIO, LYBALVI, VIVITROL and microspheres for RISPERDAL CONSTA at our Wilmington, Ohio facility. We outsource our packaging operations for ARISTADA, ARISTADA INITIO, LYBALVI and VIVITROL to third-party contractors. Janssen is responsible for packaging operations for RISPERDAL CONSTA. Our Wilmington, Ohio facility has been inspected by U.S., European (including the UK Medicines and Healthcare products Regulatory Agency), Chinese, Japanese, Brazilian, Turkish, Russian 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 FAMPYRA and VUMERITY. This facility has been inspected by U.S., Irish, Brazilian, Turkish, Gulf Health States, including Saudi Arabia, Korean, Belarusian, Russian and Chinese regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

Clinical Products

We have established, and are operating, facilities with the capability to manufacture clinical supplies of injectable extended-release products and solid dosage form 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.

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, ARISTADA INITIO and LYBALVI, we hold the marketing authorization and related regulatory documentation ourselves.

Marketing, Sales and Distribution

We are responsible for the marketing of VIVITROL, ARISTADA, ARISTADA INITIO, and LYBALVI 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, schizophrenia and bipolar I disorder. We provide, and contract with third-party vendors to provide, customer services 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 110 individuals. VIVITROL is primarily sold to pharmaceutical wholesalers, pharmacies, specialty distributors and treatment providers. Product sales of VIVITROL during the year ended December 31, 2022 to Cardinal Health, McKesson Corporation and AmerisourceBergen Corporation ("AmerisourceBergen") represented approximately 25%, 22% and 16%, respectively, of total VIVITROL gross sales.

Our sales force for ARISTADA, ARISTADA INITIO and LYBALVI in the U.S. consists of approximately 315 individuals. ARISTADA, ARISTADA INITIO and LYBALVI are primarily sold to pharmaceutical wholesalers. Product sales of ARISTADA and ARISTADA INITIO during the year ended December 31, 2022 to Cardinal Health, McKesson Corporation and AmerisourceBergen represented approximately 47%, 23% and 23%, respectively, of total ARISTADA and ARISTADA INITIO gross sales. Product sales of LYBALVI during the year ended December 31, 2022 to Cardinal Health, McKesson Corporation and AmerisourceBergen represented approximately 38%, 30% and 27%, respectively, of total LYBALVI gross sales.

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

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

Competition

We face intense competition in the development, manufacture, marketing and commercialization of our products from many and varied sources, such as 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 products, systems, and other methods of preventing or reducing disease, and new small-molecule and other classes of drugs.

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 for use in similar indications or with similar technologies to ours 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 healthcare 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; our ability to complete clinical development and obtain regulatory approvals for our products, and the timing and scope of any such regulatory approvals; our ability to successfully manufacture and 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, technology from MedinCell S.A., which underpins Teva Pharmaceuticals Industries Ltd.'s development of a risperidone extended-release injectable suspension for subcutaneous use, technology from Pharmathen S.A., which underpins aripiprazole formulations in development, and technology underpinning Teva Pharmaceuticals Industries Ltd.'s once every two weeks injectable microsphere formulation, each for the treatment of schizophrenia, and Teva Pharmaceuticals USA, Inc.'s 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, the long-acting INVEGA products 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; generic versions of branded injectable products; and, once it launches in the U.S., RYKINDO (risperidone), a once-every-two-weeks injectable formulation of risperidone developed by Luye Pharma Group.

In the treatment of schizophrenia, LYBALVI competes with other oral antipsychotic products, including CAPLYTA (lumateperone) developed and marketed by Intra-Cellular Therapies, Inc.; LATUDA, which is marketed and sold by Sunovion Pharmaceuticals Inc.; REXULTI, which is co-marketed by Otsuka Pharm Co. and H. Lundbeck A/S plc; VRAYLAR, which is marketed and sold by Abbvie Inc.; other oral compounds currently on the market; and generic versions of branded oral products.

In the treatment of bipolar disorder, LYBALVI and RISPERDAL CONSTA compete with antipsychotics such as oral aripiprazole; REXULTI; LATUDA; VRAYLAR; ABILIFY MAINTENA; CAPLYTA; RYKINDO; 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; ZEPOSIA from Bristol-Myers Squibb Company; PONVORY from Janssen; and, once it launches in the U.S., BRIUMVI™ (ublituximab-xiiy) from TG Therapeutics, Inc.

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 depends, 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
11,518,745	ARISTADA; ARISTADA INITIO	2030
11,273,158	ARISTADA; ARISTADA INITIO	2039
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
11,097,006	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
10,973,816	ARISTADA	2035
11,406,632	ARISTADA	2035
10,016,415	ARISTADA INITIO	2035
10,688,091	ARISTADA INITIO	2035
10,849,894	ARISTADA INITIO	2035
11,115,552	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 expired in the U.S. in January 2023 and expired in the EU in 2021.

We own one unexpired Orange-Book listed U.S. patent covering VIVITROL, which expires in the U.S. in 2029 and expired 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 Directors' Report.

INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and INVEGA HAFYERA/BYANNLI

Our NanoCrystal technology patent portfolio, licensed to Janssen, 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 to expire of the patents subject to our license agreement expires in 2030 in the U.S., the EU and certain other countries. 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, one that covers INVEGA TRINZA in the U.S. and expires in 2036 and two that cover INVEGA HAFYERA in the U.S. and expire in 2041. For a discussion of legal proceedings related to patents covering INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' 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.

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 Covered	Expiration Date
7,262,298	LYBALVI	2025
8,680,112	LYBALVI	2030
9,119,848	LYBALVI	2031
10,005,790	LYBALVI	2031
8,778,960	LYBALVI	2032
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
11,185,541	LYBALVI	2031
11,241,425	LYBALVI	2031
11,351,166	LYBALVI	2031

We also have a portfolio of patents and patent applications covering our Key Development Program.

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. U.S. Patent No. 11,246,906, expiring in 2040, covers subcutaneous dosing regimens of nemvaleukin. U.S. Patent No. 11,248,050, expiring in 2040, covers certain combination therapies utilizing 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 typically 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 the section entitled “Principal Risks” in this Directors’ 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 for INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, INVEGA HAFYERA/BYANNLI and RISPERDAL CONSTA, which are registered trademarks of Johnson & Johnson or its affiliated companies, VUMERITY, which is a registered trademark of Biogen (and used by us under license) and FAMPYRA, which is a registered trademark 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 an NDA or a Biologics License Application ("BLA"). The NDA or BLA also include 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 in a timely manner or at all.

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 an NDA or BLA, the FDA may grant marketing approval, or issue a complete response letter to communicate to the applicant the reasons the application cannot be approved in its then-current form and provide input on the additional information that the FDA requires and/or changes that must be made before an application can be approved. Even if such additional information is submitted to the FDA or such changes made, the FDA may ultimately decide that the NDA or BLA 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, products that may be deemed 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 adding a new indication, we would be 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. For example, pharmaceutical products that act on the CNS are often evaluated for abuse potential; if a product is then classified as a controlled substance, it must undergo scheduling by the DEA, which is a separate process that may delay the commercial launch of such product even after FDA approval of the NDA for such product. Further, 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.

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 impose a requirement on 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.

Federal law also requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Services' (including the Indian Health Services, "PHS") pharmaceutical pricing program (the "340B program"), in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the Health Resources and Services Administration ("HRSA") requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered drugs used in an outpatient setting. These 340B covered entities include certain qualifying community health clinics, a variety of entities that receive health services grants from the Public Health Service, and multiple categories of hospitals, including children's hospitals, critical access hospitals, free standing cancer hospitals and hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula,

which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program. A regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities became effective on January 1, 2019. The scope and implementation of the 340B program continue to be the subject of legislative and regulatory interest and ongoing litigation, the outcomes of which are difficult to predict.

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 ("Tricare") 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 August 2022, the Inflation Reduction Act of 2022 (the "Inflation Reduction Act") was signed into law. The Inflation Reduction Act includes several provisions that will impact our business to varying degrees, including those that impose new manufacturer financial liability on all drugs in Medicare Part D beginning in 2025, allow the U.S. government to negotiate prices for some drugs covered under Medicare Part D beginning in 2026 and Medicare Part B beginning in 2028, and require companies to pay rebates to Medicare beginning in 2023 for drug prices that increase faster than inflation. 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 to the extent that they process personal data as well as any of its subsidiaries that are established outside the EU to the extent that they process personal data relating to EU residents for certain purposes, 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 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, stringent 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 in order to introduce further conditions, including limitations, with regard to 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 company publicly-listed 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.

Review of the Performance of the Business

Overview

We have a portfolio of proprietary products that we manufacture, market and sell in the U.S. —VIVITROL, ARISTADA, ARISTADA INITIO and most recently, LYBALVI, which we launched commercially in October 2021. We also earn manufacturing and/or royalty revenues on net sales of products commercialized by our licensees, the most significant of which in 2022 were the long-acting INVEGA products and VUMERITY. We expect VIVITROL, ARISTADA, ARISTADA INITIO, LYBALVI and VUMERITY to generate significant revenues for us in the near- and medium-term as we believe these products are singular or competitively advantaged products in their classes.

In 2022, we incurred an operating loss of $142.3 million, as compared to an operating loss of $29.3 million in 2021. The increase in the operating loss was primarily due to an increase in cost of sales and operating expenses of $51.0 million and a decrease in revenues of $62.0 million. These items are discussed in further detail within the "Results of Operations" section below.

In November 2022, we announced our intent, as approved by our board of directors, to explore a separation of our neuroscience business and oncology business. We are exploring a separation of the oncology business into an independent, publicly-traded company as part of an ongoing review of strategic alternatives for the oncology business. Following the planned separation, we would focus on driving growth of our proprietary commercial products: LYBALVI, ARISTADA, ARISTADA INITIO and VIVITROL and on advancing the development of pipeline programs focused on neurological disorders. We also expect to retain manufacturing and royalty revenues related to our licensed products and third-party products using our proprietary technologies under license. Oncology Co. would focus on the discovery and development of cancer therapies, including the continued development of nemvaleukin alfa and our portfolio of novel, preclinical, engineered cytokines. The separation, if consummated, is expected to be completed in the second half of 2023 and is subject to customary closing conditions, including final approval by our board of directors and, if sought, receipt of a private letter ruling from the IRS and/or tax opinion from our tax advisors.

Results of Operations

Product Sales, Net

Our product sales, net consist of sales in the U.S. of VIVITROL, ARISTADA, ARISTADA INITIO, and following its commercial launch in October 2021, LYBALVI, 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, ARISTADA INITIO and LYBALVI in the U.S. during the years ended December 31, 2022 and 2021:

	Year Ended December 31,			
(In millions, except for % of Sales)	**2022**	**% of Sales**	**2021**	**% of Sales**
Product sales, gross	$ 1,548.9	100.0 %	$ 1,315.1	100.0 %
Adjustments to product sales, gross:				
Medicaid rebates	(344.0)	(22.2) %	(331.9)	(25.2) %
Chargebacks	(157.2)	(10.2) %	(129.1)	(9.8) %
Product discounts	(124.1)	(8.0) %	(107.0)	(8.1) %
Medicare Part D	(68.1)	(4.4) %	(59.8)	(4.5) %
Other	(77.9)	(5.0) %	(59.9)	(4.6) %
Total adjustments	(771.3)	(49.8) %	(687.7)	(52.2) %
Product sales, net	$ 777.6	50.2 %	$ 627.4	47.8 %

Product sales, net during the years ended December 31, 2022 and 2021 were as follows:

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**Change**
VIVITROL	$ 379.5	$ 343.9	$ 35.6
ARISTADA and ARISTADA INITIO	302.1	275.4	26.7
LYBALVI	96.0	8.1	87.9
Product sales, net	$ 777.6	$ 627.4	$ 150.2

VIVITROL product sales, gross, increased by 7% in 2022 which was primarily due to an increase of 2% in the number of VIVITROL units sold and a 6% increase in the selling price of VIVITROL that went into effect in April 2022. ARISTADA and ARISTADA INITIO product sales, gross, increased by 11% in 2022 which was primarily due to an increase of 8% in the number of ARISTADA and ARISTADA INITIO units sold and a 3% increase in the selling price of ARISTADA and ARISTADA INITIO that went into effect in April 2022. The increase in LYBALVI during 2022, as compared to 2021, was due to the product having a full year of sales in 2022 following its commercial launch in October 2021.

The decrease in Medicaid rebates as a percentage of sales was primarily due to actual Medicaid utilization rates related to VIVITROL being lower than original estimates as such rates normalize from initial pandemic levels and due to the increased sales of LYBALVI, which had lower Medicaid utilization than VIVITROL and ARISTADA.

A number of companies 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 will expire in 2029 in the U.S. and expired in Europe 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 Directors' Report and for information regarding the risks relating to these legal proceedings, see the section entitled "Principal Risks" in this Directors' 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". A number of companies currently market and/or are developing products to treat schizophrenia and/or bipolar I disorder that may compete with and negatively impact future sales of ARISTADA, ARISTADA INITIO and LYBALVI. Increased competition may lead to reduced unit sales of ARISTADA, ARISTADA INITIO and LYBALVI and increased pricing pressure. The latest to expire of our patents covering ARISTADA, ARISTADA INITIO and LYBALVI in the U.S. will expire in 2039, 2039 and 2032, respectively; and, as such, we do not anticipate any generic versions of these products to enter the market in the near term. We expect our product sales, net will continue to grow as VIVITROL continues to penetrate the alcohol dependence and opioid dependence markets in the U.S., as ARISTADA and ARISTADA INITIO continue to gain market share in the U.S., and as we continue the commercial launch of LYBALVI.

Manufacturing and Royalty Revenues

Manufacturing revenue from RISPERDAL CONSTA and VUMERITY are recognized at the point in time that the product has been fully manufactured. 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. 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, 2022 and 2021:

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**Change**
Manufacturing and royalty revenues:			
Long-acting INVEGA products	$ 115.7	$ 303.1	$ (187.4)
VUMERITY	115.5	87.4	28.1
RISPERDAL CONSTA	49.9	50.9	(1.0)
Other	50.9	100.4	(49.5)
Manufacturing and royalty revenues	$ 332.0	$ 541.8	$ (209.8)

Our agreements with Janssen related to the long-acting INVEGA products provide for 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 expiry of the agreement. For more information about the license agreement with Janssen in respect of the long-acting INVEGA products, see "Collaborative Arrangements—Janssen" in this Directors' Report.

In November 2021, we received notice of partial termination of our license agreement with Janssen under which we provided Janssen with rights to, and know-how, training and technical assistance in respect of, our small particle pharmaceutical compound technology, known as NanoCrystal technology, which was used to develop INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, and INVEGA HAFYERA/BYANNLI. The partial termination became effective in February 2022, at which time Janssen ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. In April 2022, we commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of this license agreement and Janssen's royalty and other obligations under the agreement. On December 21, 2022, we received the Interim Award for these proceedings from the Tribunal, in which the Tribunal agreed with our position that, while Janssen may terminate the agreement, it may not continue to sell Products (as defined in the agreement) developed during the term of the agreement without paying royalties pursuant to the term of the agreement. This award is not yet final. We will engage with Janssen and the Tribunal in additional proceedings prior to the Tribunal's issuance of a final award. Accordingly, we have not recognized royalty revenue related to U.S. sales of long-acting INVEGA products since February 2022. For additional information regarding the arbitration proceedings with Janssen, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report. For information about risks relating to the notice of partial termination and our collaborative arrangements more broadly, see the section entitled "Principal Risks" in this Directors' Report and specifically the section entitled "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, or if disputes arise in respect of our contractual arrangements, our revenues could be materially adversely affected."

The decrease in royalty revenues from the long-acting INVEGA products was primarily due to Janssen's partial termination of our license agreement related to such products. When the partial termination of the license agreement became effective in February 2022, Janssen ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. and we stopped recognizing royalty revenue related to net sales of these products. During 2022, Janssen's rest of world net sales were $1,426.0 million, as compared to $1,472.0 million during 2021. We expect royalty revenues from net sales of XEPLION, TREVICTA and BYANNLI to decrease over time. The amount, timing and duration of royalty revenues from sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA depend upon the outcome of our dispute with Janssen related to the impact of its partial termination of our license agreement on its obligations to continue to pay us know-how royalties in accordance with the terms of the agreement.

In addition, 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. Increased competition from new products or generic versions of these products may lead to reduced unit sales of such products and increased pricing pressure. For a discussion of these legal proceedings, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report, and for information about risks relating to these legal proceedings, see the section entitled "Principal Risks" in this Directors' 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 recognize manufacturing revenue for 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 Janssen's end-market net sales, in the period that the end-market sales of RISPERDAL CONSTA occur. The decrease in revenue from RISPERDAL CONSTA was primarily due to a decrease of $3.2 million in royalty revenue, partially offset by a $2.2 million increase in manufacturing revenue. This decrease in royalty revenue was due to a decrease in end-market sales of RISPERDAL CONSTA, which was $485.0 million during 2022, as compared to $592.0 million during 2021. The increase in manufacturing revenue was primarily due to an increase in the number of units approved for shipment to Janssen. We expect revenues from RISPERDAL CONSTA to decrease over time. The latest to expire patent covering RISPERDAL CONSTA expired in 2021 in the EU and expired in January 2023 in the U.S., and we are aware of potential generic competition for RISPERDAL CONSTA that may lead to reduced unit sales and increased pricing pressure.

We receive a 15% royalty on worldwide net sales of VUMERITY for product manufactured and packaged by us, subject to increases for VUMERITY manufactured and/or packaged by Biogen or its designees, in the period that the end-market sales of VUMERITY occur. We also recognize manufacturing revenue related to VUMERITY at cost plus 15%, upon making available bulk batches of VUMERITY to Biogen and, to the extent we package such product, then also when packaged batches of VUMERITY are made available to Biogen. The increase in revenue from VUMERITY was due to increases of $6.7 million and $21.4 million in manufacturing revenue and royalty revenue, respectively. The increase in manufacturing revenue was due to an increase in the number of packaged batches that were manufactured for Biogen, partially offset by a manufacturing issue related to VUMERITY, which, for a period during 2022, negatively impacted the number of commercial batches we were able to manufacture. The increase in royalty revenue was due to an increase in net sales of VUMERITY, which were $553.4 million during 2022, as compared to $410.0 million during 2021.

The decrease in other manufacturing and royalty revenue was primarily due to the decision from an arbitration panel in October 2022, which found that we must return to Acorda $16.5 million (inclusive of prejudgment interest and administrative fees) previously paid by Acorda under a license agreement between the Company and Acorda. In November 2022, the panel found that we must pay to Acorda an additional $1.8 million (inclusive of prejudgment interest). These amounts represent a portion of the royalty revenue paid to us by Acorda since July 2020 related to AMPYRA. We paid the $16.5 million in October 2022 and paid the additional $1.8 million in December 2022. In addition, during the three months ended June 30, 2022, we had recorded $3.2 million of royalty revenue related to AMPYRA as we believed that we had met the necessary revenue recognition criteria under the Financial Accounting Standards Board Accounting Standards Codification 606, *Revenue from Contracts with Customers* ("Topic 606"). However, as a result of the arbitration ruling, we reversed the $3.2 million as the panel found that we were no longer entitled to be paid those royalties. During the three months ended September 30, 2022, we recorded both the approximately $18.3 million in repayments and the $3.2 million reversal as reversals of royalty revenue within "Manufacturing and royalty revenue" in the accompanying consolidated statements of operations and comprehensive loss. As a result of the arbitration ruling, we no longer have a contractual obligation to manufacture and supply AMPYRA or a contractual right to receive future manufacturing or royalty revenue related to AMPYRA. In January 2023, Acorda filed a petition with the U.S. District Court for the Southern District of New York

asking the court to confirm in part and modify in part the final arbitral award rendered by the arbitration panel in October 2022 and, as part of the requested modification, seeking an additional approximately $66.0 million in damages. We intend to contest this petition and believe it is without merit.

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 the section entitled “Currency Exchange Rate Risk” in this Directors’ Report for information on currency exchange rate risk related to our revenues and the section entitled “Principal Risks” in this Directors’ Report, and specifically the section entitled “Currency exchange rates may affect revenues and expenses” for risks related to currency exchange rates.

Costs and Expenses

Cost of Goods Manufactured and Sold

(In millions)	Year Ended December 31, 2022	2021	Change
Cost of goods manufactured and sold	$ 218.1	$ 197.4	$ 20.7

The increase in cost of goods manufactured and sold was primarily due to increases of $6.4 million and $4.8 million, respectively, in the cost of goods manufactured for VUMERITY and RISPERDAL CONSTA and increases of $5.6 million and $10.2 million, respectively, in the cost of goods sold for VIVITROL and LYBALVI. The increases related to VUMERITY and RISPERDAL CONSTA were primarily due to increased manufacturing activity, as discussed above. The increase related to LYBALVI was primarily due to the increase in sales activity, as discussed above. The increase related to VIVITROL was primarily due to an increase in costs incurred for out-of-specification batches, as well as an increase in sales activity, as discussed above.

Research and Development Expenses

For each of our R&D programs, we incur both external and internal expenses. External R&D expenses include fees for clinical and non-clinical activities performed by contract research organizations (“CROs”), consulting fees, and costs related to laboratory services, the purchase of drug product materials and third-party manufacturing development activities. 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 can benefit multiple programs or our technologies in general.

The following table sets forth our external R&D expenses for the years ended December 31, 2022 and 2021 relating to our then-current development programs and our internal R&D expenses, listed by the nature of such expenses:

(In millions)	Year Ended December 31, 2022	2021	Change
External R&D expenses:			
Development programs:			
nemvaleukin	$ 77.8	$ 80.1	$ (2.3)
LYBALVI	23.1	26.0	(2.9)
ALKS 1140	3.5	29.3	(25.8)
Other external R&D expenses	76.1	65.7	10.4
Total external R&D expenses	180.5	201.1	(20.6)
Internal R&D expenses:			
Employee-related	159.0	148.6	10.4
Occupancy	17.8	19.5	(1.7)
Depreciation	12.0	12.2	(0.2)
Other	24.5	25.1	(0.6)
Total internal R&D expenses	213.3	205.4	7.9
Research and development expenses	$ 393.8	$ 406.5	$ (12.7)

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, our expectations regarding the likelihood of their regulatory approval and our view of their future potential commercial viability, among other factors.

The decrease in expenses related to nemvaleukin was primarily due to decreased spend on the ARTISTRY-1 study, partially offset by increased spend on the ARTISTRY-7 study. For additional detail on the ARTISTRY development program

for nemvaleukin, see the section entitled “Key Development Program – nemvaleukin alfa” in this Directors’ Report. The decrease in expenses related to LYBALVI was primarily due to decreased R&D activities for the product in light of its commercial launch in October 2021, partially offset by continued spend on ongoing clinical studies. The decrease in expenses related to ALKS 1140 was primarily due to the termination of the ALKS 1140 clinical development program in the second quarter of 2022, as the initial data did not support further clinical development, and a $25.0 million development milestone in the third quarter of 2021 related to the submission of a clinical trial authorization for ALKS 1140. The increase in other external R&D expenses was primarily due to an increase of $10.2 million related to our early-stage development programs.

The increase in employee-related expense was primarily related to an increase of $5.5 million in labor and benefits, primarily due to increases in recruitment costs and temporary labor and an increase of $3.2 million in R&D-related share-based compensation, primarily due to an increase in the fair value of the awards granted in 2022.

Selling, General and Administrative Expenses

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**Change**
Selling and marketing expense	$ 392.2	$ 365.9	$ 26.3
General and administrative expense	213.5	195.1	18.4
Selling, general and administrative expense	$ 605.7	$ 561.0	$ 44.7

The increase in selling and marketing expense was primarily due to a $14.6 million increase in employee-related expenses due to an increase in selling-and-marketing-related salaries and benefits and an increase of $10.0 million in marketing activity related to the commercial launch of LYBALVI.

The increase in general and administrative expense was primarily due to a $9.9 million increase in professional service fees, primarily due to increased spend on legal fees and fees related to the proposed separation of the Company’s oncology business. We also had a $3.5 million increase in our branded prescription drug fee due to an increase in sales of our commercialized products and a $1.9 million increase in travel and expense, primarily due to resuming in-person meetings as travel restrictions loosened.

Amortization of Acquired Intangible Assets

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**Change**
Amortization of acquired intangible assets	$ 36.4	$ 38.1	$ (1.7)

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, 2022 is expected to be approximately $35.0 million and $1.0 million in the years ending December 31, 2023 and 2024, respectively.

Other Expense, Net

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**Change**
Interest income	$ 7.6	$ 2.4	$ 5.2
Interest expense	(13.0)	(11.2)	(1.8)
Change in the fair value of contingent consideration	(2.6)	(20.6)	18.0
Other income, net	2.1	0.2	1.9
Total other expense, net	$ (5.9)	$ (29.2)	$ 23.3

The increase in total other expense, net was primarily due to the change in the fair value of contingent consideration and an increase in interest expense, partially offset by increases in interest income and other income, net. The change in the fair value of the contingent consideration was due to the determination that it was unlikely that we would collect any further contingent consideration proceeds from Baudax Bio, Inc. (“Baudax”), and accordingly, we reduced the fair value of the contingent consideration to zero, as discussed in Note 7, *Fair Value*, in the “Notes to Consolidated Financial Statements” in this Directors’ Report. Interest expense consists primarily of interest incurred on our 2026 Term Loans. Interest income

consists primarily of interest earned on our available-for-sale investments. The increases in interest income and interest expense were primarily due to increases in interest rates. The increase in interest expense was partially offset by a decrease in certain financing costs related to the Term Loan Refinancing completed in March 2021. The Term Loan Refinancing is discussed in Note 6, *Long-Term Debt* in the "Notes to Consolidated Financial Statements" in this Directors' Report. The increase in other income, net was primarily due to proceeds received in connection with the Company's investment in Fountain Healthcare Partners II, L.P. of Ireland ("Fountain") in March 2022, partially offset by the write down of certain construction in progress due to the determination that certain construction in progress related to our agreement with Baudax had no future value, as discussed in Note 10, *Tangible Fixed Assets*, in the "Notes to Consolidated Financial Statements" in this Directors' Report. The Fountain investment is discussed in Note 14, *Investments*, in the "Notes to Consolidated Financial Statements" in this Directors' Report.

Income Tax Benefit (Provision)

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**Change**
Income tax benefit (provision)	$ 9.0	$ (8.9)	$ (17.9)

The income tax benefit in 2022 was primarily due to an enhanced foreign derived intangible income ("FDII") deduction that resulted from a change to Section 174 of the U.S. Tax Cuts and Jobs Act in relation to capitalization and amortization of R&D expenses. The income tax provision in 2021 was primarily due to U.S. federal and state taxes on income earned in the U.S. and the tax impact of employee equity activity. No provision for income tax has been provided on undistributed earnings of our foreign subsidiaries because such earnings are indefinitely reinvested in the foreign operations. Cumulative unremitted earnings of overseas subsidiaries totaled approximately $812.8 million at December 31, 2022. In the event of a repatriation of those earnings in the form of dividends or otherwise, we may be liable for income taxes, subject to adjustment, if any, for foreign tax credits and foreign withholding taxes payable to foreign tax authorities. We estimate that approximately $55.0 million of income taxes would be payable on the repatriation of the unremitted earnings to Ireland.

As of December 31, 2022, we had $1.7 billion of Irish NOL carryforwards, $15.1 million of U.S. federal NOL carryforwards, $43.2 million of state NOL carryforwards, $5.7 million of federal R&D credits and $29.0 million of state tax credits which will either expire on various dates through 2042 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 our ordinary shares.

As discussed in "Principal Risks" in this Directors' Report and specifically the section entitled "Changes in tax rules and regulations, or interpretations thereof, may adversely affect our financial condition", effective in 2022, the Tax Cuts and Jobs Act of 2017 requires us to capitalize, and subsequently amortize R&D expenses over five years for research activities conducted in the U.S. and over fifteen years for research activities conducted outside of the U.S. In 2022, this resulted in a material increase to our U.S. income tax liability and net deferred tax assets and a material decrease to our cash flows provided from operations. We expect an impact from this legislative change throughout the amortization period.

In December 2022, the EU agreed to implement a corporate minimum tax rate of 15% on companies with combined annual revenue of at least €750.0 million. The Irish government will be required to transpose these rules into Irish legislation. The new rules are expected to come into effect on January 1, 2024. The Company is currently monitoring these developments and assessing the potential impact.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

	December 31, 2022			December 31, 2021		
(In millions)	**U.S.**	**Ireland**	**Total**	**U.S.**	**Ireland**	**Total**
Cash and cash equivalents	$ 208.4	$ 84.1	$ 292.5	$ 88.6	$ 248.9	$ 337.5
Investments—short-term	207.6	108.4	316.0	144.5	54.3	198.8
Investments—long-term	70.3	61.3	131.6	163.0	66.4	229.4
Total cash and investments	$ 486.3	$ 253.8	$ 740.1	$ 396.1	$ 369.6	$ 765.7
Outstanding borrowings—short and long-term	$ 293.3	$ —	$ 293.3	$ 295.8	$ —	$ 295.8

At December 31, 2022, 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	$ 320.6	$ —	$ (4.6)	$ —	$ 316.0
Investments—long-term available-for-sale	134.6	—	(4.8)	—	129.8
Investments—long-term held-to-maturity	1.8	—	—	—	1.8
Total	$ 457.0	$ —	$ (9.4)	$ —	$ 447.6

Sources and Uses of Cash

We generated $21.0 million and $101.7 million of cash from operating activities during the years ended December 31, 2022 and 2021, respectively. We expect that our existing cash, cash equivalents 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 this Directors' Report was approved. 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 2026 Term Loans have an incremental facility capacity in an amount of $175.0 million, plus additional potential amounts provided that 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. However, the value of these securities may be adversely affected by the instability of the global financial markets, which could, in turn, adversely impact our financial position and our overall liquidity. Our available-for-sale investments consist primarily of short and long-term U.S. government and agency debt securities, corporate debt securities and debt securities issued and backed by non-U.S. governments. Our held-to-maturity investments consist of investments that are held as collateral under certain letters of credit related to certain of our lease agreements.

We classify available-for-sale investments in an unrealized loss position that 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.

We have no off-balance sheet arrangements that are reasonably likely to have a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources in the next twelve months. As discussed above, we made a $25.0 million development milestone payment to the former shareholders of Rodin Therapeutics, Inc. ("Rodin") during the year ended December 31, 2021. We are obligated to make up to $825.0 million in future payments, $225.0 million of which would be triggered upon achievement of certain specified clinical milestones, $300.0 million of which would be triggered by the achievement of certain regulatory milestones and $325.0 million of which would be triggered upon the attainment of certain sales thresholds. At December 31, 2022, we had not recorded a liability related to these milestone payments as none of the future events that would trigger a milestone payment were considered probable of occurring.

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, 2022 and 2021:

(In millions)	Year Ended December 31, 2022	2021
Cash and cash equivalents, beginning of period	$ 337.5	$ 273.0
Cash flows provided by operating activities	21.0	101.7
Cash flows used in investing activities	(64.4)	(66.2)
Cash flows (used in) provided by financing activities	(1.6)	29.0
Cash and cash equivalents, end of period	$ 292.5	$ 337.5

Operating Activities

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. We expect cash provided from operating activities will continue to be our primary source of funds to finance operating needs and capital expenditures for the foreseeable future. Operating cash flow is derived by adjusting our net loss for non-cash operating items such as depreciation, amortization and share-based compensation as well as changes in operating assets and liabilities, which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in our results of operations.

The decrease in cash flows provided by operating activities was primarily due to an increase in our net loss of $110.1 million and an increase in cash used for our lease liabilities of $15.3 million related to an early payment of our lease of approximately 231,000 square feet of office and laboratory space located at 900 Winter Street in Waltham, Massachusetts. Please refer to Note 11, *Leases*, in the "Notes to Consolidated Financial Statements" in this Directors' Report for additional information related to such early payment. These were partially offset by an increase in the cash provided by working capital, primarily due to an increase in cash provided by receivables of $63.3 million and from accounts payable and accrued expenses of $4.0 million.

Investing Activities

The decrease in cash flows used in investing activities was primarily due to a $17.4 million decrease in net purchase of investments and a $6.7 million decrease in payments received in connection with the contingent consideration resulting from the Gainesville Transaction, partially offset by a $10.2 million increase in capital expenditures.

We expect to spend approximately $35.0 million to $40.0 million during the year ending December 31, 2023 for capital expenditures. We continue to evaluate our manufacturing capacity based on expectations of demand for the products that we manufacture and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service, or we determine we have sufficient existing capacity and the assets are no longer required, at which time we would recognize an impairment charge. We continue to periodically evaluate whether facts and circumstances indicate that the carrying value of these long-lived assets to be held and used may not be recoverable.

Financing Activities

The change in cash flows from financing activities was primarily due to $23.6 million in proceeds from the Term Loan Refinancing, which we received in 2021, and a $7.3 million decrease in the amount of cash that we received upon the exercise of employee stock options, net of employee taxes.

Borrowings

At December 31, 2022, our borrowings consisted of $294.8 million outstanding under the 2026 Term Loans. The 2026 Term Loans bear interest at LIBOR plus 2.5%, with a LIBOR floor of 0.5%. Principal payments of $0.8 million are to be made quarterly through 2025, with a final payment of $285.8 million due in March 2026. Please refer to Note 6, *Long-Term Debt*, in the "Notes to Consolidated Financial Statements" in this Directors' Report for a discussion of our outstanding term loans.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that are reasonably likely to have a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources in the next twelve months. As discussed above, we made a $25.0 million development milestone payment to the former shareholders of Rodin during the year ended December 31, 2021. We are obligated to make up to $825.0 million in future payments, $225.0 million of which would be triggered upon achievement of certain specified clinical milestones, $300.0 million of which would be triggered by the achievement of certain regulatory milestones and $325.0 million of which would be triggered upon the attainment of certain sales thresholds. At December 31, 2022, we had not recorded a liability related to these milestone payments as none of the future events that would trigger a milestone payment were considered probable of occurring.

Financial Risk Management

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.

Although we have seen a significant increase in the number of our investment securities in unrealized loss positions, we do not believe our exposure to liquidity and credit risk to be significant as approximately 47% and 45% of our investments at December 31, 2022 are in corporate debt securities with a minimum rating of A2 (Moody's)/A (Standard and Poor's) and debt securities issued by the U.S. government or its agencies, respectively. We have the intent and ability to hold these securities until recovery, which may be at maturity.

At December 31, 2022, our borrowings consisted of $294.8 million outstanding under the 2026 Term Loans. The 2026 Term Loans bear interest at the one-, three- or six-month LIBOR rate of our choosing, plus 2.5% with a 0.5% LIBOR floor. We are currently using the one-month LIBOR rate, which was 4.32% at December 31, 2022. A 10% increase in the one-month LIBOR rate would have increased the amount of interest we owed by approximately $1.3 million. At December 31, 2021, a 10% increase in the three-month LIBOR rate, which was the LIBOR rate in use at the time, would not have increased the amount of interest we owed under this agreement as the LIBOR floor of 0.5% was higher than the then-current LIBOR rate of 0.21% plus 10%.

In 2017, the U.K. Financial Conduct Authority announced its intention to phase out LIBOR after 2023. Currently, it is anticipated that LIBOR will be completely phased out by June 30, 2023. On July 29, 2021, the ARRC, a steering committee comprised of large U.S. financial institutions, formally recommended SOFR as its preferred alternative replacement rate for USD LIBOR. The 2026 Term Loans contain customary ARRC hardwired benchmark replacement language to transition from LIBOR to SOFR. At this time, it is not possible to predict the effect that the anticipated discontinuance of LIBOR, or the establishment of alternative reference rates such as SOFR, will have on us or our borrowing costs. SOFR is a relatively new reference rate and its composition and characteristics are not the same as LIBOR. Given SOFR's very limited history and potential volatility as compared to other benchmark or market rates, the future performance of SOFR cannot be predicted based on historical performance. The consequences of using SOFR could include an increase in the cost of our variable rate indebtedness. We are monitoring these transition efforts and, although the 2026 Term Loans contain provisions designed to accommodate an alternate reference rate, we may need to amend these and other contracts, such as interest rate hedges that reference these contracts to accommodate any replacement rate. The potential effect of any such event on our cost of capital cannot yet be determined, but we do not expect it to have a material impact on our consolidated financial condition, results of operations, or cash flows. For a discussion about risks relating to LIBOR, see "Principal Risks" in this Directors' Report and specifically the section entitled "Discontinuation, reform or replacement of LIBOR and SOFR, or uncertainty related to the potential for any of the foregoing, may adversely affect us."

Currency Exchange Rate Risk

Manufacturing and royalty revenues that 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, 2022, 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 $1.1 million, as compared to a reduction in revenues of approximately $33.1 million for the year ended December 31, 2021.

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, 2022, 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 $7.5 million, as compared to an increase in our expenses of approximately $8.3 million in the year ended December 31, 2021.

Principal Risks

You should consider carefully the risks described below in addition to the financial and other information contained in this Directors' Report, including our financial statements and related notes hereto and the matters addressed under the caption "Cautionary Note Concerning Forward-Looking Statements," and in our other public filings. 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 the Potential Separation of Our Oncology Business

The potential separation of our neuroscience and oncology businesses, including a potential separation of our oncology business into an independent, publicly-traded company, is subject to various risks and uncertainties and may not be completed on the timeline currently contemplated or at all, and will involve significant time, effort and expense, which could disrupt or adversely affect our business and our financial condition, results of operations and cash flows.

In November 2022, we announced our intent, as approved by our board of directors, to explore a separation of our neuroscience business and oncology business. We are exploring a separation of the oncology business into an independent, publicly-traded company (referred to in this Directors' Report as "Oncology Co.") as part of an ongoing review of strategic alternatives.

Our business may face significant risks and uncertainties as a result of the exploration and/or execution of the potential separation, including, without limitation:

- the diversion of management's attention from operating our neuroscience and oncology businesses and the overall disruption of, and impact on, our businesses;
- potential difficulty in maintaining employee morale and retaining and/or recruiting key management and other employees;
- potential difficulty in separating our oncology business from our neuroscience business, including allocation of operations, services, products and personnel;
- difficulty and/or delays in obtaining regulatory approvals related to the potential separation of the businesses, including any approvals needed to effect the separation and/or those related to ongoing clinical trials of our oncology products;
- the need to obtain third-party consents related to the potential separation of the businesses, which may be difficult to obtain and/or cause delay in our intended timelines for the separation or disrupt third-party relationships that are important to our business;
- foreseen and unforeseen dis-synergy costs, costs of restructuring transactions (including potential taxes) and other significant costs and expenses, including costs related to the capitalization of Oncology Co.; and
- potential negative reactions from the financial markets, including reactions related to the proposed structure or other details of the potential separation or any potential delay or failure in completing the potential separation.

No assurance can be given as to whether we will be successful in managing these or any other significant risks that we may encounter in the potential separation of our businesses, and any of these risks could have a material adverse effect on our businesses, financial condition, results of operations, cash flows and/or the market price of our ordinary shares. We have already incurred certain expenses, and expect to incur significant additional expenses, in connection with the exploration and potential consummation of a separation, and such costs and expenses may be greater than we anticipate, and may not yield the benefits that we or others may anticipate.

Adverse market conditions or tax consequences, litigation or other legal proceedings that may arise as a result of the potential separation, or delays or difficulties effecting the potential separation, including possible delays in obtaining any necessary stock exchange, regulatory or other approval or the failure to obtain any such approvals, possible delays in obtaining any required tax opinions or rulings or the failure to obtain any such tax opinions or rulings, changes in relevant law and other challenges, could delay, prevent or otherwise adversely impact the anticipated benefits of the potential separation.

No assurance can be given as to whether we will complete any separation on our anticipated timeline or at all. Any of the foregoing may result in our not achieving the operational, financial, strategic and other benefits we anticipate realizing as a result of the potential separation, and in each case, our business, results of operations and financial condition and/or the market price of our ordinary shares could be adversely affected.

We may fail to realize some or all of the anticipated benefits of the potential separation of our neuroscience and oncology businesses and the market price of our ordinary shares may fluctuate significantly in connection with the potential separation.

Even if a separation of our neuroscience and oncology businesses is completed, the anticipated operational, financial, strategic and other benefits of a potential separation may not be achieved. These anticipated benefits are based on a number of assumptions and uncertainties, which may prove to be incorrect or incomplete. Furthermore, if separated, the two independent businesses will be smaller and less diversified than the combined company, with a narrower business focus, and may be more vulnerable to changing market conditions.

In addition, the market price of our ordinary shares may experience volatility around the time of announcements of plans for the potential separation, consummation of the potential separation and thereafter. We also cannot predict the effect of a completed separation on the market price of our ordinary shares, which, following a separation, may be less than, equal to or greater than the market price of our ordinary shares prior to the separation. Further, the combined value of our ordinary shares and those of Oncology Co. may not be equal to or greater than what the value of our ordinary shares would have been had the separation not occurred. The combined value of the ordinary shares of the two companies could be lower than anticipated for a variety of reasons, including, but not limited to, a failure of Oncology Co. to operate and compete effectively as an independent company.

We continue to assess the tax consequences of potential structures for the separation of our oncology business from our neuroscience business, including a potential separation of the oncology business into an independent, publicly-traded company. If such a separation does not qualify as a transaction that is generally tax-free for U.S. federal and Irish tax purposes, we and/or our shareholders could be subject to significant tax liabilities.

In connection with the potential separation, we may seek a private letter ruling from the IRS (the "IRS Ruling") and/or an opinion from our U.S. tax advisor (the "U.S. Tax Opinion") regarding U.S. federal and state income tax consequences of the separation, including that, among other things, the separation would generally qualify as tax-free for U.S. federal income tax purposes under Sections 368(a)(1)(D) and 355 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"). The IRS Ruling and/or the U.S. Tax Opinion would be based on and rely on, among other things, certain facts, assumptions, representations, and undertakings from us and Oncology Co., including those relating to past and future conduct of the companies' respective business operations and other matters. If any of these facts, assumptions, representations, statements or undertakings are, or become, inaccurate or incomplete, or if we or Oncology Co. breach any of our respective covenants in the separation documents, the IRS Ruling and/or the U.S. Tax Opinion may be invalid and the conclusions reached therein could be jeopardized. Notwithstanding a U.S. Tax Opinion or IRS Ruling, the U.S. Internal Revenue Service, or the IRS, could determine that a distribution or any related transaction is taxable for U.S. federal income tax purposes if it determines that any of these facts, assumptions, representations or undertakings are not correct or have been violated, or that the distribution should be taxable for other reasons, including if the IRS were to disagree with the conclusions in the U.S. Tax Opinion. The U.S. Tax Opinion will not be binding on the IRS or the courts. Accordingly, the IRS or the courts may challenge the conclusions stated in the U.S. Tax Opinion and such challenge could prevail. If the potential separation transaction is ultimately determined to be taxable, we and/or our shareholders that are subject to U.S. federal income tax could incur significant tax liabilities.

Furthermore, in connection with the potential separation, we may seek an opinion from our Irish tax advisor (the "Irish Tax Opinion") regarding the Irish tax consequences of the separation. The Irish Tax Opinion would be based on and rely on, among other things, certain facts, assumptions, representations, and undertakings from us, including those relating to past and future conduct of our business operations and other matters. If any of these facts, assumptions, representations, statements or undertakings are, or become, inaccurate or incomplete the Irish Tax Opinion may be invalid and the conclusions reached therein could be jeopardized. The Irish Tax Opinion will not be binding on the Irish Tax Authority or the Irish courts. Accordingly, the Irish Tax Authority or the Irish courts may challenge the conclusions stated in the Irish Tax Opinion and such challenge could prevail. In such an event, we and/or our shareholders could incur significant tax liabilities.

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 ongoing 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 may continue to impact, many aspects of society, including the operation of healthcare systems, global travel, supply and labor markets and other business and economic activity worldwide. Ireland, all U.S. states, and many local jurisdictions and countries around the world have, at times during the pandemic, issued and implemented quarantines, vaccine and masking mandates, executive orders and other similar government orders, restrictions and recommendations for their residents to help control the spread of COVID-19. Such orders, mandates, restrictions and/or recommendations have, at times during the pandemic, resulted in widespread interruptions and closures of businesses, including healthcare systems that serve people living with addiction and serious mental illness, work stoppages, slowdowns and/or delays, remote work 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— including injectable medications administered by healthcare professionals—have been, and we expect may continue to be, adversely impacted as a result of COVID-19-related restrictions, labor shortages and other developments that have transpired, and may continue to transpire, many of which have contributed to limited access to, or reduced willingness to access, healthcare providers and locations where injectable medications may be administered. Further, this pandemic has had, and may continue to have, an adverse effect on global economic conditions, which could have an adverse effect on the demand for, and ability of patients to access, our and our licensees' medicines, reimbursement for our products and for services related to the use of our products, or our ability to obtain financing, if needed, on favorable terms or at all.

The COVID-19 pandemic has caused, and may continue to cause, varying degrees of disruption to our employees, our communities and our business operations. While we have continued to operate our manufacturing facilities and to supply our medicines without interruption throughout the pandemic, we have, at times during the pandemic, experienced labor or supply chain delays or disruptions at our manufacturing facilities, and may continue to experience such delays or disruptions while the pandemic persists, which could impact our ability to manufacture our products and the third-party products from which we receive revenue in a timely matter or at all. In addition, while we have continued to conduct our R&D activities, including our ongoing clinical trials, the COVID-19 pandemic has, at times, impacted the timelines of certain of our early-stage discovery efforts and clinical trials, and may continue to impact such timelines while the pandemic persists. We work with our internal teams, our clinical investigators, R&D vendors and critical supply chain vendors to continually assess, and endeavor to mitigate, potential adverse impacts of COVID-19 on our manufacturing operations and R&D activities.

In addition, we rely upon third parties for many aspects of our business, including the provision of goods and services related to the manufacture of our clinical products and our and our partners' marketed products, the conduct of our clinical trials, and the sale of our proprietary marketed products and the marketed products of our licensees from which we receive manufacturing and/or royalty revenue. The COVID-19 pandemic has, to varying degrees, disrupted 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, including with respect to enrollment rates, availability of investigators and clinical trial sites, and monitoring of data, 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. Any prolonged material disruption to these or other third parties on which we rely could negatively impact our ability to conduct business in the manner and on the timelines presently planned, which could have a material adverse impact on our business, results of operations and financial condition.

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, including the FDA, the HPRA and other regulatory agencies, which may, in turn, negatively impact expected timelines for regulatory interactions related to, and/or review and approval of, our product candidates, which could have an adverse effect on our business and the market price of our ordinary shares.

The degree to which the ongoing COVID-19 pandemic may continue to impact our employees, business, financial condition and results of operations will depend on the ultimate severity and duration of the pandemic and the manner in which it continues to evolve, including the emergence, prevalence and severity of new COVID-19 variants, and future developments in response thereto, including developments in the labor market and market practices related to remote work and our ability to attract and retain employees, which are highly uncertain and cannot be predicted as of the date of this Directors' Report.

We receive substantial revenue from our key proprietary products and our success depends on our ability to successfully manufacture and commercialize 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 adults with alcohol dependence and opioid dependence, ARISTADA for the treatment of adults with schizophrenia, ARISTADA INITIO for initiation onto ARISTADA for the treatment of adults with schizophrenia, and LYBALVI for the treatment of adults with schizophrenia and for the treatment of adults with bipolar I disorder, 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 commercialize 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, or if disputes arise in respect of our contractual arrangements, 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 the long-acting INVEGA products and RISPERDAL CONSTA and from Biogen's sales of VUMERITY and FAMPYRA. 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 use of our technology, including know-how, in third-party products, 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, impact the timing or amount of revenue that we receive in respect of such products, or result in expensive arbitration, litigation or other dispute resolution, which may not be resolved in our favor and may adversely impact our financial condition.

Further, certain of our license agreements may be terminated, with or without cause, or assigned in connection with a change in control or other event, 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, including development, commercialization or payment 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 and on the market price of our ordinary shares.

For example, in November 2021 we received notice of partial termination of an exclusive license agreement with Janssen. Under this license agreement, we provided Janssen with rights to, and know-how, training and technical assistance in respect of, our small particle pharmaceutical compound technology, known as NanoCrystal technology, which was used to develop INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, and INVEGA HAFYERA/BYANNLI. When the partial termination became effective in February 2022, Janssen ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. The announcement of Janssen's partial termination, expectations regarding the loss of royalty revenues from U.S. sales of such products resulting from such termination, and actual losses of royalty revenues that have resulted from such termination, caused the market price of our ordinary shares to decline significantly. In April 2022, we commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of this license agreement and Janssen's royalty and other obligations under the agreement. On December 21, 2022, we received an Interim Award in these proceedings from the Tribunal, in which the Tribunal agreed with our position that, while Janssen may terminate the agreement, it may not continue to sell Products (as defined in the agreement) developed during the term of the agreement without paying royalties pursuant to the term of the agreement. This award is not yet final. We will engage with Janssen and the Tribunal in additional proceedings prior to the Tribunal's issuance of a final award and cannot be certain of the outcome of the final award or the impact that such final award may have 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, and related commercial milestone payments, 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 products ARISTADA and LYBALVI compete with the long-acting INVEGA products and RISPERDAL CONSTA, products from which we receive 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 this Directors’ 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.

Our revenues from sales of our products may decrease or grow at a slower than expected rate due to many factors.

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;
- 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, arbitrations, litigation or other legal proceedings, including government requests for information regarding VIVITROL, securities litigation, IP litigation, including so-called “Paragraph IV” litigation relating to VIVITROL and other products from which we receive revenue, 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 and any other litigation or arbitration 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 Risk Evaluation and Mitigation Strategy ("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 use of our technology in, and marketing and sale of, products from which we received, or currently receive, manufacturing and/or royalty revenue and the amounts to be paid with respect to such products, including the dispute relating to our license agreement with Janssen described above;
- exchange rate valuations and fluctuations;
- U.S. and global political changes and/or instability, and any related changes in applicable laws and regulations, that may impact resources and markets for our products;
- the impacts that the ongoing COVID-19 pandemic may have on the development, 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, in part, 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) and cost-control measures imposed, and any reductions in payment rate or reimbursement or increases in our or in patients' financial obligation to payers could result in decreased sales of our products and/or decreased revenues.

In both U.S. and non-U.S. markets, sales of our products depend, in part, on adequate coverage, pricing and 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.

The availability of government and private reimbursement for our products and coverage restrictions that may be imposed for our products are uncertain, as is the amount for which our products will be reimbursed. Pricing and reimbursement for our products may be adversely affected by a number of factors, including: changes in, and implementation of, federal or state government regulations or private third-party payors' reimbursement policies; pressure by employers on private health insurance plans to reduce costs; and consolidation and increasing assertiveness of payors seeking price discounts or rebates in connection with the placement of our products on their formularies and, in some cases, the imposition of restrictions on access or coverage of particular drugs or pricing determined based on perceived value. We cannot predict the availability, amount, or consistency of reimbursement for, or the prevalence and extent of other access barriers to, 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. In August 2022, the Inflation Reduction Act was signed into law. The Inflation Reduction Act includes several provisions that will impact our business to varying degrees, including those that impose new manufacturer financial liability on all drugs in Medicare Part D beginning in 2025, allow the U.S. government to negotiate prices for some drugs covered under Medicare Part D beginning in 2026 and Medicare Part B in 2028, and require companies to pay rebates to Medicare beginning in 2023 for drug prices that increase faster than inflation.

In addition, 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. State Medicaid programs are increasingly requesting that manufacturers pay supplemental rebates and are 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. U.S. 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.

Furthermore, we may face uncertainties as a result of efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA, whether by legislative means or through litigation, and further potential reforms to government negotiation or regulation of drug pricing. The PPACA significantly expanded coverage of mental health and substance use disorders and provided federal parity protections to such coverage benefits. If successful, such efforts and proposed legislation or other future federal or state legislative or administrative changes relating to healthcare reform and drug pricing could adversely affect our business and financial results. Additional discounts, rebates, coverage or plan changes, restrictions or exclusions as described above could have a material adverse effect on sales of our affected products. Our failure to obtain or maintain adequate coverage, pricing or reimbursement for our products could have an adverse effect on our business, reputation, revenue and results of operations.

Many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients, including more limited benefit plan designs, higher patient co-pay or co-insurance obligations and limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs). Significant consolidation in the health insurance industry has resulted in a few large insurers and pharmacy benefit managers exerting greater pressure in pricing and usage negotiations with drug manufacturers, significantly increasing discounts and rebates required of manufacturers and limiting patient access and usage. In addition, pharmacy benefit managers have combined with specialty and mail order pharmacies and provider groups. Further consolidation among insurers, pharmacy benefit managers, other entities in the pharmaceutical supply chain and other payors would increase the negotiating leverage such entities have over us and other drug manufacturers.

In the U.S., to help patients afford our approved products, we may utilize programs to assist them, including patient assistance programs and co-pay programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. Our co-pay programs could become the target of similar insurer actions. In addition, in November 2013, CMS issued guidance to the issuers of qualified health plans sold through the PPACA’s marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the Office of Inspector General of the U.S. Department of Health and Human Services issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay programs. It is possible that changes in insurer policies regarding co-pay programs and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

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

In order to obtain regulatory approvals for the commercial sale of any product, we or our licensees must demonstrate, through preclinical testing and clinical trials, that such product is 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 expenses for preclinical testing, 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 and other regulatory agencies;

- impacts of the potential separation of our neuroscience and oncology businesses; 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 we and/or third parties fail to manage or conduct clinical trials in a timely manner or in accordance with study protocols or 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, data from future trials or real-world results.

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, in oncology studies, 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, data from future trials or real-world results. In addition, such data may 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 disclosed. 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 agree with our regulatory approval strategies or components of our filings for our products and may not approve, or may delay approval of, our products.

We must obtain government approvals before marketing or selling our products. The FDA in the U.S., 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 other regulatory agencies 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 other 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 applicable regulatory agencies' standards;
- data from preclinical testing and clinical trials may be interpreted by applicable regulatory agencies in different ways than we or our licensees interpret it;

- 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;
- 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;
- 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 Good Clinical Practices ("GCP"), or EU legislation governing GCP, or to pass FDA, EMA or EU member state inspections of clinical trials;
- 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, a prolonged U.S. government shutdown, or other political or economic conditions, could cause delays to the regulatory approval process for our products.

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 programs 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 approvals for our products.

Even if regulatory approval to market a product is granted by the FDA or other regulatory agencies, the approved label for the product may not be consistent with our initial expectations or commercial plans. For example, the FDA or other regulatory agencies may impose limitations on the clinical data that may be included in the label for the product or the indicated uses for which, or the manner in which, the product may be marketed, or 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 such product, or if such post-approval requirements significantly restrict the marketing, sale or use of such product.

In addition, legislation and regulatory policies relating to post-approval requirements and restrictions on promotional activities for pharmaceutical products, or FDA or other regulatory agency 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. We have in the past, and may in the future, face unanticipated interruptions or delays in manufacturing through our internal or external supply chain and resources. Such disruptions can occur for many reasons, including, but not limited to, the supply and quality of API, drug product and other product components and any potential shortages of such materials; regulatory actions; failures relating to materials, manufacturing equipment or processes, quality deviations or safety issues, vendor error, operator error, labor shortages or disputes, utility or transportation disruptions, or physical or electronic security breaches; site-specific incidents (such as fires), environmental incidents, natural disasters and other severe weather events, including those that may occur as a result of climate change , or global disruptions such as the current global pandemic and the ongoing war in Ukraine; and many other factors.

Any such problems with manufacturing processes, whether at our facilities or those of our licensees or other third parties that manufacture or package products or components of products on our behalf, could result in product defects or shortages, 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 or our licensees' ability to receive regulatory approval for a product, commercially launch 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, which could result in declines in sales and reputational damage as well as significant remediation costs to address any issues that arise.

We rely solely on our manufacturing facility in Wilmington, Ohio for the manufacture of RISPERDAL CONSTA, VIVITROL, ARISTADA, ARISTADA INITIO and LYBALVI and on our manufacturing facility in Athlone, Ireland for the manufacture of FAMPYRA, VUMERITY, other products using our NanoCrystal or OCR technologies and certain of our other products in development. Due to regulatory and technical requirements, we have limited ability to shift production among our facilities or to outsource any portions of our manufacturing to third parties in the event of an interruption in manufacturing or demand for manufacturing that exceeds our capacity at the applicable facility. Any need to shift production among our facilities or transition our manufacturing processes, or portions thereof, to a third party, whether due to an interruption in our manufacturing or to demand for a product that exceeds our manufacturing capacity, could take a significant amount of time and money, may not be successful, and could cause significant interruption or delay in our ability to supply product.

Any interruption or delay in supply, whether resulting from issues with equipment, materials, personnel, manufacturing processes, or internal or external quality audits or reviews, could result in delays in meeting our contractual obligations and could damage our reputation and relationships with our licensees, including the loss of manufacturing and supply rights and/or revenues.

Our manufacturing facilities also require specialized personnel and are expensive to operate and maintain. Any interruption in manufacturing, 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 significant personnel shortages at our manufacturing facilities, whether temporary or prolonged, including shortages resulting from impacts of the COVID-19 pandemic or related to the labor market more broadly, may cause significant interruptions to our manufacturing facilities and to our supply of products.

We are also dependent in certain cases on third parties who manufacture or distribute certain products from which we receive revenue. 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 goods and services in connection with the manufacture and distribution of the products we manufacture.

We rely on third parties for the timely supply of goods and services that play a role in our manufacturing activities, including, among others, specified raw materials, equipment, contract manufacturing, formulation and packaging services, storage and product distribution services, customer service activities and product returns processing, and some of these goods 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, including natural disasters and other severe weather events, including those that may occur as a result of climate change, or global disruptions such as the current global pandemic and the ongoing war in Ukraine, could negatively impact the continuity of supply of such materials and/or services, their quality and their compliance with applicable standards. 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, including any issues related to regulatory permits, audits or requirements, could require us to delay shipment of saleable products, recall products previously shipped or 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 provider issues. Nonetheless, any such third-party provider 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 in the U.S. 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, our business, financial condition, cash flows and results of operations could be materially adversely affected.

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 the third-party providers that play a role in our manufacturing activities are generally required to comply with cGMP regulations and other applicable non-U.S. standards in the manufacture of our products or components of our products. If any of our products or components of our products in the U.S. are scheduled by the DEA as controlled substances, we would also be subject to DEA regulations. We and our third-party providers are subject to unannounced inspections by the FDA and other agencies to confirm compliance with all applicable laws. Any changes to our suppliers or modifications of methods of manufacturing require submission of amendments to our NDAs or other marketing applications to the FDA or other applicable 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 compliance with cGMP or other regulatory requirements 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 operations 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 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 affect 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. However, we cannot guarantee that the FDA or any other regulatory agencies will approve any other facility that 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 for use in the U.S. must be licensed by the FDA. Failure by us or our third-party providers to gain or maintain regulatory compliance with and approvals from the FDA or other regulatory agencies could materially adversely affect our business, financial condition, cash flows and results of operations.

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

Adverse market conditions or other business developments may cause disruptions, delays or significant financial impact to our business or to the businesses of third parties from which we receive revenues, or reductions in the availability or extent of reimbursement available to us. For example, we depend on our licensees and customers for substantial portions of our revenue, and the contracts with our licensees and customers 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 market conditions, organizations that provide reimbursement for use of our products, such as government health administration authorities and private health insurers, may be unable to satisfy such reimbursement obligations or may delay payment. In addition, U.S. federal and state health authorities may reduce the extent of their 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 or unwilling 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 may be materially adversely affected.

Our success largely depends upon our ability to attract, recognize 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 our ability to attract, recognize and retain 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. We face intense competition for employees, due, among many factors, to the geographic locations in which we operate and the competitive benefits and compensation practices in our industry, and in recent years, new competition as employees are increasingly able to work remotely. The loss of key personnel due to any of these factors 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, financial and other operational and strategic business objectives.

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

Social media is increasingly being used as a means of corporate communications and for purposes of social networking and commentary. We are increasingly using social media tools to communicate certain information about our business, our employees, our company values and corporate responsibility initiatives, to support disease state education in our areas of focus, and to provide information about our products or development programs. Despite our efforts to monitor evolving social media guidance and to comply with applicable rules, regulations and regulatory guidance relating to social media, such practices are evolving and not always clear. There is a risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements and could result in regulatory actions or legal claims against us related to off-label marketing or other prohibited activities. In addition, our employees may knowingly or inadvertently engage on social media in ways that may not comply with our social media policy or other legal, contractual or regulatory requirements, which may give rise to liability, lead to the loss of trade secrets and other intellectual property, or result in public disclosure of personal information of our employees, clinical trial patients, customers, and others. In addition, negative or inaccurate posts or comments about us or our products on any social media platforms could damage our reputation, brand image and goodwill. If such disclosures were to occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend the Company or the public's legitimate interests due to restrictions on what we may say about our products or our business. Any of these events, if they were to occur, could cause us to incur liability, face overly restrictive regulatory actions or suffer reputational or 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 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. 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. The development of new technologies or products may take a number of years, and there can be no assurance that any patents which may be granted in respect of such technologies or products will not have expired or be due to expire by the time such products are commercialized, or that such patents will successfully withstand any challenges during their respective terms.

Although we 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.

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.

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 third parties may assert are 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 on 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 IP rights may be expensive, protracted and distracting to management, with no certainty of success. 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 IP 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 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. A trial was held in February 2023, and we anticipate a decision in the second half of 2023.

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 generic versions 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 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 include 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. Such legal proceedings and the preparation therefor may result in substantial costs to us and diversion of management's attention and resources, which in turn could harm our business. Moreover, if any of such legal proceedings were to result in an adverse outcome, such outcome 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 legal proceedings to which we are subject, or whether or not we are found as a result of such lawsuits 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 on 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/or 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 perceptions 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 litigation, costs, penalties and business losses.

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 inspections 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 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. 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 or other laws, 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, 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. Additionally, regardless of whether or not there is merit to claims underlying any investigation or legal proceedings to which we are subject, or whether or not we are found as a result of such investigations or lawsuits 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. 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, regulations or 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 laws, regulations or interpretations, a range of actions could result, including the suspension or termination of clinical trials, the failure to approve a product, restrictions on sales of our products or our 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, environmental issues or product pricing and marketing, could also adversely affect our revenues, our public reputation or our potential to be profitable. For example, and as discussed above, the Inflation Reduction Act, signed into law in August 2022, includes several provisions that will impact our business to varying degrees, including those that impose new manufacturer financial liability on all drugs in Medicare Part D beginning in 2025, allow the U.S. government to negotiate prices for some drugs covered under Medicare Part B and Part D beginning in 2026, and require companies to pay rebates to Medicare beginning in 2023 for drug prices that increase faster than inflation. This law and any further 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.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate Program, the 340B program, the U.S. Department of Veterans Affairs, FSS pricing program, and the Tricare program, and have obligations to report the average sales price for certain of our drugs to the Medicare program. For calendar quarters beginning January 1, 2022, manufacturers will need to start reporting the average sales price for drugs under the Medicare program regardless of whether they are enrolled in the Medicaid Drug Rebate Program. Currently, only manufacturers participating in the Medicaid Drug Rebate Program are obligated to do so.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts, which can change and evolve over time. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are generally obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and give rise to an obligation to refund entities participating in the 340B program for overcharges during past quarters impacted by a price recalculation.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. The CMS could also decide to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental programs could negatively impact our financial results. CMS issued a final regulation, which became effective in April 2016, to implement the changes to the Medicaid Drug Rebate Program under the Affordable Care Act. In December 2020, CMS issued a final regulation that modified prior Medicaid Drug Rebate Program regulations to permit reporting multiple best price figures with regard to value-based purchasing arrangements (beginning in 2022); and provided definitions for “line extension,” “new formulation,” and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula (beginning in 2022). Regulatory and legislative changes, and judicial rulings relating to the Medicaid Drug Rebate Program and related policies (including coverage expansion), have increased and will continue to increase our costs and the complexity of compliance, have been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS or another agency challenges the approach we take in our implementation.

The HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective in January 2019. Implementation of this regulation could affect our obligations and potential liability under the 340B program in ways we cannot anticipate. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated this regulation or other requirements of the program could negatively impact our financial results. Moreover, HRSA newly established an administrative dispute resolution (“ADR”) process under a final regulation effective January 2021, for claims by covered entities that a manufacturer engaged in overcharging, including claims that a manufacturer limited the ability of a covered entity to purchase the manufacturer’s drugs at the 340B ceiling price, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. This ADR regulation has been challenged in separate litigation instituted by PhRMA and by pharmaceutical manufacturers in multiple federal courts. Under the ADR final rule which became effective in January 2021, an ADR proceeding could potentially subject us to discovery by covered entities and other onerous procedural requirements and could result in additional liability. HRSA could also decide to terminate a manufacturer’s agreement to participate in the 340B program for a violation of that agreement or other good cause shown, in which case the manufacturer’s covered outpatient drugs may no longer be eligible for federal payment under the Medicaid or Medicare Part B program. In November 2022, HRSA issued a proposed rule to revise the ADR procedures contained in its January 2021 final regulation for disputes arising under the 340B drug pricing program between covered entities and manufacturers.

Further, legislation may be introduced that, if passed, would, among other things, further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting, and any additional future changes to the definition of average manufacturer price or the Medicaid rebate amount could affect our 340B ceiling price calculations and negatively impact our results of operations. Additionally, certain pharmaceutical manufacturers are involved in ongoing litigation regarding contract pharmacy arrangements under the 340B Program. The outcome of those judicial proceedings and the potential impact on the way in which manufacturers extend discounts to covered entities through contract pharmacies remain uncertain.

We have obligations to report the average sales price for certain of our drugs to the Medicare program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Pursuant to applicable law, knowing provision of false information in connection with price reporting under the U.S. Department of Veterans Affairs, FSS or Tricare programs can subject a manufacturer to civil monetary penalties. These program obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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, 2022, our accumulated deficit was $1.7 billion, which was primarily the result of net losses incurred from 1987, the year Alkermes, Inc., was founded, through December 31, 2022, 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, LYBALVI, VUMERITY, RISPERDAL CONSTA, the long-acting INVEGA products, 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;
- successfully manufacture our products and third-party products efficiently and in a cost-effective manner;
- obtain adequate reimbursement coverage for our products and third-party products from insurance companies, government programs and other third-party payers;
- achieve certain product development and sales milestones under our collaborative arrangements; and
- resolve favorably any commercial disputes that may arise in respect of collaborative arrangements from which we receive revenues.

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, if sought, 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 costs 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 other legal proceedings or government requests for information;
- the costs of defending against potential or actual proxy contests or other activist shareholder actions;
- the costs associated with the planning for and/or execution of the potential separation of our neuroscience and oncology businesses; and
- the costs associated with recruiting, compensating and retaining a highly-skilled workforce in an environment where competition for highly-skilled 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 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 our securities.

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, 2022, we had $37.7 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 financial condition, cash flows and results of operations.

Changes in tax rules and regulations, or interpretations thereof, may adversely affect our financial condition.

Effective January 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct R&D expenses in the year incurred and instead requires taxpayers to capitalize, and subsequently amortize such expenses over five years for research activities conducted in the U.S., and over fifteen years for research activities conducted outside of the U.S. As such, we expect a material decrease in cash flows provided from operations and a material increase in our net deferred tax assets over the next number of years.

Unless the U.S. Department of the Treasury issues regulations that narrow the application of this provision to a smaller subset of our R&D expenses or the provision is deferred, modified or repealed by the U.S. Congress, there will be a material increase in our U.S. income tax liability over the next number of years.

Our deferred tax assets may not be realized.

As of December 31, 2022, we had $115.6 million of net deferred tax assets in the U.S. 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, an enlarged foreign derived intangible income deduction due to the capitalization of R&D expenses, 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 financial condition and results of operations.

Furthermore, we have included within our U.S. net deferred tax assets of $115.6 million an amount of $36.4 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. 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 in 2011 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 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 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 as a result of 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 2021, we amended and refinanced our then-existing term loan (the "2023 Term Loans"), in order to, among other things, provide for a new class of replacement term loans equal to $300.0 million; extend the due date of the loan from March 26, 2023 to March 12, 2026; amend the interest payable from LIBOR plus 2.25% with no LIBOR floor to LIBOR plus 2.50% with a LIBOR floor of 0.5%; and increase covenant flexibility (such refinancing, the "Term Loan Refinancing" and the 2023 Term Loans as so amended and refinanced, the "2026 Term Loans"). The 2026 Term Loans were also amended to include customary Alternative Reference Rates Committee ("ARRC") hardwired benchmark replacement language. As of December 31, 2022, our borrowings consisted of $294.8 million outstanding under the 2026 Term Loans.

The 2026 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 2026 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 our ability to make our debt payments 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 2017, the U.K. Financial Conduct Authority announced its intention to phase out LIBOR after 2023. Currently, it is anticipated that LIBOR will be completely phased out by June 30, 2023. The U.S. Federal Reserve, in conjunction with the ARRC, a steering committee comprised of large U.S. financial institutions, has proposed a new index calculated by short term repurchase agreements, backed by U.S. Treasury securities, called the Secured Overnight Financing Rate ("SOFR") as an alternative to LIBOR for use in contracts that are currently indexed to U.S. dollar ('USD") LIBOR and has proposed a paced market transition plan to SOFR. On July 29, 2021, the ARRC formally recommended SOFR as its preferred alternative replacement rate for USD LIBOR. The 2026 Term Loans contain customary ARRC hardwired benchmark replacement language to transition from LIBOR to SOFR. 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, or our access to funding required to operate our business. In addition, SOFR is a relatively new reference rate and its composition and characteristics are not the same as LIBOR. Given SOFR's very limited history and potential volatility as compared to other benchmark or market rates, the future performance of SOFR cannot be predicted based on historical performance. The consequences of using SOFR could include an increase in the cost of our variable rate indebtedness. We are monitoring these transition efforts and, although the 2026 Term Loans contain provisions designed to accommodate an alternate reference rate, we may need to amend these and other contracts to accommodate any replacement rate.

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 and acquisitions, licenses and collaborations, and development and supply, commercialization or co-promotion arrangements, among others. We may choose to enter into one or more of these or other 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 global economic conditions, credit and financial market conditions, interest rates and other factors. If we issue additional equity securities or securities convertible into equity securities, our shareholders would suffer dilution of their investment, and it may adversely affect the market price of our ordinary shares. In addition, under Irish law, the directors of an Irish public limited company must have specific authority, as approved by the company's shareholders, to

allot and issue any ordinary shares (other than pursuant to employee equity plans) and, if such directors desire to allot and issue ordinary shares for cash, such shares must first be offered on the same or more favorable terms to the company's existing shareholders on a pro-rata basis, unless this statutory pre-emption right is disapplied by approval of the company's shareholders. In July 2022, our shareholders authorized our board of directors to allot and issue ordinary shares in an amount equal to approximately 33% of our issued share capital (at the date of such authorization), and to issue ordinary shares for cash on a non-pre-emptive basis in an amount equal to approximately 5% of our issued share capital (at the date of such authorization) or in an amount equal to approximately 10% of our issued share capital (at the date of such authorization) under certain specified circumstances; however, these share issuance authorities were granted for eighteen months only, at which point they lapse unless renewed by our shareholders. If we are unable to obtain renewal of share issuance authorities from our shareholders, or are otherwise limited by the terms of new share issuance authorities approved by our shareholders, our ability to use our authorized but unissued share capital to effect or to fund acquisition or other transaction opportunities, or to otherwise raise capital, could be adversely affected.

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.

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, TREVICTA and BYANNLI revenues from sales in countries other than the U.S., and these sales are denominated in non- 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 "Currency Exchange Rate Risk" in this Directors' Report for additional information relating to our foreign currency exchange rate risk.

Risks Related to our Ordinary Shares

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

The market price of our ordinary shares has fluctuated significantly from time to time. During the year ended December 31, 2022, the closing price of our ordinary shares on the Nasdaq Global Select Market ranged from $21.94 to $31.87 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 principal risks described in this Directors' Report. 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.

In addition, 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 harm, the market price of our ordinary shares, regardless of our operating performance.

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.

Since 2021, we have engaged in extensive dialogue with principals of Sarissa Capital Offshore Master Fund LP and its affiliates. These engagements and activities related to these engagements required the expenditure of significant time and energy by management and our board of directors.

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 perceived uncertainties as to the future direction of the Company or its business that may result in the loss of potential acquisitions, collaborations or in-licensing opportunities and make it more difficult to attract and retain qualified personnel and business partners.

In addition, 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 of our ordinary shares to experience periods of significant volatility.

Risks Related to Information Security and Data Privacy

Information 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 recent years, we have implemented additional remote work flexibility for certain of 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 our dependency on, and the complexity of, our IT systems increases, the confidentiality, integrity and availability of our IT 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. Moreover, the prevalent use of mobile devices to access confidential information increases the risk of security breaches. Cyber-attacks have increased in frequency, persistence, sophistication and intensity, often conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage, hactivists and organized come). In addition to the extraction of important information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of our information. Certain types of attacks or breaches on our IT systems or infrastructure may go undetected for a prolonged period. Although to our knowledge we have not experienced any material incident or interruption to date, 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, demands for ransom or other forms of blackmail, disruptions to our development programs or commercial operations, damage to our reputation and adverse effects on our business. We retain cybersecurity insurance to cover costs and expenses related to a breach or similar event; however, there is no guarantee that such costs and expenses would not exceed the insurance that we retain.

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 stringent 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 in order to introduce further conditions, including limitations, with regard to 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.

General Risk Factors

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 Nasdaq or the SEC or other regulatory authorities.

Going Concern

The Company’s board of directors formed a judgment at the time of approving these financial statements that there was a reasonable expectation that the Company has adequate resources to continue in operational existence for the next twelve months. In arriving at this conclusion, the Company’s board of directors has taken account of current and anticipated trading performance, recognizing the impact of the current macroeconomic environment and including current and anticipated uncertainties including those related to driven by driven by the COVID-19, together with the current and anticipated levels of net debt and the availability of the committed borrowing facilities. The Company’s forecasts and projections, taking account of reasonably possible changes in trading performance, show that the Company should be able to operate within the level of its current facilities. After making enquiries, the directors have a reasonable expectation that the Company has adequate resources to continue in operational existence for a period of not less than 12 months from the date of approval of these financial statements. Therefore, these financial statements have been prepared on a going concern basis.

Likely Future Developments

We expect to invest in R&D associated with internal initiatives in conjunction with external acquisitive investments, and to focus these investments on products that we believe will offer the greatest potential for near and long-term growth. We plan to invest in areas in which we can benefit from our core competencies and global infrastructure. We plan to allocate resources to support product lines that are fast-growing, high-margin opportunities in which we have developed or may be able to develop a competitive advantage. In fiscal year 2023, we plan to continue to analyze our business portfolio, which may lead to the acquisition or divestiture of assets and/or businesses.

In November 2022, we announced our intent, as approved by our board of directors, to explore a separation of our neuroscience business and oncology business. See Note 1, *Description of Business* within the "Notes to Consolidated Financial Statements" in this Directors' Report for additional information regarding such potential separation.

Accounting Records

The board of directors is responsible for ensuring that the Company keeps adequate accounting records and appropriate accounting systems to ensure compliance with the requirements of Sections 281 to 285 of the Companies Act. To achieve this, the Chief Financial Officer makes regular reports to the Audit and Risk Committee of the board of directors (the "Audit and Risk Committee"). The Audit and Risk Committee, in turn, briefs the full board of directors on significant financial matters arising from reports of the Chief Financial Officer and the external auditor.

The measures taken by the directors to secure compliance with the Company's obligation to keep adequate accounting records include the use of appropriate systems and procedures and employment of competent persons. The accounting records are kept at Connaught House, 1 Burlington Road, Dublin 4, Ireland, D04 C5Y6.

Corporate Governance

The Company's corporate governance policies and procedures are available on the Investors' page of the Company's website at www.alkermes.com.

Directors and Secretary

The names of the persons who served as directors or secretary of the Company at any time during the year ended December 31, 2022 are set out below.

Directors	Date of Service as a Director or Secretary
Emily Peterson Alva	(Reappointed July 7, 2022)
David W. Anstice	(Resigned effective July 7, 2022)
Shane M. Cooke	(Reappointed May 20, 2020)
David A. Daglio, Jr.	(Reappointed June 14, 2021)
Wendy L. Dixon	(Resigned effective July 7, 2022)
Richard B. Gaynor	(Reappointed May 20, 2020)
Cato T. Laurencin	(Reappointed July 7, 2022)
Brian P. McKeon	(Reappointed July 7, 2022)
Richard F. Pops	(Reappointed May 20, 2020)
Nancy L. Snyderman	(Reappointed June 14, 2021)
Frank A. Wilson	(Reappointed June 14, 2021)
Christopher I. Wright	(Reappointed July 7, 2022)
Nancy J. Wysenski	(Reappointed June 14, 2021)
Secretary	
David J. Gaffin	(Appointed December 12, 2017)

Acquisition or Disposal of Own Shares

Own shares held by the Company (par value, $0.01 per share) (Value in thousands)	Number	Value
January 1, 2022	3,853,222	$ 142,658
Acquired during the year	720,962	18,204
December 31, 2022	4,574,184	$ 160,862

The shares acquired during the year were received by the Company for the purchase of employee stock options or to satisfy minimum tax withholding obligations related to employee share-based awards and the value above represents the consideration paid. At December 31, 2022, the shares acquired represented 2.7% of the total ordinary shares issued and outstanding by the Company (at December 31, 2021: 2.3%).

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 (at December 31, 2021: none). 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 that our board of directors deems relevant.

Directors' and Secretary's Interests in Shares

No director, the secretary or any member of their immediate families had any interest in shares or debentures of any subsidiary of Alkermes plc. Directors' remuneration is set forth in Note 24, *Directors' Remuneration,* of the consolidated financial statements. The interests of the directors and secretary in office at January 1 and December 31, 2022 in the ordinary share capital of Alkermes plc are shown in the table below.

	Ordinary Shares[(1)] At December 31, 2022			Ordinary Shares[(1)] At January 1, 2022		
	Shares	Options	Restricted Share Units	Shares	Options	Restricted Share Units
Directors						
Emily Peterson Alva	12,311	51,105	13,548	1,650	39,551	19,504
David W. Anstice	62,235	181,709	—	77,320	206,709	7,585
Shane M. Cooke	94,118	458,838	5,957	90,478	497,284	7,585
David A. Daglio, Jr.	90,724	57,949	14,847	45,000	46,395	23,144
Wendy L. Dixon	40,000	181,709	—	45,539	181,709	7,585
Richard Gaynor	15,829	124,563	5,957	8,939	113,009	7,585
Cato T. Laurencin	7,479	43,693	14,120	—	32,139	16,405
Brian P. McKeon	20,724	57,949	14,847	10,000	46,395	23,144
Richard F. Pops	968,299	3,027,897	587,462	837,455	3,178,853	444,605
Nancy L. Snyderman	16,256	149,263	5,957	8,939	137,709	7,585
Frank A. Wilson	15,829	124,563	5,957	8,939	113,009	7,585
Christopher I. Wright	—	30,041	16,039	—	—	—
Nancy J. Wysenski	27,071	234,513	5,957	20,181	222,959	7,585
Company Secretary						
David J. Gaffin	97,766	675,057	155,180	80,518	546,563	114,112

(1) All interests declared are in the ordinary shares of $0.01 par value of Alkermes plc.

Political Donations

No political contributions that require disclosure under Section 26(1) of the Electoral Act 1997 (as amended) were made during the financial year 2022.

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 the section entitled "Review of the Performance of the Business" in this Directors' Report for additional information relating to our R&D expenditures.

Subsidiary Companies and Branches

Information regarding our subsidiaries is provided in Note 26, *Subsidiaries*, to the consolidated financial statements.

Audit and Risk Committee

Our board of directors has established an Audit and Risk Committee.

Statutory Auditors

The Company's independent statutory auditors, PricewaterhouseCoopers, have indicated their willingness to continue in office and a non-binding, advisory proposal to ratify their appointment will be proposed at the Company's 2023 annual general meeting of shareholders.

Disclosure of Information to Auditors

The directors in office at the date of this Directors' Report have each confirmed that:

- As far as he/she is aware, there is no relevant audit information of which the Company's auditor is unaware; and
- He/she has taken all the steps that he/she ought to have taken as a director in order to make himself/herself aware of any relevant audit information and to establish that the Company's auditor is aware of that information.

Non-Financial Statement

The European Union (Disclosure of Non-Financial and Diversity Information by certain large undertakings and groups) Regulations 2017 (S.I. 360/2017) (as amended) require us to disclose certain non-financial information in our Directors' Report.

A description of our business can be found under "Business Overview" beginning on page 5 in this Directors' Report and a description of risks related to our business, including those related to environmental, social and governance matters can be found under the section entitled "Principal Risks" on pages 33-55 in this Directors' Report. The following is a summary of our key policies, actions and key performance indicators in the areas of: (a) Environmental Matters (including climate-related information); (b) Social and Employee Matters; (c) Human Rights; and (d) Bribery and Corruption. A description of matters relating to our supply chain can be found under the heading entitled "Manufacturing and Product Supply" on page 12 in this Directors' Report. These policies and actions aim to support risk management in these areas and support the Company in its achievement of its environmental, social and governmental goals.

The descriptions of our policies set forth in the sections below include references to our Code of Business Conduct and Ethics (the "Code of Conduct"). The Code of Conduct and certain other policies pertaining to our business are available on the Company's website at www.alkermes.com. Our most recently published Corporate Responsibility Report is available on the Responsibility page of the Company's website at www.alkermes.com.

Environmental Matters

At Alkermes, our goal is to conduct our business activities in a manner that:

- Protects the health and safety of our employees;
- Minimizes the environmental impacts of our operations and promotes effective stewardship of environmental resources; and
- Maintains an unwavering focus on product quality and safety.

We are committed to complying with applicable laws, rules, and regulations and operating with the highest standards of conduct. As a global business, our environmental activities are structured to meet all relevant local and national regulatory agencies' requirements in the countries where we operate, including routine Environmental Health, Safety and Security ("EHSS")-focused regulatory inspections.

We strive to create a culture of environmental sustainability throughout the organization. We work collaboratively across stakeholder groups and business units to identify ways to reduce our environmental impact, mitigate EHSS risk, and increase operational efficiencies.

Alkermes is committed to operating in a way that protects our employees, our environment, and our communities. We implement a variety of EHSS risk management strategies to help ensure compliance with EHSS policies and protocols, proactively reduce EHSS risk, and drive awareness of our environmental impacts and priorities. The core goals established by our EHSS function include working to:

- Preserve and protect the health, safety and well-being of our employees;
- Meet or exceed applicable environmental, health, and safety regulations and statutory obligations for the regions in which we operate;
- Protect the environment and promote sustainability in our operations; and
- Secure our infrastructure and support the manufacture and supply of our medicines for patients.

With committed leadership from management and an engaged workforce, our operations are supported by teams of highly qualified and experienced EHSS professionals who provide strategic oversight and governance of EHSS activities and evaluate and establish appropriate EHSS performance goals for our operations.

Our EHSS strategy is integrated across our business, including in our R&D, manufacturing, facilities, external operations, commercial and general and administrative functions. This strategy is supported by numerous EHSS initiatives ranging from our high-level, systemic compliance and risk management frameworks to programs focused on creating a culture of EHSS risk awareness and active workforce engagement.

We maintain a robust, enterprise-wide EHSS Risk Management System ("RMS"), based on the structured principles of the international standards ISO 14001:2015 (environmental management) and ISO 45001:2018 (occupational health and safety management). Our RMS framework is designed to rapidly identify existing and emerging risks and assign appropriate resources for effective mitigation of such risks at each of our operating facilities. This framework enables us to:

- Comply with statutory and regulatory requirements and Alkermes' internal policies, and adhere to the terms of our environmental permits and licenses;
- Proactively identify and prioritize EHSS risks and potential mitigations for internal and external operations;
- Maintain effective emergency and crisis response preparedness;
- Conduct periodic audits for system effectiveness; and
- Drive improvement in our risk management and mitigation program.

Alkermes is committed to the safe and sustainable research, development, manufacturing, and commercialization of medicines. We implement this commitment by integrating EHSS risk management requirements throughout the lifecycle of each of our products. Our approach to product stewardship oversight and control includes:

- Generation of occupational and environmental toxicology data, which is iterated and augmented as each product progresses through its lifecycle;
- Development and application of appropriate occupational health, safety and environmental risk controls for each product based on scale, potency, task and other processing considerations;
- Utilization of protocols and risk assessments to support safe and responsible technology transfers within Alkermes or to external contract manufacturing organizations ("CMOs"), CROs or other third parties;
- Development of "green chemistry" processes designed to eliminate or reduce the use or generation of hazardous substances in the design and manufacture of our products; and
- Implementation of a global program for process hazard management with embedded controls as early as the candidate discovery stage and through full commercial-scale manufacturing of a product.

External Operations Risk Management

We have integrated certain EHSS risk management procedures and our formal RMS framework into our vendor management and governance processes. EHSS considerations and metrics are monitored and discussed as part of routine business review meetings with our external operations partners. This approach enables transparent conversations about EHSS risk and performance and provides a forum for Alkermes to communicate our expectations for responsible development and manufacture to our vendors.

To assess whether our vendors operate to Alkermes' standards and encourage adherence to such standards, EHSS risk considerations and metrics are embedded into our vendor due diligence assessments, on-boarding procedures, technology transfers and routine business reviews. We also incorporate EHSS-related provisions, as appropriate, into our service-level agreements related to our products. Our vendor assessment tools, which we developed based on the Pharmaceutical Supply Chain Initiative's 'Pharmaceutical Industry Principles for Responsible Supply Chain Management', evaluate key areas such as: EHSS management systems; performance and regulatory compliance; environmental sustainability; occupational health and safety systems; process safety management controls; physical security; labor and ethics policies; business continuity systems; and capability to safely handle Alkermes products. We have conducted on-site audits or tabletop reviews to assess all external CMOs directly involved in the manufacture or packaging of proprietary Alkermes medicines, and use the information gained from these assessments to help us prioritize areas of focus for our ongoing risk management efforts.

Environmental Protection and Sustainability

We strive to conduct our business activities in a manner that minimizes the environmental impacts of our operations and promotes effective stewardship of environmental resources. We are committed to complying with applicable laws, rules and regulations and operating with the highest standards of conduct. All Alkermes facilities are subject to routine regulatory inspections, including in respect of EHSS, to confirm compliance with applicable laws and regulations.

Energy Usage

We continually monitor and review our energy usage in order to identify opportunities for further optimization and reduction. Our activities in support of this objective include: analysis of data and trends from electricity and natural gas monitoring systems at our facilities; replacement of legacy equipment with more energy-efficient alternatives; incorporation of sustainable design and building techniques into new facilities to promote less energy use; and assessments of options to procure and further integrate renewable energy sources into our operations. A forum of engineering leaders from each of our sites meets regularly to develop best practices for our facilities and utility systems. A sub-team of this group is responsible for integrating sustainability principles and practices into the design of our capital projects, monitoring company-wide energy audits and developing multi-year plans for energy reduction initiatives.

Greenhouse Gas Emissions and Renewables

Alkermes recognizes the serious environmental, economic and societal impacts caused by climate change. Our environmental sustainability efforts include proactively taking action to reduce greenhouse gas emissions arising from our operations. We are focused on energy efficiency in our facility operations, and we also encourage employees to use more sustainable forms of transportation when commuting to work, including by providing shuttle bus service between our Waltham, Massachusetts site and public transportation locations and installing charging stations for electric vehicles at our Athlone, Ireland facility.

Water Conservation

We recognize that water is a scarce and invaluable resource that we must endeavor to conserve and use efficiently and sustainably. We have implemented programs across our organization to assess, reduce and optimize our water consumption, and we examine opportunities to further conserve water on an ongoing basis.

Pharmaceuticals in the Environment

We understand the potential impacts that pharmaceuticals can have on the environment. We maintain strict internal protocols to adhere to the parameters of our applicable licenses and permits, mitigate the impacts of our operations on natural resources such as surface water and groundwater and assist us in effectively controlling our air and wastewater emissions. We have implemented science- and data-driven environmental risk mitigation strategies and continually evaluate opportunities to improve our emissions control systems in order to better protect the environment and enhance the environmental sustainability of our operations.

Waste Optimization

All Alkermes facilities have comprehensive waste management plans in place and we strive to reduce our generation of waste at each source. Our waste streams are fully segregated, and disposal methods are carefully evaluated to support compliance with statutory and permit requirements and to minimize our environmental impacts. For non-hazardous waste, we actively seek to eliminate landfilling where practicable and pursue recycling, composting and/or other re-use opportunities. We also employ other forms of responsible disposal, such as treatment in third-party “waste-to-energy” facilities. For hazardous waste, we recognize that landfill is not an environmentally responsible disposal route. We actively explore recycling opportunities for our hazardous waste and, when feasible, select disposal routes that include potential energy recovery benefits.

Social and Employee Matters

Our employees are the foundation upon which our business is built. Their expertise, intelligence and creativity drive our innovation, and their passion and commitment to excellence are the cornerstone of our success. We strive to support our employees’ well-being in a transparent, diverse, inclusive and collaborative culture and provide employees with training, support and resources to allow them to succeed professionally while appropriately balancing their professional and personal lives. Beyond our employee initiatives, we are committed to broader social engagement through local volunteering opportunities, grant programs, and engagement with caregivers, patients and their loved ones. We also support advocacy efforts to raise awareness of patient needs and to increase access to medicines and other forms of treatment in support of patient health and well-being.

We have more than 2,000 employees across the U.S. and Ireland who are key to our ability to develop, produce and advance treatment options for patients and who contribute to our culture of collaboration and commitment to the work we do. 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 principles of equal employment

opportunity and other legitimate criteria 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 laws.

In 2022, employee health, safety and wellness continued to be of particular focus and importance for the Company. Since the emergence of the COVID-19 pandemic, we have adjusted and enhanced our remote work policies and opportunities, and our communication strategies, to keep employees connected and informed. We also enhanced employee resources, including wellness and stress-reduction resources, guidance on how to effectively engage and work remotely, and increased childcare benefits.

Diversity, Inclusion and Belonging

Across our sites, we seek to cultivate a work environment that reflects our values of collaboration at our core, respect for each voice and unwavering commitment. Over the past several years, we have continued to focus on fostering an environment that respects and celebrates Diversity, Inclusion & Belonging ("DIB") in our workplaces and our communities and have actively evolved our DIB strategy to reflect the needs of our employees and our business. We have a robust DIB governance structure, consisting of our DIB Steering Committee, Employee Resource Groups ("ERGs"), and a DIB Executive Committee. Our global cross-functional DIB Steering Committee, comprised of representatives from all of our locations, including field-based employees, is focused on creating connections, fostering conversations, helping ensure our efforts are aligned with the diverse range of perspectives within our organization and developing and advancing practices, tools and resources that can be used to strengthen the sense of belonging among our employees Our five ERGs include: Limitless, a network to support people impacted by disability or illness; Mosaic, a multicultural network; Operation Salute, a veterans' network; Pride@Work, an LGBTQ+ network; and Women Inspired Network (WIN), a women's network. These ERGs share 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. Our DIB Executive Committee, which includes our Chief Executive Officer and other senior leaders, is tasked with continuing to refine our DIB strategy and championing its implementation and impact across the business. These groups work together to set goals, establish and execute strategic initiatives, measure our progress and promote a culture of understanding and inclusion throughout our organization. In 2022, through the collaboration of these groups, we introduced an annual performance goal focused on DIB for all senior leaders (Vice President level and above) at Alkermes with an emphasis on talent management, including recruiting and development. Additionally, as part of our increased focus on social and racial justice, diversity and inclusion, we have held company-wide town hall conversations, sponsored recognition events and have enhanced our Company's diversity education and awareness training.

We remain focused on achieving greater representation of diverse talent through targeted recruitment and development efforts. In 2022, we achieved a notable increase in the percentage of our Vice Presidents/Senior Vice Presidents who are female (from 29.0% to 38.8%). We also established a Women's Mentoring Circle to provide internal resources for the continued development of our female talent pool. Additionally, we have continued to focus on increasing the representation of people of color ("POC") across our workforce and have partnered with outside organizations such as The Partnership and Connexion to support continued leadership development of POC within our organization.

Professional Development

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 encourage and support our employees in their adoption of Individual Development Plans designed to identify professional development and growth opportunities to help support their career aspirations. We frequently offer company-hosted trainings that cover topics including performance management, problem-solving, leadership development, diversity, communication, and mentorship, and, as appropriate, more specialized skills-based programs. We also provide all employees access to our LinkedIn Learning platform, which provides on-demand learning opportunities to our employees.

We also conduct ongoing health and safety training in compliance with all federal, state, and local regulations.

Culture of Employee Engagement

We encourage active employee engagement to help ensure that employees feel part of our mission and that they have a voice in the Alkermes community. Since 2017, we have conducted periodic employee engagement surveys to understand employee sentiment regarding, and satisfaction with, their work and experience at Alkermes and have used the data collected to help inform and evolve our human capital management strategy and initiatives. In 2022, we conducted approximately 30 focus groups with more than 225 employees and managers across the organization as part of our efforts to enhance key company processes related to "employee listening" and performance management. Also in 2022, we implemented function- and site-specific mentoring programs, conducted open forums with leaders, and hosted various company events to foster connections and visibility between leadership and employees and build strong peer-to-peer connections.

Patient Advocacy and Community Engagement

Patient advocacy is core to our mission. We are inspired by the courage of individuals who face the challenges of living with addiction, serious mental illness and cancer, and the perspectives of those affected by these conditions are paramount to our work. We regularly engage with these individuals and their caretakers, and with policymakers and leaders in the patient advocacy community, to better understand their perspectives and goals and the complex system of care for these diseases. Learnings from these interactions help to inform our business activities, including the design of clinical development and lifecycle management programs for our investigational and marketed medicines with specific patient outcomes in mind, and the nature and substance of our policy and advocacy efforts.

Access

We believe that every patient deserves quality care and we are committed to collaborating with policy-makers and other industry stakeholders to preserve and enhance access to important medicines. We strive to price our medicines in a responsible manner that facilitates broad access. We also offer programs, such as our Patient Assistance Programs and our Co-Pay Savings Programs, to provide support to eligible patients who are prescribed our medicines.

Supporting Our Communities

We respect the culture, customs and values of the people in the communities in which we operate. We seek to support and positively impact such communities through our grant programs, sponsorship contributions and volunteer support.

Sponsorships

We are proud to be part of a broader healthcare community that supports individuals with addiction, serious mental illness and cancer. In support of those efforts, we foster and maintain relationships with a variety of health-related and public policy organizations.

Funding in Support of Research and Charitable Organizations

Innovative research, programming and funding are urgently needed to support those who are living with addiction, serious mental illness and cancer. Since 2016, our ALKERMES INSPIRATION GRANTS® program has awarded more than $4.5 million in funding to innovative programs that support the needs of people impacted by addiction, serious mental illness and cancer. In 2022, grants were awarded to 9 nonprofit organizations working to address the needs of people living with alcohol dependence, opioid dependence, schizophrenia, bipolar I disorder or cancer. The selected programs also have a focus on addressing unmet needs in historically under-resourced or underrepresented communities with longstanding and widespread health disparities. Since 2018, our ALKERMES PATHWAYS RESEARCH AWARDS® program has provided funding to 21 researchers working to advance our understanding of diseases in the field of neuroscience.

Community Engagement

Our employees are passionate about helping to care for people and the environment in the local communities in which we work, supporting not only organizations and programs that are connected to the diseases that our medicines treat, but also causes for which they feel a personal connection through their own experience or those of their loved ones.

United States

We are committed to giving back to our communities. Since 2009, many of our employees have volunteered each year as part of our Alkermes in Action volunteer program. In 2022, this consisted of a mix of remote and in-person events with local organizations focused on education, caring for veterans, maintaining outdoor community spaces and providing for children and families in need.

Ireland

Our employees in Ireland proudly support local organizations that seek to address a range of needs including mental health, cancer care, education, shelter and domestic abuse services and homelessness, among others.

Respect for Human Rights

We strive to uphold human rights in all of our business activities and support the principles in the United Nations Declaration on Human Rights, including the prohibition of human trafficking, child labor and slavery of any kind. We believe this is evidenced by the information summarized above in Social and Employee Matters as well as in our EHSS and Procurement policies and practices.

At Alkermes, we work to foster a culture of respect, inclusion and equality supported by our Code of Conduct and the policies and programs championed by our human resources organization.

Consistent with our Respect in the Workplace policy, we are fundamentally committed to creating and maintaining a work environment that reflects our core Company values, and in which employees are treated fairly, with dignity, decency and respect, and in accordance with all applicable laws. We believe that all employees have the right to work in an environment that is free of discrimination and harassment of any kind and do not tolerate any harassment or discriminatory behavior.

Bribery and Corruption

Integrity is a core Alkermes value and a foundation of the way we do business. Alkermes is dedicated to upholding legal, regulatory and ethical standards in the markets in which we operate and to maintaining a strong culture of compliance. Our focus on compliance applies to all aspects of our business, beginning with preclinical research and continuing through clinical trials, manufacturing and commercialization. This focus on compliance helps to build trust with healthcare professionals, institutional purchasers, relevant government agencies and other stakeholders.

Compliance is a responsibility shared by employees across all levels of the Company. We expect each employee to take an active role in supporting our culture of compliance and to perform all activities and conduct all interactions with integrity and in accordance with the highest ethical standards.

Our commitment to compliance is embodied in our comprehensive compliance program which is built on the following core elements:

- Written policies and procedures that address the compliance risk areas relevant to pharmaceutical manufacturers, including those identified in the guidance of the Office of Inspector General of the U.S. Department of Health & Human Services and the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals.
- The Company's Chief Compliance Officer oversees our compliance program and reports directly to the Company's Chief Executive Officer. The Company's Corporate Compliance Committee helps oversee the Company's compliance program and assists with identifying any compliance issues that may need to be brought to the attention of the Company's board of directors.
- Alkermes conducts extensive training and education programs for all employees that begin with new hire training and include regular, ongoing training on topics, processes and policies relevant to their positions.
- Alkermes has established and continues to foster a culture of compliance that maintains effective lines of communication and encourages all employees to seek guidance on ethical or legal issues as they arise. This culture of compliance is further supported by a policy obligating employees to report possible compliance violations and a strong anti-retaliation policy (discussed below) that protects personnel who report issues in good faith.
- Regular monitoring and auditing of the compliance program enables Alkermes to detect and prevent potential non-compliance.
- The Company's policies and training ensure that all employees, including management, are informed of the consequences of failing to adhere to our compliance policies.
- Our compliance program is designed to promptly respond to and address, through corrective action, any detected instances of non-compliance.

Our Code of Conduct applies to all directors, officers and employees of the Company. Among other things, the Code of Conduct requires:

- honest and ethical conduct by directors, officers and employees of the Company, including the ethical handling of actual or apparent conflicts of interest;
- full, fair and understandable disclosure of the Company's activities in reports filed with the SEC and in the Company's other public communications; and
- prompt internal reporting of any violations of the Code of Conduct to a supervisor, the Company's Chief Legal Officer or the Company's Chief Compliance Officer (which role is currently held by the Company's Chief Legal Officer).

The Code of Conduct also requires compliance with all applicable laws, rules and regulations including, but not limited to, those guiding our interactions with government officials and health care providers. In this context, the Code of Conduct expressly prohibits any bribes, kickbacks or other improper payments, transfers or receipts.

Our employees are obligated to raise concerns about any violations of our Code of Conduct or any other ethics or conduct violations with their supervisor, the Company's Chief Legal Officer or Chief Compliance Officer, the Audit and Risk Committee of the board of directors and/or the Nominating and Corporate Governance Committee of the board of directors or through the Company's Corporate Governance hotline set forth in the Company's Procedures for Reporting Financial and Compliance Matters; No Retaliation Policy (Whistleblower Policy). A current copy of the Whistleblower Policy is available on the Corporate Governance page of the Investors section of our website at www.alkermes.com.

Directors' Compliance Statement

The directors acknowledge that they are responsible for securing the Company's compliance with its relevant obligations. The directors confirm that they have:

1. Drawn up a compliance policy statement setting out the Company's policies respecting compliance by the Company with its relevant obligations.
2. Put in place appropriate arrangements or structures that are designed to secure material compliance with the Company's relevant obligations.
3. Conducted a review, during the financial year ended 31 December 2022, of the arrangements and structures, referred to at 2 above.

On behalf of the directors

/s/ RICHARD F. POPS
Richard F. Pops
Chairman

/s/ FRANK A. WILSON
Frank A. Wilson
Director

April 6, 2023

ALKERMES PLC

STATEMENT OF DIRECTORS' RESPONSIBILITIES

The directors are responsible for preparing the Directors' Report and the financial statements in accordance with Irish law.

Irish law requires the directors to prepare financial statements for each financial year that give a true and fair view of the Group's and Parent Company's (as defined below) assets, liabilities and financial position and of the profit or loss of the Group (as defined below) for the financial year. Under that law the directors have prepared the consolidated financial statements in accordance with U.S. accounting standards, as defined in Section 279(1) of the Companies Act 2014, as amended (the "Companies Act"), to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Act or of any regulations made thereunder and the standalone parent company financial statements in accordance with generally accepted accounting practice in Ireland (accounting standards issued by the Financial Reporting Council of the UK, including Financial Reporting Standard 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* and Irish law).

Under Irish law, the directors shall not approve the financial statements unless they are satisfied that they give a true and fair view of the Group's and Parent Company's assets, liabilities and financial position as at the end of the financial year and the profit or loss of the Group for the financial year.

In preparing these financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgments and estimates that are reasonable and prudent;
- state that the consolidated financial statements of Alkermes plc and its subsidiaries (the "Group") comply with accounting principles generally accepted in the United States of America ("U.S. GAAP") to the extent that it does not contravene Irish company law and that the standalone entity balance sheet of Alkermes plc (the "Parent Company") comply with accounting standards issued by the UK Financial Reporting Council and Irish Law; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group and Parent Company will continue in business.

The directors are responsible for keeping adequate accounting records that are sufficient to:

- correctly record and explain the transactions of the Parent Company;
- enable, at any time, the assets, liabilities, financial position and profit or loss of the Parent Company to be determined with reasonable accuracy; and
- enable the directors to ensure that the financial statements comply with the Companies Act and enable those financial statements to be audited.

The directors are also responsible for safeguarding the assets of the Parent Company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website at www.alkermes.com. Legislation in Ireland concerning the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

Independent auditors' report to the members of Alkermes Public Limited Company

Report on the audit of the financial statements

Opinion

In our opinion:

- Alkermes Public Limited Company's consolidated financial statements and parent company financial statements (the "financial statements") give a true and fair view of the group's and the parent company's assets, liabilities and financial position as at 31 December 2022 and of the group's loss and cash flows for the year then ended;
- the consolidated financial statements have been properly prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP"), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of group financial statements does not contravene any provision of Part 6 of the Companies Act 2014;
- the parent company financial statements have been properly prepared in accordance with Generally Accepted Accounting Practice in Ireland (accounting standards issued by the Financial Reporting Council of the UK, including Financial Reporting Standard 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" and Irish law); and
- the financial statements have been properly prepared in accordance with the requirements of the Companies Act 2014.

We have audited the financial statements, included within the Directors' Report And Consolidated Financial Statements (the "Annual Report"), which comprise:

- the Consolidated Balance Sheet as at 31 December 2022;
- the Parent Company Balance Sheet as at 31 December 2022;
- the Consolidated Profit and Loss Account and Consolidated Statement of Comprehensive Loss for the year then ended;
- the Consolidated Statement of Cash Flows for the year then ended;
- the Consolidated Reconciliation of Movement in Shareholders' Funds for the year then ended;
- the Parent Company Reconciliation of Movement in Shareholders' Funds for the year then ended; and
- the Notes to the Financial Statements, which include a description of the significant accounting policies.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) ("ISAs (Ireland)") and applicable law. Our responsibilities under ISAs (Ireland) are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Independence

We remained independent of the group in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, which includes IAASA's Ethical Standard as applicable to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirement.

Our audit approach

Overview

	Overall materiality • $8.1 million (2021: $8.8 million) - Consolidated financial statements • Based on c. 0.75% of Turnover. • $31.6 million (2021: $36.0 million) - Parent company financial statements • Based on c. 1% of net assets. Performance materiality • $6.1 million (2021: $6.6 million) - Consolidated financial statements. • $23.7 million (2021: $27.1 million) - Parent company financial statements.
	Audit scope • The group has one reportable segment consisting of two primary geographic reporting components – United States ("US") and Ireland. • We conducted full scope audits on both reporting components.
	Key audit matters • Rebate Accruals - Medicaid Drug Rebate Program.

The scope of our audit

As part of designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we looked at where the directors made subjective judgements, for example in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits we also addressed the risk of management override of internal controls, including evaluating whether there was evidence of bias by the directors that represented a risk of material misstatement due to fraud.

Key audit matters

Key audit matters are those matters that, in the auditors' professional judgement, were of most significance in the audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by the auditors, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters, and any comments we make on the results of our procedures thereon, were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. This is not a complete list of all risks identified by our audit.

Key audit matter	***How our audit addressed the key audit matter***
Rebate Accruals - Medicaid Drug Rebate Program Refer to note 2 "Summary of significant accounting policies - Turnover from Contracts with Customers" and note 17 "Provisions for liabilities". As described in note 2, as referenced above, to the consolidated financial statements, turnover from product sales is recorded net of reserves established for applicable discounts and allowances that are offered within contracts with the Company's customers, health care providers or payers. Accruals for rebates in the United States ("US") under the Medicaid Drug Rebate Program are recorded as a reduction to product sales when the product is shipped into the distribution channel using the expected value method. As of December 31, 2022, total accrued Medicaid rebates	We tested 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 for the Medicaid Drug Rebate Program. We assessed the appropriateness of management's methodology used to determine the accruals for the Medicaid Drug Rebate Program. We assessed the reasonableness of management's estimate of the rebate accruals for the Medicaid Drug Rebate Program by: (i) developing an independent estimate of the rebate accruals for the Medicaid Drug Rebate Program by utilising third-party data related to product sales, the historical trend of actual rebate claims paid and consideration of contractual requirement changes and market events;

amounted to $208.3 million of which a significant amount related to the Medicaid Drug Rebate Program. The Company rebates individual US 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. At the year end, management estimates expected unit sales to individuals covered by Medicaid and rebates per unit under the Medicaid program. These estimates are based on assumptions developed using historical experience, current contractual requirements, specific known market events and payment patterns. We determined accruals for the Medicaid Drug Rebate Program to be a key audit matter due to the significant judgement exercised by management in developing the Medicaid Drug Rebate accrual.	(ii) comparing the independent estimate to management's estimate; and (iii) testing rebate claims processed by the Company. We considered the historical accuracy of the accrual for the Medicaid Drug Rebate Program.

How we tailored the audit scope

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole, taking into account the structure of the group, the accounting processes and controls, and the industry in which the group operates.

The group has one reportable segment consisting of two primary geographic reporting components – United States ("US") and Ireland.

We conducted full scope audits on both reporting components. In determining our audit scope we determined the type of work that needed to be performed at the reporting components by us, as the Irish group engagement team and PwC US as the global engagement team and component auditor. Where the work was performed by PwC US, we determined the level of involvement we needed to have in the audit work to be able to conclude whether sufficient appropriate audit evidence had been obtained as a basis for our opinion on the financial statements as a whole.

We allocated materiality levels and issued instructions to PwC US. In addition to the audit report from PwC US, we received a detailed memorandum of examination on work performed and relevant findings which supplemented our understanding of the US component, its results and the audit findings. Our supervision of the component team included a site visit to the PwC US component team together with a combination of regular video calls with senior members of the PwC US component team and review of certain working papers. The meetings with PwC US, both physical and virtual, also involved discussing and understanding the significant audit risk areas and obtaining updates on local laws and regulations and other relevant matters. This, together with additional procedures performed at Group level, gave us the evidence we needed for our opinion on the financial statements as a whole.

Materiality

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

Based on our professional judgement, we determined materiality for the financial statements as a whole as follows:

	Consolidated financial statements	***Parent company financial statements***
Overall materiality	$8.1 million (2021: $8.8 million).	$31.6 million (2021: $36 million).
How we determined it	c. 0.75% of Turnover.	c. 1% of net assets.
Rationale for benchmark applied	We deem turnover to be an appropriate benchmark having regard for the volatility in the loss before tax. This benchmark is utilised by management, analysts and the general market when assessing the results of the group.	As the parent company is a holding company we consider that net assets is the most appropriate benchmark to calculate materiality. For group audit purposes the lower consolidated financial statements materiality of $8.1 million (2021: $8.8 million) was applied in testing balances that do not eliminate in the consolidated financial statements.

We use performance materiality to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements exceeds overall materiality. Specifically, we use performance materiality in determining the scope of our audit and the nature and extent of our testing of account balances, classes of transactions and disclosures, for example in determining sample sizes. Our performance materiality was 75% of overall materiality, amounting to $6.1 million (group audit) and $23.7 million (parent company audit).

In determining the performance materiality, we considered a number of factors - the history of misstatements, risk assessment and aggregation risk and the effectiveness of controls - and concluded that an amount at the upper end of our normal range was appropriate.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above $0.61 million (group audit) (2021: $0.66 million) and $1.6 million (parent company audit) (2021: $1.8 million) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

Conclusions relating to going concern

Our evaluation of the directors' assessment of the group and parent company's ability to continue to adopt the going concern basis of accounting included:

- Obtaining management's going concern assessment for the going concern period of twelve months from the date on which the financial statements are authorised for issue;
- Evaluating management's cashflow forecasts for the period of the going concern assessment (being the period of twelve months from the date on which the financial statements are authorised for issue), and evaluating these forecasts by considering the group's historic performance and its past record of achieving strategic objectives;
- Considering whether the assumptions underlying the forecast were consistent with related assumptions considered in other parts of the audit, for example in testing for non-financial asset impairment;
- Considering available financing and maturity profile and the covenants attaching to long term debt to assess liquidity for the going concern assessment period; and
- Testing management's controls over the going concern assessment.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the group's or the parent company's ability to continue as a going concern for a period of at least twelve months from the date on which the financial statements are authorised for issue.

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

However, because not all future events or conditions can be predicted, this conclusion is not a guarantee as to the group's or the parent company's ability to continue as a going concern.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

Reporting on other information

The other information comprises all of the information in the Directors' Report And Consolidated Financial Statements other than the financial statements and our auditors' report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except to the extent otherwise explicitly stated in this report, any form of assurance thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If we identify an apparent material inconsistency or material misstatement, we are required to perform procedures to conclude whether there is a material misstatement of the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report based on these responsibilities.

With respect to the Directors' Report, we also considered whether the disclosures required by the Companies Act 2014 (excluding the information included in the "Non Financial Statement" as defined by that Act on which we are not required to report) have been included.

Based on the responsibilities described above and our work undertaken in the course of the audit, ISAs (Ireland) and the Companies Act 2014 require us to also report certain opinions and matters as described below:

- In our opinion, based on the work undertaken in the course of the audit, the information given in the Directors' Report (excluding the information included in the "Non Financial Statement" on which we are not required to report) for the year ended 31 December 2022 is consistent with the financial statements and has been prepared in accordance with the applicable legal requirements.
- Based on our knowledge and understanding of the group and parent company and their environment obtained in the course of the audit, we have not identified any material misstatements in the Directors' Report (excluding the information included in the "Non Financial Statement" on which we are not required to report).

Responsibilities for the financial statements and the audit

Responsibilities of the directors for the financial statements

As explained more fully in the Statement of Directors' Responsibilities set out on page 65, the directors are responsible for the preparation of the financial statements in accordance with the applicable framework and for being satisfied that they give a true and fair view.

The directors are also responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the group's and the parent company's ability to continue as a going concern, disclosing as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the group or the parent company or to cease operations, or have no realistic alternative but to do so.

Auditors' responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud, is detailed below.

Based on our understanding of the group and industry, we identified that the principal risks of non-compliance with laws and regulations related to the US Foreign Corrupt Practices Act, breaches of pharmaceutical products regulations, environmental regulations and health and safety regulations, and we considered the extent to which non-compliance might have a material effect on the financial statements. We also considered those laws and regulations that have a direct impact on the preparation of the financial statements such as tax legislation and the Companies Act 2014. We evaluated management's incentives and opportunities for fraudulent manipulation of the financial statements (including the risk of override of controls), and determined that the principal risks were related to posting inappropriate journal entries to manipulate financial results and potential management bias in accounting estimates. Audit procedures performed by the engagement team included:

- Discussions with the Audit & Risk Committee, management and Chief Legal Officer including consideration of known or suspected instances of non-compliance with laws and regulations and fraud;
- Review of meeting minutes of the Board, Audit & Risk and Compensation Committees;
- Discussions with PwC US as the component team, review of their work papers and consideration of their reporting relating to compliance with applicable laws and regulations and procedures performed to address assessed fraud risk;
- Evaluating whether there was evidence of management bias that represents a risk of material misstatement due to fraud by challenging assumptions made by management in its significant accounting estimates, particularly in relation to the key audit matter;
- Assessing the design and testing operating effectiveness of key controls addressing assessed fraud risk;
- Identifying and testing manual journal entries, including non standard turnover entries based on our risk assessment; and
- Designing audit procedures to incorporate elements of unpredictability around the nature, timing or extent of audit procedures performed.

There are inherent limitations in the audit procedures described above. We are less likely to become aware of instances of non-compliance with laws and regulations that are not closely related to events and transactions reflected in the financial statements. Also, the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one

resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion.

Our audit testing might include testing complete populations of certain transactions and balances, possibly using data auditing techniques. However, it typically involves selecting a limited number of items for testing, rather than testing complete populations. We will often seek to target particular items for testing based on their size or risk characteristics. In other cases, we will use audit sampling to enable us to draw a conclusion about the population from which the sample is selected.

A further description of our responsibilities for the audit of the financial statements is located on the IAASA website at:

https://www.iaasa.ie/getmedia/b2389013-1cf6-458b-9b8f-a98202dc9c3a/Description_of_auditors_responsibilities_for_audit.pdf

This description forms part of our auditors' report.

Use of this report

This report, including the opinions, has been prepared for and only for the company's members as a body in accordance with section 391 of the Companies Act 2014 and for no other purpose. We do not, in giving these opinions, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

Other required reporting

Companies Act 2014 opinions on other matters

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the parent company were sufficient to permit the parent company financial statements to be readily and properly audited.
- The Parent Company Balance Sheet is in agreement with the accounting records.

Other exception reporting

Directors' remuneration and transactions

Under the Companies Act 2014 we are required to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by sections 305 to 312 of that Act have not been made. We have no exceptions to report arising from this responsibility.

Prior financial year Non Financial Statement

We are required to report if the company has not provided the information required by Regulation 5(2) to 5(7) of the European Union (Disclosure of Non-Financial and Diversity Information by certain large undertakings and groups) Regulations 2017 in respect of the prior financial year. We have nothing to report arising from this responsibility.

Therese Cregg
for and on behalf of PricewaterhouseCoopers
Chartered Accountants and Statutory Audit Firm
Dublin
6 April 2023

- The maintenance and integrity of the Alkermes Public Limited Company website is the responsibility of the directors; the work carried out by the auditors does not involve consideration of these matters and, accordingly, the auditors accept no responsibility for any changes that may have occurred to the financial statements since they were initially presented on the website.
- Legislation in the Republic of Ireland governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

ALKERMES PLC

CONSOLIDATED PROFIT AND LOSS ACCOUNT

	Notes	Year Ended December 31, 2022	2021
		(In thousands, except per share amounts)	
Product sales, net	3	$ 777,552	$ 627,424
Manufacturing and royalty turnover	3	331,983	541,807
License turnover	3	2,000	3,500
Research and development turnover	3	260	1,020
Total turnover		1,111,795	1,173,751
Cost of sales		218,108	197,387
Gross profit		893,687	976,364
Research and development expense		393,842	406,526
Selling, general and administrative expense		605,747	560,977
Amortization of acquired intangible assets	5	36,363	38,148
Operating loss		(142,265)	(29,287)
Interest income		7,629	2,408
Interest expense	6	(13,040)	(11,219)
Change in the fair value of contingent consideration	7	(2,642)	(20,535)
Other income, net		2,122	219
Total other expense, net		(5,931)	(29,127)
Loss before income taxes		(148,196)	(58,414)
Income tax benefit (provision)	8	9,037	(8,863)
Loss after income taxes		$ (139,159)	$ (67,277)
LOSS PER ORDINARY SHARE:			
Basic and diluted	9	$ (0.85)	$ (0.42)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:			
Basic and diluted	9	163,742	160,942

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

ALKERMES PLC

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

	Year Ended December 31,	
	2022	2021
	(In thousands, except per share amounts)	
NET LOSS	$ (139,159)	$ (67,277)
Unrealized losses on marketable securities:		
Unrealized losses, net of tax	(7,166)	(2,374)
Unrealized losses on marketable securities	(7,166)	(2,374)
COMPREHENSIVE LOSS	$ (146,325)	$ (69,651)

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

ALKERMES PLC

CONSOLIDATED BALANCE SHEET

	Notes	December 31, 2022	December 31, 2021
		(In thousands, except share and per share amounts)	
ASSETS			
Fixed Assets			
Intangible assets—Goodwill	5	$ 92,873	$ 92,873
Intangible assets—Intellectual property	5	37,680	74,043
Tangible assets	10, 11	441,216	456,681
Financial assets	5, 14	139,482	235,562
Total fixed assets		711,251	859,159
Current Assets			
Stock	12	181,418	150,335
Debtors	13	462,844	459,571
Investments	14	315,992	198,767
Cash at bank and in-hand		292,473	337,544
Total current assets		1,252,727	1,146,217
TOTAL ASSETS		$ 1,963,978	$ 2,005,376
CAPITAL, RESERVES AND LIABILITIES			
Capital and Reserves			
Called-up share capital presented as equity	15	$ 1,690	$ 1,658
Share premium		642,530	622,932
Profit and loss account		(341,948)	(202,789)
Treasury shares	15	(160,862)	(142,658)
Other reserves		902,343	814,333
Total equity		1,043,753	1,093,476
Provisions for liabilities	17	265,612	243,818
Creditors			
Debt	6, 11	398,821	416,206
Creditors	18	255,792	251,876
Total for creditors		654,613	668,082
TOTAL CAPITAL, RESERVES AND LIABILITIES		$ 1,963,978	$ 2,005,376

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

The consolidated financial statements were approved by the board of directors on April 6, 2023 and signed on its behalf by:

/s/ RICHARD F. POPS
Richard F. Pops
Chairman

/s/ FRANK A. WILSON
Frank A. Wilson
Director

ALKERMES PLC

CONSOLIDATED STATEMENT OF CASH FLOWS

	Year Ended December 31,	
	2022	2021
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Loss after tax	$ (139,159)	$ (67,277)
Adjustments to reconcile net loss to after tax to cash flows from operating activities:		
Depreciation and amortization	77,862	78,652
Share-based compensation expense	94,254	87,622
Deferred income taxes	(32,795)	5,081
Change in the fair value of contingent consideration	2,642	20,535
Other non-cash charges	5,531	2,650
Changes in assets and liabilities, excluding the effect of acquisitions:		
Trade receivables	25,250	(38,011)
Contract assets	4,434	6,037
Stock	(31,021)	(24,769)
Prepaid expenses and other assets	(5,328)	11,481
Right-of-use assets	16,569	17,051
Creditors	15,534	11,514
Accrued sales discounts, allowances and reserves	14,899	18,339
Contract liabilities	(7,129)	(6,080)
Operating lease liabilities	(33,225)	(16,777)
Other long-term liabilities	12,726	(4,333)
Cash flows provided by operating activities	21,044	101,715
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property, plant and equipment	(38,255)	(28,020)
Proceeds from the sale of equipment	—	287
Proceeds from contingent consideration	1,273	7,937
Return of Fountain Healthcare Partners II, L.p. investment	485	—
Payment made for licensed Intellectual Property ("IP")	—	(1,000)
Purchases of investments	(309,671)	(340,418)
Sales and maturities of investments	281,627	295,010
Cash flows used in investing activities	(64,541)	(66,204)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	19,630	25,319
Employee taxes paid related to net share settlement of equity awards	(18,204)	(16,571)
Proceeds from the issuance of long-term debt	—	23,567
Principal payments of long-term debt	(3,000)	(2,250)
Payment made in connection with debt refinancing	—	(993)
Cash flows (used in) provided by financing activities	(1,574)	29,072
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(45,071)	64,583
CASH AND CASH EQUIVALENTS—Beginning of period	337,544	272,961
CASH AND CASH EQUIVALENTS—End of period	$ 292,473	$ 337,544
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Cash paid for interest	$ 13,563	$ 6,904
Cash paid for taxes	$ 20,749	$ 1,888
Non-cash investing and financing activities:		
Purchased capital expenditures included in creditors	$ 2,950	$ 6,025

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

ALKERMES PLC

CONSOLIDATED RECONCILIATION OF MOVEMENT IN SHAREHOLDERS' FUNDS

(In thousands)	Share Capital	Share Premium	Profit and Loss Account	Treasury Shares	Other Reserves	Total
BALANCE — January 1, 2021	$ 1,620	$ 597,651	$ (135,512)	$ (126,087)	$ 729,310	$ 1,066,982
Net loss	—	—	(67,277)	—	—	(67,277)
Other comprehensive loss	—	—	—	—	(2,374)	(2,374)
Share-based payment reserve	—	—	—	—	87,397	87,397
Shares issued under employee stock plans	38	25,281	—	—	—	25,319
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	(16,571)	—	(16,571)
BALANCE — December 31, 2021	$ 1,658	$ 622,932	$ (202,789)	$ (142,658)	$ 814,333	$ 1,093,476
Net loss	—	—	(139,159)	—	—	(139,159)
Other comprehensive loss	—	—	—	—	(7,166)	(7,166)
Share-based payment reserve	—	—	—	—	95,176	95,176
Shares issued under employee stock plans	32	19,598	—	—	—	19,630
Receipt of Alkermes' shares to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	(18,204)	—	(18,204)
BALANCE — December 31, 2022	$ 1,690	$ 642,530	$ (341,948)	$ (160,862)	$ 902,343	$ 1,043,753

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

1. DESCRIPTION OF BUSINESS

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 the fields of neuroscience and oncology. Alkermes has a portfolio of proprietary commercial products focused on alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder and a pipeline of product candidates in development for neurological disorders and cancer. 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.

On November 2, 2022, the Company announced its intent, as approved by its board of directors, to explore a separation of its neuroscience business and oncology business. The Company is exploring a separation of the oncology business into an independent, publicly- traded company (referred to herein as "Oncology Co.") as part of an ongoing review of strategic alternatives for the oncology business. Following the planned separation, the Company would retain its focus on driving growth of its proprietary commercial products: LYBALVI, ARISTADA/ARISTADA INITIO and VIVITROL, and advancing the development of pipeline programs focused on neurological disorders. The Company also expects to retain manufacturing and royalty revenues related to its licensed products and third-party products using its proprietary technologies under license. Oncology Co. would focus on the discovery and development of cancer therapies, including the continued development of nemvaleukin alfa and the Company's portfolio of novel, preclinical engineered cytokines. The separation, if consummated, is expected to be completed in the second half of 2023 and is subject to customary closing conditions, including final approval by the Company's board of directors and, if sought, receipt of a private letter ruling from the IRS and/or tax opinion from the Company's tax advisors.

The registered office of the Company is located in Connaught House, 1 Burlington Road, Dublin 4 D04 C5Y6 and its registration number is 498284.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Preparation

Irish law requires the Company's directors to prepare financial statements for each financial year that give a true and fair view of the consolidated and the standalone parent company's assets, liabilities and financial position as at the end of the financial year and of the profit or loss of the Company for the financial year. Under that law, the Company's directors have prepared the consolidated financial statements in accordance with accounting standards generally accepted in the United States ("U.S. GAAP"), as defined in Section 279(1) of the Companies Act 2014, as amended (the "Companies Act"), to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Act or of any regulations made thereunder and the standalone parent company financial statements in accordance with Generally Accepted Accounting Practice in Ireland (accounting standards issued by the Financial Reporting Council and Irish law).

The consolidated financial statements are prepared in accordance with Irish company law, to present to the shareholders of Alkermes plc and file with the Companies Registration Office in Ireland. Accordingly, these consolidated financial statements include disclosures required by the Companies Act in addition to those required under U.S. GAAP.

The preparation of the consolidated financial statements in conformity with U.S. GAAP accepted accounting principles requires management to use judgment in making estimates and assumptions based on the relevant information available at the end of each period. These estimates and assumptions have a significant effect on reported amounts of assets and liabilities, revenue and expenses as well as the disclosure of contingent assets and liabilities because they result primarily from the need to make estimates and assumptions on matters that are inherently uncertain. Actual results may differ from estimates.

Going Concern

The Company's board of directors formed a judgment at the time of approving these financial statements that there was a reasonable expectation that the Company has adequate resources to continue in operational existence for the next twelve months. In arriving at this conclusion, the Company's board of directors has taken account of current and anticipated trading performance, recognizing the impact of the current macroeconomic environment and including current and anticipated uncertainties driven by the COVID-19 pandemic (as described in greater detail under the heading "Risks and Uncertainties" within this note), together with the current and anticipated levels of net debt and the availability of the committed borrowing facilities. The Company's forecasts and projections, taking account of reasonably possible changes in trading performance, show that the Company should be able to operate within the level of its current facilities. After making enquiries, the directors have a reasonable expectation that the Company has adequate resources to continue in operational existence for a period of not less than 12 months from the date of approval of these financial statements. Therefore, these financial statements have been prepared on a going concern basis.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

Use of Estimates

The preparation of the Company's consolidated financial statements in accordance with U.S. 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 but not limited to, 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 at Bank and In-Hand

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 non-U.S. agencies and backed by non-U.S. 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, 2022, substantially all these investments were classified as available-for-sale and were recorded at fair value. Unrealized gains and losses are included in accumulated other comprehensive loss in equity, net of related tax, in accumulated other comprehensive loss unless: (i) the security has experienced a credit loss; (ii) the Company has determined that it has the intent to sell the security; or (iii) it has determined that it is more likely than not that the Company will have to sell the security before its expected recovery.

Periodic reviews are conducted to identify and evaluate each investment that has an unrealized loss in accordance with the meaning of other-than-temporary impairment. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis.

For available-for-sale debt 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 the amortized cost basis. Where 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 reflected in 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 "Financial assets" 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, 2022, the Company's financial assets consisted of cash equivalents, investments and contingent consideration and are classified within the fair value hierarchy as follows:

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

- *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, 2022 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, 2022 included U.S. government agency debt securities, debt securities issued by non-U.S. agencies and backed by non-U.S. 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, 2022, no assets utilized Level 3 inputs.

The carrying amounts reflected in the consolidated balance sheets for cash at bank and in-hand, debtors and creditors approximate fair value due to their short-term nature.

Stock

Stock is stated at the lower of cost and net realizable value. Cost is determined using the first-in, first-out method. Included in stock 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 stock 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 profit and loss account.

The Company capitalizes stock 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 stock 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 stock batches less likely or unlikely to be commercialized and to result in future economic benefit.

Tangible Fixed Assets

Tangible fixed assets 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 related to the sale of a business 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 the corresponding likelihood of receiving related payments. The Company revalues its contingent consideration each reporting period, with changes in the fair value of contingent consideration recognized within the consolidated statements of operations and comprehensive loss. Changes in the fair value of contingent consideration can result from changes to one or multiple assumptions, including adjustments to 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, changes in the assumed probability associated with regulatory approvals and changes in the probability of collection or default of portions of the contingent consideration due to the Company.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

These fair value measurements are based on significant inputs, including 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 (such acquisition, 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.

Consistent with U.S. GAAP, 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 the reporting unit, then the Company would record an impairment loss equal to the difference.

Irish law requires goodwill and indefinite lived intangible assets to be amortized. However, the Company does not believe this gives a true and fair view, as not all goodwill and intangible assets decline in value. In addition, since goodwill that does decline in value rarely does so on a straight-line basis, straight-line amortization of goodwill and indefinite lived intangible assets over an arbitrary period does not reflect the economic reality. Therefore, goodwill and indefinite lived intangible assets are not amortized.

The Company's finite-lived intangible assets, consisting of core developed technology and collaboration agreements acquired as part of the Business Combination, 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.

In situations where the Company has significant influence, but not control, of an entity, it applies the equity method of accounting. Under the equity method of accounting, the Company's share of the investee's underlying net income or loss is recorded within "Other income, net" in the accompanying consolidated profit and loss account. Refer to Note 5, *Goodwill, Intangible Assets and Associated Undertakings*, for further discussion of the Company's equity method investments.

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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 the third quarter of 2022, the Company determined that certain construction in progress related to the manufacture of ANJESO®, the first approved Meloxicam Product, was impaired, as it had no alternative future use. See Note 10, *Tangible Fixed Assets*, within the "Notes to Consolidated Financial Statements" in this Directors' Report for details related to such construction in progress.

In the fourth quarter of 2022, the Company determined that an impairment triggering event occurred related to an arbitration panel's ruling relative to the Company's manufacturing and royalty revenue arrangement with Acorda related to AMPYRA®. Following this triggering event, the Company evaluated certain of its intangible assets for impairment under a held-and-used model. The Company concluded in this instance that the long-lived assets evaluated for impairment were recoverable based on an analysis of the undiscounted cash flows to be generated from the use of these assets and that there was no impact to the remaining useful lives of these assets.

Turnover from Contracts with Customers

The Company recognizes turnover 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 turnover 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 in the U.S. of VIVITROL®, ARISTADA® and ARISTADA INITIO® and, following its commercial launch in October 2021, LYBALVI®, 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.

Turnover from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with the Company's customers, healthcare 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 turnover 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:

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

- *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 its 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 Centers for Medicare and Medicaid Services, 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 Pharmaceuticals, 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") related to INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, INVEGA HAFYERA/BYANNLI (the "long-acting INVEGA products") and RISPERDAL CONSTA®, and Biogen Swiss Manufacturing GmbH (together with its affiliates, "Biogen") related to 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 Turnover

The Company recognizes manufacturing turnover from the sale of products it manufactures for resale by its licensees. Manufacturing turnover for the Company's partnered products, with the exception of those from Janssen related to RISPERDAL CONSTA and from Biogen related to VUMERITY, 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 turnover 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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 turnover 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 Company recognizes manufacturing revenue related to VUMERITY at cost plus 15%, upon making available bulk batches of VUMERITY to Biogen, to the extent the Company packages such product, then also when packaged batches of VUMERITY are made available to Biogen. Control of the product passes to Biogen when VUMERITY, in either bulk or finished form, is made available to Biogen.

The sales price for certain of the Company's manufacturing turnover is based on the end-market sales price earned by its licensees. As end-market sales generally occur after the Company has recorded manufacturing turnover, 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 turnover and estimated manufacturing turnover 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 turnover has not been material to date.

Royalty Turnover

The Company recognizes royalty turnover 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) such 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 that the products are sold by the Company's licensee and the Company has a present right to payment.

Certain of the Company's royalty turnover 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 turnover and estimated royalty turnover 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 turnover has not been material to date.

Research and Development Turnover

R&D turnover 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. Turnover is recognized as the obligations under the R&D arrangements are performed.

License Turnover

The Company recognizes turnover 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 that the customer is able to direct the use of and obtain substantially all of the benefits from the license.

Foreign Currency

The Company's functional and reporting currency is the U.S. dollar ("USD"). 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 USD at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within "Other income, net" in the accompanying consolidated profit and loss account. During the years ended December 31, 2022 and 2021, the Company recorded a gain of $0.7 million and a loss of $0.3 million on foreign currency translation, respectively.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 turnover and receivables from the Company's customers exceeding 10% of the total in each category as of and for the years ended December 31, 2022 and 2021:

	Year Ended December 31,			
	2022		2021	
Customer	Receivables	Turnover	Receivables	Turnover
Janssen	*	15%	30%	30%
Biogen	19%	13%	11%	10%
Cardinal Health	24%	24%	17%	20%
AmerisourceBergen	18%	14%	13%	11%
McKesson	12%	16%	11%	13%

* Indicates receivables for the customer did not exceed 10% of the Company's total receivables as of December 31, 2022, 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 turnover by geographic location, as determined by the location of the customer, and the location of its assets, are as follows:

	Year Ended December 31,	
(In thousands)	2022	2021
Turnover by region:		
U.S.	$ 931,991	$ 984,235
Ireland	1,829	2,175
Rest of world	177,975	187,341
Assets by region:		
Current assets:		
U.S.	$ 702,564	$ 485,083
Ireland	427,742	577,086
Rest of world	—	—
Long-term assets:		
U.S.:		
Other	$ 529,002	$ 591,217
Ireland:		
Intangible assets	$ 37,680	$ 74,043
Goodwill	92,873	92,873
Other	174,117	204,182

Research and Development Expenses

For each of its R&D programs, the Company incurs both external and internal expenses. External R&D expenses include fees related to clinical and non-clinical activities performed by contract research organizations, consulting fees and costs related to 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 are not tracked by individual program as they benefit multiple programs or the Company's technologies in general.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 2022 and 2021, advertising costs totaled $41.4 million and $38.9 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 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 and incentive 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 date of grant 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, annual 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,	
	2022	2021
Expected option term	5 - 8 years	5 - 7 years
Expected stock volatility	43 % - 51 %	43 % - 54 %
Risk-free interest rate	1.83 % - 4.26 %	0.67 % - 1.46 %
Expected annual dividend yield	—	—

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

Other Reserves

Other reserves includes: a share-based payment reserve, which represents the share-based compensation expense for the cost of the awards granted to the Company's subsidiaries' employees less an additional capital contribution made by the Company's subsidiaries to the Company equal to the fair value of the Company's ordinary shares on the date options are exercised or RSUs vest, less the proceeds received; and unrealized gains (losses) on marketable securities.

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 non-Irish 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 investments.

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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 2022 and 2021, the Company contributed $15.3 million and $14.6 million, respectively, to match employee deferrals under the 401(k) Plan.

Defined Contribution Plan

The Company maintains a defined contribution plan for its Ireland-based employees (the "Defined Contribution Plan"). The Defined Contribution Plan provides for eligible employees to contribute up to 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, 2022 and 2021, the Company contributed $5.1 million and $5.2 million, respectively, in contributions to the Defined Contribution Plan.

Risks and Uncertainties

COVID-19

The COVID-19 pandemic has impacted, and may continue to impact, many aspects of society, including the operation of healthcare systems, global travel, supply and labor markets and other business and economic activity worldwide. A number of the marketed products from which the Company derives revenue, including manufacturing and royalty revenue, are injectable medications administered by healthcare professionals, which have been, and the Company expects may continue to be, adversely impacted to varying degrees as a result of COVID-19 related closures restrictions, labor shortages and other disruptions that have transpired, and may continue to transpire, while the pandemic persists.

The COVID-19 pandemic has caused, and the Company expects may continue to cause, varying degrees of disruption to its employees and business operations. While the Company has continued to operate its manufacturing facilities and supply its medicines throughout the pandemic, the Company has at times during the pandemic experienced labor or supply chain disruptions at its manufacturing facilities and may continue to experience such disruptions while the pandemic persists, which could impact the Company's ability to manufacture its products and the third-party products from which it receives revenue in a timely matter or at all. In addition, while the Company has continued to conduct R&D activities, including its ongoing clinical trials, the COVID-19 pandemic has at times impacted the timelines of certain of its early-stage discovery efforts and clinical trials, and may continue to impact such timelines while the pandemic persists. The Company works with its internal teams, its clinical investigators, R&D vendors and critical supply chain vendors to continually assess, and mitigate, the potential impact of COVID-19 on its manufacturing operations and R&D activities.

The degree to which the COVID-19 pandemic may continue to impact the Company's employees, business, financial condition and results of operations will depend on the ultimate severity and duration of the pandemic and the manner in which it continues to evolve, including the emergence, prevalence and severity of new COVID-19 variants, and future developments in response thereto. Due to these and numerous other uncertainties surrounding the ongoing COVID-19 pandemic, the actual impact of the pandemic on the Company's financial condition and operating results may differ from its current projections. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact the Company's business, financial condition or results of operations, see the section entitled "Principal Risks" in this Directors' Report and specifically the section entitled "—Our business, financial condition and results of operations have been, and may continue to be, adversely affected by the ongoing COVID-19 pandemic or other similar outbreaks of contagious diseases."

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Potential Separation

In November 2022, the Company announced its intent, as approved by its board of directors to explore a separation of its neuroscience business and oncology business. See Note 1, *Description of Business* within the "Notes to Consolidated Financial Statements" in this Directors' Report for additional information regarding such potential separation. For information on risks associated with Oncology Co., see the section entitled "Principal Risks" in this Directors' Report and specifically the sections entitled "—The potential separation of our neuroscience and oncology businesses, including a potential separation of our oncology business into an independent, publicly-traded company, is subject to various risks and uncertainties and may not be completed on the timeline currently contemplated or at all, and will involve significant time, effort and expense, which could disrupt or adversely affect our business and our financial condition, results of operations and cash flows" and "—We may fail to realize some or all of the anticipated benefits of the potential separation of our neuroscience and oncology businesses and the market price of our ordinary shares may fluctuate significantly in connection with the potential separation."

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.

3. TURNOVER FROM CONTRACTS WITH CUSTOMERS

During the years ended December 31, 2022 and 2021, the Company recorded product sales, net, as follows:

	Year Ended December 31,	
(In thousands)	2022	2021
VIVITROL	$ 379,478	$ 343,853
ARISTADA and ARISTADA INITIO	302,052	275,356
LYBALVI	96,022	8,215
Total product sales, net	$ 777,552	$ 627,424

During the years ended December 31, 2022 and 2021, the Company recorded manufacturing and royalty turnover from its collaborative arrangements as follows:

	Year Ended December 31, 2022		
(In thousands)	Manufacturing Turnover	Royalty Turnover	Total
Long-acting INVEGA products[1]	$ —	$ 115,655	$ 115,655
VUMERITY	32,493	83,003	115,496
RISPERDAL CONSTA	42,670	7,243	49,913
Other	37,211	13,708	50,919
	$ 112,374	$ 219,609	$ 331,983

	Year Ended December 31, 2021		
(In thousands)	Manufacturing Turnover	Royalty Turnover	Total
Long-acting INVEGA products[1]	$ —	$ 303,106	$ 303,106
VUMERITY	25,808	61,614	87,422
RISPERDAL CONSTA	40,413	10,456	50,869
Other	39,407	61,003	100,410
	$ 105,628	$ 436,179	$ 541,807

(1) "Long-acting INVEGA products": INVEGA SUSTENNA/XEPLION (paliperidone palmitate), INVEGA TRINZA/TREVICTA (paliperidone palmitate) and INVEGA HAFYERA/BYANNLI (paliperidone palmitate).

3. TURNOVER FROM CONTRACTS WITH CUSTOMERS (Continued)

In October 2022, an arbitration panel found that the Company must return to Acorda $16.5 million (inclusive of prejudgment interest and administrative fees) previously paid by Acorda under a license agreement between the Company and Acorda, and in November 2022, the panel found that the Company must pay to Acorda an additional $1.8 million (inclusive of prejudgment interest). These amounts represent a portion of the royalty revenue paid to the Company by Acorda since July 2020 related to AMPYRA. The Company paid the $16.5 million in October 2022 and paid the additional $1.8 million in December 2022. In addition, during the three months ended June 30, 2022, the Company had recorded $3.2 million of royalty revenue related to AMPYRA as the Company believed that it had met the necessary revenue recognition criteria under the Financial Accounting Standards Board Accounting Standards Codification 606, *Turnover from Contracts with Customers* ("Topic 606"). However, as a result of the arbitration ruling, the Company reversed the $3.2 million as the panel found that the Company was no longer entitled to be paid those royalties. During the three months ended September 30, 2022, the Company recorded both the $18.3 million in repayments and the $3.2 million reversal as reversals of royalty revenue within "Manufacturing and royalty revenue" in the accompanying consolidated statements of operations and comprehensive loss. As a result of the arbitration ruling, the Company no longer has a contractual obligation to manufacture and supply AMPYRA or a contractual right to receive future manufacturing or royalty revenue related to AMPYRA. In January 2023, Acorda filed a petition with the U.S. District Court for the Southern District of New York asking the court to confirm in part and modify in part the final arbitral award rendered by the arbitration panel in October 2022 and, as part of the requested modification, seeking an additional approximately $66.0 million in damages. The Company intends to contest this petition and believe it is without merit.

In November 2021, the Company received notice of partial termination of an exclusive license agreement with Janssen. Under this license agreement, the Company provided Janssen with rights to, and know-how, training and technical assistance in respect of, the Company's small particle pharmaceutical compound technology, known as NanoCrystal technology, which it used to develop INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and INVEGA HAFYERA/BYANNLI. When the partial termination became effective in February 2022, Janssen ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. and the Company stopped recognizing royalty turnover related to net sales of these products in the U.S. In April 2022, the Company commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of the license agreement and Janssen's royalty and other obligations under the agreement. On December 21, 2022, the Company received an interim award (the "Interim Award") in these proceedings from the arbitral tribunal (the "Tribunal"), in which the Tribunal agreed with the Company's position that, while Janssen may terminate the agreement, it may not continue to sell Products (as defined in the agreement) developed during the term of the agreement without paying royalties pursuant to the terms of the agreement. This award is not yet final. The Company will engage with Janssen and the Tribunal in additional proceedings prior to the Tribunal's issuance of a final award. Accordingly, the Company has not recognized royalty revenue related to U.S. sales of the long-acting INVEGA products since February 2022. Refer to Note 19, *Commitments and Contingent Liabilities* within the "Notes to Consolidated Financial Statements" in this Directors' Report for additional information regarding the arbitration proceedings with Janssen.

4. 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 this Directors' Report for information with respect to IP protection for these products. The collaboration revenue the Company has earned in the years ended December 31, 2022 and 2021 is summarized in Note 3, *Turnover from Contracts with Customers* within the notes to the consolidated financial statements in this Directors' Report.

The Company's significant collaborative arrangements are described below:

Janssen

INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and INVEGA HAFYERA/BYANNLI

In November 2021, the Company received notice of partial termination of an exclusive license agreement with Janssen. Under this license agreement, the Company provided Janssen with rights to, and know-how, training and technical assistance in respect of, the Company's small particle pharmaceutical compound technology, known as NanoCrystal technology, which was used to develop INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, and INVEGA HAFYERA/BYANNLI. When the partial termination became effective in February 2022, Janssen ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA in the U.S. and the Company stopped recognizing royalty revenue related to net sales of these products. In April 2022, the Company commenced binding arbitration proceedings related to, among other things, Janssen's partial termination of this license agreement and Janssen's royalty and other obligations under the agreement. On December 21, 2022, we received the Interim Award in these proceedings from the Tribunal, in which the Tribunal agreed with our position that, while Janssen may terminate the agreement, it may not continue to sell Products (as defined in the agreement) developed during the term of the agreement without paying royalties pursuant to the term of the agreement. This award is not yet final. We will engage with Janssen and the Tribunal in additional proceedings prior to the Tribunal's issuance of a final award. Accordingly, the Company has not recognized royalty revenue related to U.S. sales of the long-acting INVEGA products since February 2022. For additional information about these proceedings, see Note 19, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report.

Under this license agreement, the Company granted Janssen a worldwide exclusive license under the Company's NanoCrystal technology to develop, commercialize and manufacture injectable pharmaceutical products containing paliperidone palmitate, which include the long-acting INVEGA products, and the Company received milestone payments from Janssen upon the achievement of certain development goals from Janssen; there are no further milestones to be earned under this agreement. The agreement also provides for tiered royalty payments between 5% and 9% of net sales of products subject to this agreement 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 in each individual country, subject to expiry of the 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, unless earlier terminated, terminates 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, subject to certain surviving obligations.

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.

4. COLLABORATIVE ARRANGEMENTS (Continued)

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

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

Biogen

Under a license and collaboration agreement with Biogen, 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 and milestone payments related to the achievement of certain milestones, including FDA approval of the NDA for VUMERITY and amendment of the license and collaboration agreement. The Company is 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, the Company receives a 15% royalty on worldwide net sales of VUMERITY, subject to increases for VUMERITY manufactured and/or packaged by Biogen or its designees, and 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.

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 license and collaboration agreement with Biogen, pursuant to which Biogen has elected to conduct 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.

4. COLLABORATIVE ARRANGEMENTS (Continued)

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.

5. GOODWILL, INTANGIBLE ASSETS AND ASSOCIATED UNDERTAKINGS

Goodwill and intangible assets consists of the following:

		Intangible Assets—Intellectual Property				
(In thousands)	Goodwill	Collaboration Agreements	NanoCrystal Technology	OCR Technology	Other	Total
Cost:						
At January 1, 2022	$ 92,873	$ 465,590	$ 74,600	$ 42,560	$ 1,000	$ 583,750
At December 31, 2022	$ 92,873	$ 465,590	$ 74,600	$ 42,560	$ 1,000	$ 583,750
Accumulated Depreciation:						
At January 1, 2021	$ —	$ (377,727)	$ (54,391)	$ (39,441)	$ —	$(471,559)
Expensed during the year	—	(29,285)	(7,208)	(1,655)	—	(38,148)
At December 31, 2021	—	(407,012)	(61,599)	(41,096)	—	$(509,707)
Expensed during the year	—	(28,875)	(6,436)	(1,035)	(17)	(36,363)
At December 31, 2022	$ —	$ (435,887)	$ (68,035)	$ (42,131)	$ (17)	$(546,070)
Net Book Amount:						
At December 31, 2022	$ 92,873	$ 29,703	$ 6,565	$ 429	$ 983	$ 37,680
At December 31, 2021	$ 92,873	$ 58,578	$ 13,001	$ 1,464	$ 1,000	$ 74,043

The Company's finite-lived intangible assets consist of collaborative agreements and the NanoCrystal and oral controlled release technologies acquired as part of the EDT acquisition. The Company recorded $36.4 million and $38.1 million of amortization expense related to its finite-lived intangible assets during the years ended December 31, 2022 and 2021, respectively. Based on the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheets at December 31, 2022 is expected to be approximately $35.0 million and $1.0 million in the years ending December 31, 2023 and 2024, respectively. Although the Company believes such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future turnover, there is the potential for the Company's actual results to vary significantly from such expectations. If turnover are projected to change, the related amortization of the intangible assets will change in proportion to the change in turnover.

The Company performed its annual goodwill impairment test as of October 31, 2022. The Company elected to perform a qualitative impairment test and based on the weight of all available evidence, determined that the fair value of the reporting unit more-likely-than-not exceeded its carrying value.

Associated Undertakings

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, 2022, the Company's total contribution in Fountain was equal to €7.4 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 three months ended March 31, 2022, one of the companies within the Fountain portfolio was acquired by a third party. The Company's proportional share of the proceeds from this transaction was $1.1 million, of which $1.0 million was received during the three months ended March 31, 2022 and the remaining $0.1 million is being held in escrow until May 2023. The transaction was accounted for under the cumulative earnings approach whereby the return on investment of $0.6 million was recorded as a gain within "Other income, net" in the accompanying consolidated statements of operations and comprehensive loss and the return of investment of $0.5 million was recorded as a reduction in the Company's net investment in Fountain. The Company's net investment in Fountain was $7.9 million and $6.1 million at December 31, 2022 and 2021, respectively, and was included within "Other assets" in the accompanying consolidated balance sheets.

5. GOODWILL, INTANGIBLE ASSETS AND ASSOCIATED UNDERTAKINGS (Continued)

During the years ended December 31, 2022 and 2021, the Company recorded an increase in its investment in Fountain of $1.8 million and a decrease of $0.4 million, respectively, which represented the Company's proportional share of Fountain's net gains or losses for such periods.

6. LONG-TERM DEBT

Long-term debt consists of the following:

(In thousands)	December 31, 2022	December 31, 2021
2026 Term Loans, due March 12, 2026	$ 293,270	$ 295,804
Less: current portion	(3,000)	(3,000)
Long-term debt	$ 290,270	$ 292,804

In March 2021, the Company amended and refinanced its existing term loan, previously referred to as the 2023 Term Loans, in order to, among other things, provide for a new class of replacement term loans equal to $300.0 million; extend the due date of the loan from March 26, 2023 to March 12, 2026; amend the interest payable from LIBOR plus 2.25% with no LIBOR floor to LIBOR plus 2.50% with a LIBOR floor of 0.5%; and increase covenant flexibility (such refinancing, the "Term Loan Refinancing" and the 2023 Term Loans as so amended and refinanced the "2026 Term Loans"). The 2026 Term Loans were also amended to include customary ARRC hardwired benchmark replacement language.

The 2026 Term Loans have an incremental facility capacity in an amount of $175.0 million, plus additional potential amounts provided that Company meets certain conditions, including a specified leverage ratio. The 2026 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 2026 Term Loans also contain customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at December 31, 2022.

The Term Loan Refinancing involved multiple lenders who were considered members of a loan syndicate. In determining whether the Term Loan 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 2026 Term Loans was at least 10% different from the present value of the remaining cash flows under the 2023 Term Loans (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 three lenders, who owned between 2%-7% of the total outstanding principal amount of the 2023 Term Loans immediately prior to the Term Loan Refinancing whose holding amounts were accounted for as a debt extinguishment, the Term Loan Refinancing was otherwise accounted for as a debt modification.

The Term Loan Refinancing resulted in a $2.1 million charge in the year ended December 31, 2021, which was included in "Interest expense" in the accompanying consolidated statement of operations and comprehensive loss.

Scheduled maturities with respect to the 2026 Term Loans are as follows (in thousands):

Year Ending December 31:	
2023	$ 3,000
2024	3,000
2025	3,000
2026	285,750
Total	$ 294,750

The Company is subject to mandatory prepayments of principal if certain excess cash flow thresholds, as defined in the 2026 Term Loans, are met. To date, the Company has not been required to make any such mandatory prepayments.

At December 31, 2022, the Company's balance of unamortized deferred financing costs and unamortized original issue discount costs were $0.5 million and $1.0 million, respectively. These costs are being amortized to interest expense over the estimated repayment period of the 2026 Term Loans using the effective interest method. During each of the years ended December 31, 2022 and 2021, the Company had amortization expense of $0.5 million related to deferred financing costs and original issue discount.

7. 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, 2022	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 19,857	$ 19,857	$ —	$ —
U.S. government and agency debt securities	202,050	168,639	33,411	—
Corporate debt securities	204,943	—	204,943	—
Non-U.S. government debt securities	38,789	—	38,789	—
Contingent consideration	—	—	—	—
Common stock warrants	—	—	—	—
Total	$ 465,639	$ 188,496	$ 277,143	$ —

	December 31, 2021	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ -	$ -	$ —	$ —
U.S. government and agency debt securities	$ 126,139	$ 96,597	$ 29,542	$ —
Corporate debt securities	196,478	—	196,478	—
Non-U.S. government debt securities	103,760	—	103,760	—
Contingent consideration	3,940	—	—	3,940
Total	$ 430,317	$ 96,597	$ 329,780	$ 3,940

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, 2022. 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, 2022:

(In thousands)	Fair Value
Balance, January 1, 2022	$ 3,940
Purchase of corporate debt security	500
Change in the fair value of contingent consideration	(2,642)
Milestone and royalty payments received by the Company related to contingent consideration	(1,298)
Impairment of corporate debt security	(500)
Balance, December 31, 2022	$ —

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

The estimated fair value of the Company's long-term debt under the 2026 Term Loans (as defined in Note 6, *Long-Term Debt* within these "Notes to Consolidated Financial Statements" in this Directors' Report), 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 $278.9 million and $285.8 million at December 31, 2022 and 2021, respectively.

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.

7. FAIR VALUE (Continued)

In Baudax's Quarterly Report on Form 10-Q for the period ended September 30, 2022, Baudax continued to include disclosures regarding its ability to continue as a going concern, which first appeared in its Annual Report on Form 10-K for the period ended December 31, 2021. In March 2022, Baudax reduced its workforce by approximately 80%, which was designed to reduce its operational expenses and conserve its cash resources. As a result of these events and the fact that, as of March 31, 2022, Baudax had only paid $0.5 million of the $6.4 million milestone payment that was due to the Company in March 2022, the Company recorded a reduction in the fair value of the contingent consideration of $19.1 million as a subsequent event adjustment during the year ended December 31, 2021. In light of Baudax's disclosures and the fact that, as of September 30, 2022, Baudax had only paid $1.2 million of the $6.4 million that was due to the Company in March 2022, the Company determined, during the three months ended September 30, 2022, that it was unlikely to collect any further proceeds under this arrangement and recorded a $3.6 million charge to reduce the fair value of the contingent consideration to zero within "Change in the fair value of contingent consideration". In addition, during the three months ended September 30, 2022, the Company determined that certain construction in progress related to the manufacture of ANJESO had no future value. See Note 10, *Tangible Fixed Assets*, within the "Notes to Consolidated Financial Statements" in this Directors' Report for details related to such construction in progress.

In December 2022, Baudax announced that it would discontinue the sale of ANJESO and on December 28, 2022, the U.S. Food and Drug Administration ("FDA") acknowledged the discontinuation of sale of ANJESO via listing in the Orange Book.

8. INCOME TAXES

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

	Year Ended December 31,	
(In thousands)	**2022**	**2021**
Current income tax (provision):		
U.S. federal	$ (18,105)	$ (2,700)
U.S. state	(5,653)	(1,079)
Rest of world	—	(3)
Deferred income tax benefit (provision):		
U.S. federal	28,123	(5,908)
U.S. state	4,672	827
Total income tax provision	$ 9,037	$ (8,863)

The income tax benefit in 2022 was primarily due to an enhanced foreign derived intangible income ("FDII") deduction as a result of a change to Section 174 of the U.S. Tax Cuts and Jobs Act in relation to capitalization and amortization of R&D expenses. The income tax provision in 2021 was primarily due to U.S. federal and state taxes on income earned in the U.S. and the tax impact of employee equity activity.

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 U.S. subsidiaries totaled approximately $812.8 million at December 31, 2022. 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 $55.0 million of income taxes would be payable on the repatriation of the unremitted earnings to Ireland.

The distribution of the Company's loss before income taxes by geographical area consists of the following:

	Year Ended December 31,	
(In thousands)	**2022**	**2021**
Ireland	$ (164,720)	$ (73,178)
U.S.	16,524	14,764
Rest of world	—	—
Loss before income taxes	$ (148,196)	$ (58,414)

8. INCOME TAXES (Continued)

The components of the Company's net deferred tax assets consist of the following:

(In thousands)	December 31, 2022	December 31, 2021
Deferred tax assets:		
NOL carryforwards	$ 235,734	$ 224,902
Research and development expenses	66,464	—
Accrued expenses and reserves	55,755	52,308
Share-based compensation	41,075	40,455
Tax credits	22,932	58,704
Other	9,993	7,758
Less: valuation allowance	(269,123)	(251,506)
Total deferred tax assets	162,830	132,621
Deferred tax liabilities:		
Property, plant and equipment	(46,274)	(50,187)
Other	(1,502)	(1,150)
Total deferred tax liabilities	(47,776)	(51,337)
Net deferred tax assets	$ 115,054	$ 81,284

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

(In thousands)	Balance at Beginning of Period	(Additions) / Reductions [1]	Balance at End of Period
Deferred tax asset valuation allowance for the year ended December 31, 2021	$ (253,649)	$ 2,143	$ (251,506)
Deferred tax asset valuation allowance for the year ended December 31, 2022	$ (251,506)	$ (20,011)	$ (271,517)

(1) The (additions)/reductions in each of the periods presented relate primarily to Irish NOLs.

At December 31, 2022, the Company maintained a valuation allowance of $25.7 million against certain U.S. state deferred tax assets and $245.8 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, 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, 2022, the Company had $1.7 billion of Irish NOL carryforwards, $15.1 million of U.S. federal NOL carryforwards, $43.2 million of state NOL carryforwards, $5.7 million of federal R&D credits and $29.0 million of state tax credits which will either expire on various dates through 2042 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. Included within these loss and credit carryforwards are $15.1 million of U.S. federal NOL carryforwards and $6.8 million of state NOL carryforwards, acquired as part of the acquisition of Rodin, each of which are subject to a $0.5 million annual limitation.

8. INCOME TAXES (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, 2022	2021
Statutory tax rate	12.5 %	12.5 %
Loss before income taxes at statutory rate	$ (18,519)	$ (7,307)
Share-based compensation	4,461	7,841
Foreign rate differential[1]	(2,122)	5,811
Change in valuation allowance	19,061	(2,143)
Intercompany amounts[2]	(1,694)	10,707
Irish rate differential[3]	4,926	1,817
Uncertain tax positions	602	704
Non-deductible lobbying expenses	775	637
U.S. state income taxes, net of U.S. federal benefit	598	248
In-process R&D[4]	—	2,724
Foreign derived intangible income	(10,405)	(3,875)
R&D credit	(7,863)	(8,488)
Other permanent items[5]	1,143	187
Income tax (benefit) provision	$ (9,037)	$ 8,863
Effective tax rate	5.4 %	(22.5) %

(1) Represents income or losses of 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) Represents the tax effect of the research and development expense recorded in connection with the acquisition of Rodin.
(5) 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 was as follows:

(In thousands)	Unrecognized Tax Benefits
Balance, December 31, 2020	$ 7,668
Reductions based on tax positions related to prior periods	(27)
Additions based on tax positions related to the current period	731
Balance, December 31, 2021	$ 8,372
Reductions based on the lapse of applicable statues of limitations	$ (438)
Additions based on tax positions related to prior periods	449
Additions based on tax positions related to the current period	590
Balance, December 31, 2022	$ 8,973

The unrecognized tax benefits at December 31, 2022, if recognized, would affect the Company's effective tax rate. The Company does not anticipate that the amount of existing unrecognized tax benefits will materially 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, 2022 and 2021, the Company's accrued interest and penalties related to uncertain tax positions were not material.

8. INCOME TAXES (Continued)

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 2019 through 2022 fiscal years remain subject to examination by the respective tax authorities, however, some states have longer statutes of limitations and additional fiscal years remain subject to examination. In Ireland, the 2018 through 2022 fiscal years 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 2002 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.à.r.l, a former indirect subsidiary of Alkermes plc that was liquidated during the year ended December 31, 2020, are currently under examination by the Tax Authorities in Luxembourg (the "LTA"). In November 2022, the Company received a notice of assessment in the amount of €2.2 million for the year ended December 31, 2017 from the LTA. The Company disagrees with this assessment and believes this assessment to be incorrect. The Company will timely appeal the notice of assessment and pursue available administrative and judicial avenues as may be necessary or appropriate. As of December 31, 2022, the Company had not received a notice of assessment from the LTA in relation to the year ended December 31, 2018.

9. 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, 2022 and 2021, as the Company was in a net loss position, the diluted loss per share calculation did not assume conversion or exercise of stock options and restricted stock unit 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 share calculation because the effect would have been anti-dilutive:

	Year Ended December 31,	
(In thousands)	**2022**	**2021**
Stock options	12,777	14,794
Restricted stock unit awards	5,040	3,981
Total	17,817	18,775

10. TANGIBLE FIXED ASSETS

Tangible fixed assets consist of the following:

(In thousands)	Land and Buildings	Furniture, Fixtures and Equipment	Leasehold Improvements	Construction in Progress	Total
Cost:					
At January 1, 2021	$ 184,754	$ 366,051	$ 52,508	$ 102,833	$ 706,146
Additions at cost	14,726	31,657	18	(14,776)	31,625
Transfers	—	1,545	—	(1,545)	—
Disposals	—	(1,154)	—	—	(1,154)
At December 31, 2021	$ 199,480	$ 398,099	$ 52,526	$ 86,512	$ 736,617
Additions at cost	2,224	22,421	1,626	8,910	35,181
Transfers	—	1,541	—	(1,541)	—
Disposals	—	(3,613)	—	—	(3,613)
Impairments	—	—	—	(9,166)	(9,166)
At December 31, 2022	$ 201,704	$ 418,448	$ 54,152	$ 84,715	$ 759,019
Accumulated Depreciation:					
At January 1, 2021	$ (77,258)	$ (256,629)	$ (22,256)	$ —	$ (356,143)
Charged during the year	(5,960)	(31,948)	(2,597)	—	(40,505)
Disposals	—	1,085		—	1,085
At December 31, 2021	$ (83,218)	$ (287,492)	$ (24,853)	$ —	$ (395,563)
Charged during the year	(6,234)	(33,118)	(2,159)	—	(41,511)
Disposals	—	3,416	—	—	3,416
At December 31, 2022	$ (89,452)	$ (317,194)	$ (27,012)	$ —	$ (433,658)
Net Book Amount:					
At December 31, 2022	$ 112,252	$ 101,254	$ 27,140	$ 84,715	$ 325,361
At December 31, 2021	$ 116,262	$ 110,607	$ 27,673	$ 86,512	$ 341,054

Depreciation expense was $41.7 million and $40.5 million for the years ended December 31, 2022 and 2021, respectively. Also, during the years ended December 31, 2022 and 2021, the Company wrote off furniture, fixtures and equipment that had an approximate carrying value of $0.5 million and $0.1 million, respectively, at the time of disposition.

Amounts included as construction in progress in the consolidated balance sheets primarily include capital expenditures at the Company's manufacturing facility in Wilmington, Ohio. The Company continues to evaluate its manufacturing capacity based on expectations of demand for its products and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service. The Company expects that approximately $44.3 million of construction in progress will be placed into service in the second half of 2023.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.

In September 2022, the Company determined that $8.7 million of its construction in progress that related to the manufacture of ANJESO had no future value. The Company had previously received $6.4 million from Baudax related to such equipment which it had recorded as contract liabilities within "Other long-term liabilities" in the accompanying consolidated balance sheets and the net amount of $2.3 million was written off through "other income, net" in the accompanying consolidated statements of operations and comprehensive loss.

11. LEASES

All of the Company's leases are accounted for as operating leases. The Company's two significant operating leases at December 31, 2022 include the following:

900 Winter Street

The Company leases approximately 231,000 square feet of office and laboratory space located at 900 Winter Street in Waltham, Massachusetts (the "900 Winter Street Lease"). The initial term of the lease commenced on January 20, 2020, expires in 2035 and includes an option to extend the term for an additional ten-year period.

11. LEASES (Continued)

In December 2022, the Company exercised an early payment option included within the terms of the 900 Winter Street Lease. The election of such early payment option resulted in a remeasurement of the remaining lease liability and right-of-use asset as of the remeasurement date of December 1, 2022 of $12.8 million. Subsequently, the Company made the early lease payment of $15.3 million in December 2022. As of December 31, 2022, the remeasurement and subsequent payment resulted in an increase in the right-of-use asset of $12.8 million and a net decrease in the lease liability of $2.5 million.

852 Winter Street

The Company leases approximately 180,000 square feet of corporate office space, administrative areas and laboratories at 852 Winter Street in Waltham, Massachusetts. The original lease commenced in 2010 and was extended, at the Company's option, for five years in 2020. The lease extension commenced in March 2021 for 163,000 square feet of space and in September 2021 for the remaining 17,000 square feet of space. The lease expires in 2026 and includes a tenant option to extend the term of the lease for an additional five-year period.

At December 31, 2022 and 2021, the operating leases held by the Company had a weighted average incremental borrowing rate of 5.25% and 5.25%, respectively, and a weighted average remaining lease term of 8.9 years and 11.7 years, respectively. During the years ended December 31, 2022 and 2021, cash paid for amounts included for the measurement of lease liabilities was $33.2 million and $16.8 million, respectively. The Company recorded operating lease expense of $16.6 million and $17.1 million for the years ended December 31, 2022 and 2021, respectively.

Right-of-use assets as of December 31, 2022 consisted of the following:

(In thousands)	Right-of-Use Assets
Balance, January 1, 2021	$ 131,718
Addition of operating lease in 2021	960
Amortization	(17,051)
Balance, December 31, 2021	$ 115,627
Addition and remeasurement of operating leases in 2022	16,797
Amortization	(16,569)
Balance, December 31, 2022	$ 115,855

At December 31, 2022 and 2021, liabilities arising from operating leases were $105.6 million and $120.4 million, respectively, of which $15.8 million and $16.2 million fall due within one year, respectively, and $89.8 million and $104.2 million fall due after more than one year, respectively.

Future lease payments under non-cancelable leases as of December 31, 2022 consisted of the following:

(In thousands)	December 31, 2022
2023	$ 16,665
2024	16,608
2025	16,855
2026	12,767
2027	9,506
Thereafter	69,474
Total operating lease payments	$ 141,875
Less: imputed interest	(36,324)
Total operating lease liabilities	$ 105,551

12. STOCK

Stock consists of the following:

(In thousands)	December 31, 2022	December 31, 2021
Raw materials	$ 61,064	$ 56,125
Work in process	76,228	59,105
Finished goods[1]	44,126	35,105
Total stock	$ 181,418	$ 150,335

(1) At December 31, 2022 and 2021, the Company had $30.9 million and $25.1 million, respectively, of finished goods stock located at its third-party warehouse and shipping service provider.

The estimated replacement cost of stocks did not differ significantly from the amounts shown above. The Company performs periodic assessments to determine the existence of obsolete, slow-moving and non-saleable stock and records provisions to reduce such stock to net-realizable value. At December 31, 2022 and 2021, the Company had a provision for stock obsolescence of none and less than $0.1 million, respectively.

13. DEBTORS

(In thousands)	December 31, 2022	December 31, 2021
Amounts falling due within one year		
Trade receivables	$ 287,967	$ 313,193
Contract assets	8,929	13,363
Prepaid expenses and other current assets	43,527	46,478
	$ 340,423	$ 373,034
Amounts falling due after more than one year		
Deferred income taxes	$ 115,602	$ 81,833
Other debtors	6,819	4,704
Total	$ 462,844	$ 459,571

Included in trade receivable at December 31, 2022 and 2021 are unbilled receivables of $72.0 million and $127.6 million, respectively, and related primarily to royalty turnover. The Company maintains an allowance for doubtful accounts to provide for the estimated amounts of trade receivables that will not be collected. The allowance is based upon an assessment of customer creditworthiness, historical payment experience and age of trade receivables. The allowance for doubtful accounts was approximately $0.2 million at December 31, 2022 and 2021, respectively.

Contract assets include unbilled amounts resulting from sales under certain of the Company's manufacturing contracts where turnover is recognized over time, except for $5.0 million of consideration related to the Company's collaboration with Biogen related to VUMERITY, which was included in contract assets at December 31, 2021 and transferred to receivables, net, as the milestone related to such amount was achieved in November 2022. 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, 2021	$ 19,401
Additions	30,609
Transferred to receivables, net	(36,647)
Contract assets at December 31, 2021	$ 13,363
Additions	42,218
Transferred to receivables, net	(46,652)
Contract assets at December 31, 2022	$ 8,929

14. INVESTMENTS

Investments consist of the following:

December 31, 2022	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses Less than One Year	Gross Unrealized Losses Greater than One Year	Estimated Fair Value
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	$ 141,418	$ —	$ (424)	$ (2,054)	$ 138,940
U.S. government and agency debt securities	143,710	16	(266)	(1,289)	142,171
Non-U.S. government debt securities	35,455	—	(28)	(546)	34,881
Total short-term investments	320,583	16	(718)	(3,889)	315,992
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	68,229	—	(1,550)	(676)	66,003
U.S. government and agency debt securities	62,220	—	(917)	(1,424)	59,879
Non-U.S. government debt securities	4,099	—	—	(191)	3,908
	134,548	—	(2,467)	(2,291)	129,790
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Total long-term investments	136,368	—	(2,467)	(2,291)	131,610
Total investments	$ 456,951	$ 16	$ (3,185)	$ (6,180)	$ 447,602
December 31, 2021					
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	$ 85,201	$ 177	$ (39)	$ —	$ 85,339
U.S. government and agency debt securities	45,349	35	(24)	—	45,360
Non-U.S. government debt securities	68,046	75	(53)	—	68,068
Total short-term investments	198,596	287	(116)	—	198,767
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	111,793	—	(654)	—	111,139
U.S. government and agency debt securities	81,296	—	(517)	—	80,779
Non-U.S. government debt securities	35,902	—	(210)	—	35,692
	228,991	—	(1,381)	—	227,610
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Total long-term investments	230,811	—	(1,381)	—	229,430
Total investments	$ 429,407	$ 287	$ (1,497)	$ —	$ 428,197

The following table is a rollforward of the fair value of the Company's investments for the year ended December 31, 2022:

(In thousands)	Corporate Debt Securities	U.S. Government and Agency Debt Securities	Non-U.S. Government Debt Securities	Certificates of Deposit	Fair Value
Balance, January 1, 2022	$ 196,478	$ 126,139	$ 103,760	$ 1,820	$ 428,197
Purchases	112,304	188,117	11,595	1,820	313,836
Maturities and redemptions	(96,347)	(108,550)	(74,911)	(1,820)	(281,628)
Trade loss	(54)	—	—	—	(54)
Amortization, accretion and inflation income, net	(3,249)	(283)	(1,078)	—	(4,610)
Base change in net unrealized gain (loss)	(4,189)	(3,373)	(577)	—	(8,139)
Balance, December 31, 2022	$ 204,943	$ 202,050	$ 38,789	$ 1,820	$ 447,602

14. INVESTMENTS (Continued)

At December 31, 2022, the Company reviewed its investment portfolio to assess whether the unrealized losses on its available-for-sale investments were temporary. Investments with unrealized losses consisted primarily of corporate debt securities and debt securities issued by non-U.S. agencies and backed by non-U.S. governments. At December 31, 2022, 280 of the Company's 289 investment securities were in an unrealized loss position and had an aggregate estimated fair value of $422.7 million. Approximately 47% and 45% of the Company's investment securities at December 31, 2022 are in corporate debt securities, with a minimum rating of A2(Moody's)/A (Standard and Poor's), and debt securities issued by the U.S. government or its agencies, respectively. In a rising interest rate environment, the Company expects its fixed-rate investment securities will carry unrealized losses. 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. The Company has the intent and ability to hold these investments until recovery, which may be at maturity.

In September 2019, the Company purchased $1.9 million of convertible promissory notes from Synchronicity Pharma, Inc. ("Synchronicity"), a related party. The notes were due to mature on the earlier of June 30, 2021, the closing of a preferred equity financing, the closing of a merger, business combination or sale of stock resulting in Synchronicity's stockholders owning less than 50% of the surviving entity, or an event of default. During the year ended December 31, 2021, the Company recorded an other-than-temporary credit loss of $0.9 million against the value of this investment and at December 31, 2021, this investment was fully impaired. The losses were recorded within "Other income, net" in the accompanying consolidated profit and loss account.

In January 2022, the Company purchased $0.5 million of convertible promissory notes from Synchronicity that matured on the earlier of September 30, 2022, the closing of a preferred equity financing, the closing of a merger, business combination or sale of stock resulting in Synchronicity's stockholders owning less than 50% of the surviving entity, or an event of default. During the year ended December 31, 2022, the Company determined there was an other-than-temporary loss related to this investment in Synchronicity and the $0.5 million was recorded within "Other income, net" in the accompanying consolidated profit and loss account.

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

	Year Ended December 31,	
(In thousands)	2022	2021
Proceeds from the sales and maturities of investments	$ 281,627	$ 295,010
Realized gains	$ —	$ 34
Realized losses	$ 529	$ 977

The Company's available-for-sale and held-to-maturity securities at December 31, 2022 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	$ 318,592	$ 313,994	$ 1,820	$ 1,820
After 1 year through 5 years	136,539	131,788	—	—
Total	$ 455,131	$ 445,782	$ 1,820	$ 1,820

15. SHARE CAPITAL PRESENTED AS EQUITY

Share Capital

	December 31,	
(In thousands, except per share amounts)	2022	2021
Authorized:		
40,000 ordinary shares of €1 par value	$ 40,000	$ 40,000
50,000,000 preferred shares of $0.01 par value	500,000	500,000
450,000,000 ordinary shares of $0.01 par value	4,500,000	4,500,000
Share Capital	$ 5,040,000	$ 5,040,000

15. SHARE CAPITAL PRESENTED AS EQUITY (Continued)

The Company's board of directors is currently authorized to allot and issue all or any of the authorized but unissued preferred shares from time to time in one or more classes or series, and to fix for each such class or series such voting powers (full or limited or without voting powers), designations, preferences and relative, participating, optional or other special rights and qualifications, limitations or restrictions thereof as are stated and expressed, or in any resolution or resolutions providing for the issue of such class or series adopted by the Company's board of directors as hereinafter provided, including, without limitation, and subject to the Company's Articles of Incorporation ("Articles") and applicable law, the authority to provide that any such class or series may be:

- redeemable at the option of the Company, with the manner of the redemption to be set by the Company's board of directors, and redeemable at such time or times, including upon a fixed date, and at such price or prices;
- entitled to receive dividends (which may be cumulative or non-cumulative) at such rates, on such conditions at such times and in respect of such dividend periods (the "Dividend Periods"), and payable in preference to, or in such relation to, the dividends payable on any other class or classes of shares or any other series;
- entitled to such rights upon the dissolution of, or upon any distribution of the assets of, the Company; or
- convertible into, or exchangeable for, shares of any other class or classes of shares, or of any other series of the same or any other class or classes of shares, of the Company at such price or prices or at such rates of exchange and with such adjustments as the Company's board of directors determines, which rights and restrictions may be as stated in such resolution or resolutions of the Company's board of directors as determined by it in accordance with this Article 14. The Company's board of directors may at any time before the allotment of any preferred share by further resolution in any way amend the designations, preferences, rights, qualifications, limitations or restrictions, or vary or revoke the designations of such preferred shares.

The holders of ordinary shares shall be:

- entitled to dividends on a *pro rata* basis in accordance with the relevant provisions of these Articles;
- entitled to participate *pro rata* in the total assets of the Company in the event of the Company's winding up; and
- entitled, subject to the right of the Company, to set record dates for the purpose of determining the identity of holders of ordinary shares entitled to notice of and/or vote at a general meeting, to attend general meetings of the Company and shall be entitled to one vote for each ordinary share registered in their name in the Register of Members, both in accordance with the relevant provisions of these Articles.

Issued Ordinary Shares (par value, $0.01 per share) **(Value in thousands)**	**Number**	**Value**
Balance at January 1, 2021	162,269,220	$ 1,620
Issuance of ordinary shares under employee stock plans	3,521,329	38
Balance at December 31, 2021	165,790,549	$ 1,658
Issuance of ordinary shares under employee stock plans	3,160,644	32
Balance at December 31, 2022	168,951,193	$ 1,690

Share Repurchase Program

On September 16, 2011, the Company's 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, 2022, 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, 2022 and 2021, the Company did not acquire any ordinary shares under the repurchase program.

15. SHARE CAPITAL PRESENTED AS EQUITY (Continued)

Treasury Shares

Treasury Shares (par value, $0.01 per share) (Value in thousands)	Number	Value
Balance at January 1, 2021	3,108,079	$ 126,087
Acquired during the year	745,143	16,571
Balance at December 31, 2021	3,853,222	$ 142,658
Acquired during the year	720,962	18,204
Balance at December 31, 2022	4,574,184	$ 160,862

The shares acquired during the year were received by the Company for the purchase of employee stock options or to satisfy minimum tax withholding obligations related to employee share-based awards.

16. SHARE-BASED COMPENSATION

Share-Based Compensation Expense

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

(In thousands)	Year Ended December 31, 2022	2021
Cost of goods manufactured and sold	$ 10,284	$ 9,175
Research and development	27,941	24,877
Selling, general and administrative	56,029	53,570
Total share-based compensation expense	$ 94,254	$ 87,622

During the years ended December 31, 2022 and 2021, $3.3 million and $2.3 million of share-based compensation expense was capitalized and recorded as "Stock" 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 unit awards, 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.

On July 7, 2022, the Company's shareholders approved an amended version of the Alkermes plc 2018 Stock Option and Incentive Plan that served to, among other things, increase the number of ordinary shares authorized for issuance thereunder by 8.3 million. At December 31, 2022, there were 12.9 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.

16. SHARE-BASED COMPENSATION (Continued)

Stock Options

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

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 2022	16,747,819	$ 34.02
Granted	3,164,468	$ 25.39
Exercised	(1,108,772)	$ 17.70
Expired	(660,093)	$ 48.03
Forfeited	(546,461)	$ 22.75
Outstanding, December 31, 2022	17,596,961	$ 33.32
Exercisable, December 31, 2022	10,138,673	$ 40.52

The weighted average grant date fair value of stock options granted during the years ended December 31, 2022 and 2021 was $12.62 and $10.09, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2022 and 2021 was $11.6 million and $8.3 million, respectively.

At December 31, 2022, there were 7.2 million stock options expected to vest with a weighted average exercise price of $23.46 per share, a weighted average contractual remaining life of 8.2 years with an aggregate intrinsic value of $24.8 million. At December 31, 2022, the aggregate intrinsic value of stock options exercisable was $14.8 million with a weighted average remaining contractual term of 4.6 years. The number of stock options expected to vest was determined by applying the pre-vesting forfeiture rate to the total number of outstanding options. The intrinsic value of a stock option is the amount by which the market value of the underlying shares exceeds the exercise price of the stock option.

At December 31, 2022, there was $32.7 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of 1.9 years. Included within the outstanding stock option balances at December 31, 2022 consisted of 382,200 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 less than $0.1 million at December 31, 2022 and is included in the unrecognized compensation cost noted above.

Time-Based Restricted Stock Unit Awards

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

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, January 1, 2022	6,322,685	$ 23.38
Granted	3,031,864	$ 25.27
Vested	(2,051,872)	$ 26.45
Forfeited	(677,255)	$ 22.96
Unvested, December 31, 2022	6,625,422	$ 23.34

The weighted average grant date fair value of time-vesting RSUs granted during the years ended December 31, 2022, and 2021 were $25.27 and $20.83, respectively. The total fair value of time-vesting RSUs that vested during the years ended December 31, 2022 and 2021, was $54.3 million and $56.3 million, respectively.

At December 31, 2022, there was $62.4 million of total unrecognized compensation cost related to unvested time-vesting RSUs, which will be recognized over a weighted average remaining contractual term of 1.9 years.

16. SHARE-BASED COMPENSATION (Continued)

Performance-Based Restricted Stock Unit Awards

In February 2022, 2021 and 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 based on the achievement of certain financial, commercial and/or 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, 2022	877,862	$ 23.20
Granted	517,683	$ 30.73
Forfeited	(45,911)	$ 24.46
Vested	—	$ —
Unvested, December 31, 2022	1,349,634	$ 26.05

The weighted average grant date fair value of performance-based RSUs granted during the years ended December 31, 2022 and 2021 were $30.73 and $23.09, respectively. The total fair value of performance-based RSUs that vested during the years ended December 31, 2022 and 2021 were none and $4.2 million, respectively. At December 31, 2022, there was $5.1 million of unrecognized compensation cost related to 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 during the applicable three-year performance period.

17. PROVISIONS FOR LIABILITIES

Provisions for liabilities consists of the following:

(In thousands)	Medicaid Rebates	Product Returns	Medicare Part D	Other	Total
Balance, January 1, 2021	$ 181,959	$ 23,695	$ 12,969	$ 10,384	$ 229,007
Additions	331,866	10,366	59,776	37,516	439,524
Amounts utilized	(318,412)	(9,748)	(58,397)	(38,156)	(424,713)
Balance, December 31, 2021	$ 195,413	$ 24,313	$ 14,348	$ 9,744	$ 243,818
Additions	344,035	19,145	68,088	43,988	475,256
Amounts utilized	(331,117)	(13,792)	(64,027)	(44,526)	(453,462)
Balance, December 31, 2022	$ 208,331	$ 29,666	$ 18,409	$ 9,206	$ 265,612

The category "Other" in the table above includes certain other provisions for sales discounts and allowances that are not individually significant.

18. CREDITORS

(In thousands)	December 31, 2022	December 31, 2021
Amounts falling due within one year		
Accrued expenses	$ 195,388	$ 161,635
Trade creditors	32,843	55,721
Contract liabilities	6,816	6,339
Payroll taxes	3,556	3,831
Accrued interest on long-term debt	952	1,940
Value added tax	319	759
Corporate tax	38	40
Other taxes	638	738
	$ 240,550	$ 231,003
Amounts falling due after more than one year		
Deferred income taxes	$ 548	$ 548
Contract liabilities	3,885	11,491
Uncertain tax positions	3,322	—
Accrued vacation	5,874	6,808
Other long-term liabilities	1,613	2,025
Total	$ 255,792	$ 251,875

Trade and other creditors are payable at various dates in the next three months in accordance with the suppliers' usual and customary credit terms. Tax amounts are repayable at various dates over the coming months in accordance with the applicable statutory provisions.

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, 2021	$ 23,909
Additions	—
Amounts recognized into revenue	(6,079)
Contract liabilities at December 31, 2021	$ 17,830
Additions	6,769
Amounts recognized into revenue	(7,514)
Amounts recognized into other income, net	(6,384)
Contract liabilities at December 31, 2022	$ 10,701

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, 2022, there were no potential material losses from claims, asserted or unasserted, or legal proceedings that the Company determined were probable of occurring.

19. COMMITMENTS AND CONTINGENT LIABILITIES (Continued)

Janssen Arbitration Proceedings

In April 2022, Alkermes Pharma Ireland Limited commenced binding arbitration proceedings to settle, among other things, whether, notwithstanding Janssen Pharmaceutica N.V.'s partial termination of two license agreements with the Company, Janssen Pharmaceutica has a continuing obligation to pay royalties on sales in the U.S. of INVEGA SUSTENNA, INVEGA TRINZA, INVEGA HAFYERA and CABENUVA. The request for arbitration seeks, among other remedies, a declaration that Janssen Pharmaceutica N.V. is in breach of the license agreements and a resumption of royalty payments for sales of the relevant products in the U.S. On December 21, 2022, the Company received the Interim Award in these proceedings from the Tribunal. In the Interim Award, the Tribunal agreed with the Company's position that, while Janssen Pharmaceutica N.V. may terminate the agreements, it may not continue to sell Products (as defined in the agreements) developed during the term of the agreements without paying royalties pursuant to the terms of the respective agreements. The Company will engage with Janssen Pharmaceutica N.V. and the Tribunal in additional proceedings prior to the Tribunal's issuance of a final award. The arbitration is to be conducted pursuant to the Institute for Conflict Prevention and Resolution (CPR) Rules for Non-Administered Arbitration.

INVEGA SUSTENNA ANDA Litigation

Janssen Pharmaceutica N.V. 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") (such lawsuit, the "Teva Lawsuit"), in August 2019 against Mylan Laboratories Limited ("Mylan Labs") and other Mylan entities (the "Mylan Lawsuit") and in December 2019 against Pharmascience, Inc. ("Pharmascience"), Mallinckrodt plc, and SpecGX LLC (the "Pharmascience Lawsuit"), and in the U.S. District Court for the District of Delaware in December 2021 against Tolmar Holding, Inc., Tolmar Pharmaceuticals, Inc., Tolmar Therapeutics, Inc., and Tolmar, Inc. ("Tolmar" and such lawsuit, the "Tolmar Lawsuit"), following the respective filings by each of Teva, Mylan Labs, Pharmascience and Tolmar 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 2021, the NJ District Court entered a judgment in favor of the Janssen entities in the Teva Lawsuit. In December 2021, the NJ District Court entered a judgment in favor of the Janssen entities in the Mylan Lawsuit, based on the parties' prior stipulation to be bound by the judgment in the Teva Lawsuit. The Teva entities and Mylan Labs each filed notices of appeal of their respective judgments with the U.S. Court of Appeals for the Federal Circuit, which were consolidated in January 2022 (the "Teva Appeal"). A trial has been scheduled in the Tolmar Lawsuit for October 2023. The Pharmascience Lawsuit was administratively terminated in July 2022, pending the outcome of the Teva Appeal. The Company is not a party to any of these proceedings.

INVEGA TRINZA ANDA Litigation

In September 2020, Janssen Pharmaceutica N.V., 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. A bench trial concluded on December 9, 2022. The Company is not a party to this proceeding.

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. A bench trial, adjourned from its prior scheduled start date due to COVID-19, was held in February 2023, and we anticipate a decision in the second half of 2023. The Company intends to vigorously defend its IP.

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.

19. COMMITMENTS AND CONTINGENT LIABILITIES (Continued)

Product Liability and Other Legal Proceedings

The Company is involved in litigation 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. In addition, on January 10, 2023, Acorda filed a petition with the U.S. District Court for the Southern District of New York asking the court to confirm in part and modify in part the final arbitral award rendered by an arbitration panel in October 2022 and, as part of the requested modification, seeking an additional approximately $66.0 million in damages. The Company intends to contest this petition and believes it is without merit. 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 proceedings would have a material adverse effect on the Company's business or financial condition.

20. CAPITAL EXPENDITURE COMMITMENTS

The Company's board of directors authorized the Company to spend $35.0 million to $40.0 million for capital expenditures in the year ended December 31, 2022.

21. RELATED PARTY DISCLOSURES

The principal related party relationships requiring disclosure in the consolidated financial statements pertain to the existence of subsidiaries and associates and transactions with these entities entered into by the Company and the identification of key management personnel as addressed in greater detail below.

Subsidiaries and Associates

The consolidated financial statements include the results of operations, financial positions and cash flows of the Company and its subsidiaries and associates over which the Company has control. A listing of principal subsidiaries and associates is provided in Note 26, *Subsidiaries*, to the consolidated financial statements.

Trading Transactions

There were no transactions requiring disclosure under Sch. 3, Section 67(1) of the Companies Act.

22. LOANS TO DIRECTORS

Irish company law prohibits the Company from making a loan or a quasi-loan to a director of the Company unless certain conditions are met. No loans or quasi-loans have been made to any director of the Company during the financial year.

23. EMPLOYEES

The average number of persons employed by the Company during the years ended December 31, 2022 and 2021, respectively, was as follows:

	December 31, 2022	December 31, 2021
Manufacturing	790	768
Research and development	434	454
Selling, general and administrative	985	996
Total	2,209	2,218

23. EMPLOYEES (Continued)

Employee costs included in profit and loss during the years ended December 31, 2022 and 2021 consisted of the following:

(In thousands)	December 31, 2022	December 31, 2021
Wages and salaries	$ 401,975	$ 389,046
Share-based compensation	94,254	87,622
Social insurance costs[1]	65,117	63,545
Defined contribution plan contributions	21,417	21,172
Total	$ 582,763	$ 561,385

(1) Social insurance costs include social security costs, employer paid payroll taxes and other employee benefits paid by the Company.

During the years ended December 31, 2022 and 2021, the Company capitalized $2.8 million and $0.3 million, respectively, as part of its tangible fixed assets and $81.7 million and $78.2 million, respectively, as part of its stock.

24. DIRECTORS' REMUNERATION

Directors' remuneration is set forth in the table below. Mr. Pops, the Company's Chairman and Chief Executive Officer ("CEO"), is not compensated for his services as a director. Accordingly, the amounts below include compensation for Mr. Pops' service as CEO (referred to as "Managerial Services") as well as compensation for all non-employee directors in their capacities as such (referred to as "Director Services").

(In thousands)	December 31, 2022	December 31, 2021
Managerial Services:		
Emoluments	$ 2,289	$ 2,267
Benefits under long term incentive schemes	1,298	3,667
Company contribution to 401(k) plan	15	15
Total	$ 3,602	$ 5,949
Director Services:		
Fees paid in cash	$ 1,022	$ 999
Total	$ 1,022	$ 999

The aggregate intrinsic value resulting from the exercise of stock options by the directors, including the Company's Chairman and CEO, during the year ended December 31, 2022 was $5.1 million (December 31, 2021: $1.5 million). The Company considers its directors to be key management personnel.

Retirement benefits are accruing to 1 director (2021: 1 director) under the 401(k) contribution plan in connection with Managerial Services, as noted above.

25. AUDITORS' REMUNERATION

Total auditors' remuneration, including expenses, accrued and paid to PricewaterhouseCoopers and its affiliated firms for the years ended December 31, 2022 and 2021, respectively, were as follows:

(In thousands)	December 31, 2022	December 31, 2021
Audit and review of group financial statements[1]	$ 2,587	$ 2,443
Audit-related fees[2]	109	41
Tax fees[3]	1,140	398
All other fees[4]	27	35
Total	$ 3,863	$ 2,917

(1) Consists of fees for services related to the audit of the Company's annual consolidated financial statements, statutory audits and the review of the Company's quarterly consolidated financial statements, including the review of the Company's internal controls over financial reporting, and other engagements related to the fiscal year. Included in these amounts for the years ended December 31, 2022 and 2021 are expenses of $22 thousand and $1 thousand, respectively.

25. AUDITORS' REMUNERATION (Continued)

(2) Consists of audit-related fees associated with the potential separation of the Company's neuroscience business and oncology business and assurance services related to employee benefit plan audits.

(3) Consists of fees for tax compliance and tax advisory services, other than those related to the audit of the Company's annual consolidated financial statements, review of the Company's quarterly consolidated financial statements and tax advisory services and general tax consulting fees related to the potential separation of the Company's neuroscience business and oncology business. No expenses are included in these amounts for the years ended December 31, 2022 or 2021.

(4) Consists of fees for access to the PricewaterhouseCoopers on-line accounting research database.

Total fees paid to PricewaterhouseCoopers Ireland in respect of the audit of the Company financial statements were $0.5 million and $0.6 million during each of the years ended December 31, 2022 and 2021. In addition, PricewaterhouseCoopers Ireland received less than $0.1 million and $0.1 million for tax advisory services during both the years ended December 31, 2022 and 2021.

26. SUBSIDIARIES

The subsidiaries of Alkermes plc are wholly-owned by Alkermes plc or one of its subsidiaries.

Name	Nature of Business	Registered Office and Country of Incorporation	Percent of Ownership
Alkermes Ireland Holdings Limited	Holding Company	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Alkermes Pharma Ireland Limited	Manufacturing and R&D	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Daravita Pharma Ireland Limited	Holding Company	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Alkermes Finance Ireland (No 3) Limited	Finance Company	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Alkermes Science Four Limited	Non-Operating	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Alkermes Science Five Limited	Non-Operating	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Alkermes US Holdings, Inc.	Holding Company	852 Winter Street, Waltham, MA 02451 United States	100%
Alkermes, Inc.	Manufacturing and R&D	852 Winter Street, Waltham, MA 02451 United States	100%
Alkermes Controlled Therapeutics, Inc.	Non-Operating	852 Winter Street, Waltham, MA 02451 United States	100%
Alkermes Europe Limited	Non-Operating	Cannon Place, 78 Cannon Street London, England ED4N 6AF, United Kingdom	100%
Rodin Therapeutics, Inc.	R&D	852 Winter Street, Waltham, MA 02451 United States	100%

During the year ended December 31, 2022, Daravita Limited, a former subsidiary of Alkermes Ireland Holdings Limited was dissolved via merger by acquisition with and into Alkermes Pharma Ireland Limited ("APIL"), and Alkermes Finance Ireland Limited and Alkermes Finance Ireland (No 2) Limited, each a former subsidiary of APIL, were dissolved via merger by absorption with and into APIL.

In February 2023, Alkermes Europe Limited, a subsidiary of Alkermes, Inc. was dissolved through a Members' Voluntary Liquidation.

27. RECONCILIATION TO ANNUAL REPORT

Following the issuance of the Company's 2021 Annual Report on Form 10-K, as filed on February 16, 2022 with the U.S. SEC, but before the approval of the 2021 Directors' Report and Consolidated Financial Statements, the Company determined there was a significant decrease in the fair value of its contingent consideration, which was considered a subsequent event. Accordingly, the Company adjusted its consolidated profit and loss account and consolidated balance sheet for the year ended December 31, 2021 and as of December 31, 2021, respectively, as presented in the 2021 Directors' Report and Consolidated Financial Statements. For purposes of this 2022 Directors' Report and Consolidated Financial Statements, the Company adjusted its consolidated profit and loss account for the year ended December 31, 2022 as reported in the Form 10-K to remove the effect of such prior year subsequent event adjustment.

ADJUSTED CONSOLIDATED PROFIT AND LOSS ACCOUNT

	Year Ended December 31, 2022			Year Ended December 31, 2021		
(In thousands, except per share amounts)	As Reported on Form 10-K	Current Year Adjustment to Reflect Prior Year Subsequent Event Adjustment	As reported in Alkermes Plc Directors' Report and Consolidated Financial Statements	As Reported on Form 10-K	Subsequent Event Adjustment	As reported in Alkermes Plc Directors' Report and Consolidated Financial Statements
Total turnover	$1,111,795	$ —	$1,111,795	$1,173,751	$ —	$1,173,751
Operating loss	(142,265)	—	(142,265)	(29,287)	—	(29,287)
Interest income	7,629	—	7,629	2,408	—	2,408
Interest expense	(13,040)	—	(13,040)	(11,219)	—	(11,219)
Change in the fair value of contingent consideration	(21,750)	19,108	(2,642)	(1,427)	(19,108)	(20,535)
Other income, net	2,122	—	2,122	219	—	219
Loss before income taxes	(167,304)	19,108	(148,196)	(39,306)	(19,108)	(58,414)
Income tax benefit (provision)	9,037	—	9,037	(8,863)	—	(8,863)
Loss after income taxes	$ (158,267)	$ 19,108	$ (139,159)	$ (48,169)	$ (19,108)	$ (67,277)
LOSS PER ORDINARY SHARE:						
Basic and diluted	$ (0.97)	$ 0.12	$ (0.85)	$ (0.30)	$ (0.12)	$ (0.42)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:						
Basic and diluted	163,742	163,742	163,742	160,942	160,942	160,942

ADJUSTED CONSOLIDATED BALANCE SHEET

	December 31, 2022			December 31, 2021		
(In thousands)	As Reported on Form 10-K	Prior Year Subsequent Event Adjustment	As reported in Alkermes Plc Directors' Report and Consolidated Financial Statements	As Reported on Form 10-K	Subsequent Event Adjustment	As reported in Alkermes Plc Directors' Report and Consolidated Financial Statements
Debtors	$ 462,844	$ —	$ 462,844	$ 478,679	$ (19,108)	$ 459,571
Total assets	$1,963,978	$ —	$1,963,978	$2,024,484	$ (19,108)	$2,005,376
Profit and loss account	(341,948)	—	(341,948)	(183,681)	(19,108)	(202,789)
Total equity	1,043,753	—	1,043,753	1,112,584	(19,108)	1,093,476
Total liabilities	920,225	—	920,225	911,900	—	911,900
Total liabilities and equity	$1,963,978	$ —	$1,963,978	$2,024,484	$ (19,108)	$2,005,376

ALKERMES PLC

PARENT COMPANY BALANCE SHEET

(In thousands)	Note	December 31, 2022	December 31, 2021
ASSETS			
Fixed Assets			
Financial assets	7	$ 2,180,334	$ 2,149,287
Associated undertakings	8	5,168	5,235
Total fixed assets		2,185,502	2,154,522
Current Assets			
Debtors	9	975,210	895,333
Cash at bank and in-hand		34,649	43,367
TOTAL ASSETS		$ 3,195,361	$ 3,093,222
EQUITY SHAREHOLDERS' FUNDS AND LIABILITIES			
Creditors			
Creditors—amounts falling due within one year	10	$ 26,744	$ 13,276
Total for creditors		26,744	13,276
Equity Shareholders' Funds			
Share capital, $0.01 par value	11	1,690	1,658
Share premium	12	638,965	619,346
Profit and loss account	12	1,791,079	1,799,031
Treasury shares	12	(160,862)	(142,658)
Other reserves	12	897,745	802,569
Total equity shareholders' funds		$ 3,168,617	$ 3,079,946
TOTAL EQUITY SHAREHOLDERS' FUNDS AND LIABILITIES		$ 3,195,361	$ 3,093,222

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

The Parent Company financial statements were approved by the Parent Company's board of directors on April 6, 2023 and signed on its behalf on by:

/s/ RICHARD F. POPS
Richard F. Pops
Chairman

/s/ FRANK A. WILSON
Frank A. Wilson
Director

ALKERMES PLC

PARENT COMPANY RECONCILIATION OF MOVEMENT IN SHAREHOLDERS' FUNDS

(In thousands)	Share Capital	Share Premium	Profit and Loss Account	Treasury Shares	Other Reserves	Total
BALANCE—January 1, 2021	$ 1,620	$ 594,045	$ 1,803,290	$ (126,087)	$ 715,172	$ 2,988,040
Net loss	—	—	(4,259)	—	—	(4,259)
Share-based payment reserve	—	—	—	—	87,397	87,397
Shares issued under employee stock plans	38	25,301	—	—	—	25,339
Receipt of Alkermes' shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards		—	—	(16,571)	—	(16,571)
BALANCE—December 31, 2021	$ 1,658	$ 619,346	$ 1,799,031	$ (142,658)	$ 802,569	$ 3,079,946
Net loss	—	—	(7,952)	—	—	(7,952)
Share-based payment reserve	—	—	—	—	95,176	95,176
Shares issued under employee stock plans	32	19,619	—	—	—	19,651
Receipt of Alkermes' shares to satisfy minimum tax withholding obligations related to share based awards	—	—	—	(18,204)	—	(18,204)
BALANCE—December 31, 2022	$ 1,690	$ 638,965	$ 1,791,079	$ (160,862)	$ 897,745	$ 3,168,617

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

1. General Information

Alkermes plc (the "Parent Company") is a public limited company incorporated in Ireland. The address of its registered office is Connaught House, 1 Burlington Road, Dublin 4, Ireland, D04 C5Y6. The registered number of the Parent Company is: 498284.

On May 9, 2011, Alkermes plc, Alkermes, Inc., Elan and certain of their respective subsidiaries entered into the Business Combination Agreement and Plan of Merger (the "Business Combination Agreement") pursuant to which Alkermes, Inc., and EDT agreed to combine their businesses under the Parent Company in a cash and share transaction (the "Business Combination"). EDT, which operated as a business unit of Elan with its principal assets predominantly located in Ireland, developed and manufactured pharmaceutical products using its proprietary drug technologies in collaboration with pharmaceutical companies worldwide. On May 4, 2011, the Parent Company was incorporated by Elan as Antler Science Two plc in connection with the negotiation and execution of the Business Combination Agreement solely to effect the Business Combination. Following the execution of the Business Combination Agreement, Elan contributed the assets and legal entities that comprised the EDT business to the Parent Company through a combination of asset transfers, share transfers and other intercompany transactions, following which the EDT business was contained in several subsidiaries under the Parent Company. On September 14, 2011, the Parent Company changed its name to Alkermes plc.

On September 16, 2011, the business of Alkermes, Inc., and EDT were combined under the Parent Company. As part of the Business Combination, a wholly owned subsidiary of the Parent Company merge with and into Alkermes, Inc., with Alkermes, Inc., surviving as a wholly-owned subsidiary of the Parent Company.

2. Statement of Compliance

The entity financial statements have been prepared on a going concern basis and in accordance with Irish GAAP (accounting standards issued by the Financial Reporting Council of the UK and the Companies Act). The entity financial statements comply with Financial Reporting Standard 102, 'The Financial Reporting Standard applicable in the UK and Republic of Ireland' ("FRS 102") and the Companies Act.

3. Summary of Significant Accounting Policies

Basis of Preparation

The financial statements of the Parent Company present the balance sheet and the reconciliation of movement in shareholders' funds on a stand-alone basis, including related party transactions.

The financial statements have been prepared under the historical cost convention.

The preparation of financial statements in conformity with FRS 102 requires the use of certain key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the financial year. It also requires the Parent Company's board of directors to exercise its judgment in the process of applying the Parent Company's accounting policies. The areas involving a higher degree of judgment or areas where assumptions and estimates have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are disclosed in Note 5, *Critical Accounting Judgments and Estimation Uncertainty*.

Going Concern

As the Parent Company's operational existence relies on the activities of the Parent Company and its subsidiaries as a group (collectively, the "Company"), a going concern assessment performed at the Company level was deemed relevant to support the Parent Company's ability to continue as a going concern. The Parent Company meets its day-to-day working capital requirements through its bank facilities. The Parent Company's forecasts and projections, taking account of reasonably possible changes in trading performance, show that the Parent Company should be able to operate within the level of its current facilities. After making enquiries, the directors have a reasonable expectation that the Parent Company has adequate resources to continue in operational existence for the foreseeable future. Therefore, these entity financial statements have been prepared on a going concern basis.

The Parent Company's board of directors formed a judgment at the time of approving these financial statements that there was a reasonable expectation that the Parent Company has adequate resources to continue in operational existence for the next twelve months. In arriving at this conclusion, the Parent Company's board of directors took account of current and anticipated uncertainties driven by the COVID-19 pandemic (as described in greater detail under the heading "*Risks and*

3. Summary of Significant Accounting Policies (Continued)

Uncertainties" within Note 2, *Summary of Significant Accounting Policies*, within the "Notes to Consolidated Financial Statements" in this Directors' Report) in its going concern assessment and believed that these uncertainties would not have a material impact on the Parent Company's ability to continue as a going concern.

For this reason, the going concern basis continues to be adopted in the preparation of the Parent Company's financial statements.

Disclosure Exemptions for Qualifying Entities Under FRS 102

FRS 102 allows a qualifying entity certain disclosure exemptions. As a qualifying entity the Parent Company has availed of a number of exemptions from the disclosure requirements of FRS 102 in the preparation of the entity financial statements.

In accordance with FRS 102, the Parent Company has availed of an exemption from the following paragraphs of FRS 102:

- Exemption from the requirements of Section 7 of FRS 102 and FRS 102 paragraph 3.17(d) to present a statement of cash flows;
- Exemption from the financial instrument disclosure requirements of Section 11 paragraphs 11.39 to 11.48A and Section 12 paragraphs 12.26 to 12.29A of FRS 102 providing the equivalent disclosures are included in the consolidated financial statements of the Company in which the entity is consolidated;
- Exemption from certain disclosure requirements of Section 26 of FRS 102 (paragraphs 26.18(b), 26.19 to 26.21 and 26.23), in respect of share-based payments; and
- Exemption from the requirement of FRS 102 paragraph 33.7 to disclose key management personnel compensation in total.

Foreign Currency

Functional and presentation currency

The Parent Company's functional and presentation currency is USD, denominated by the symbol "$" and unless otherwise stated, the financial statements have been presented in thousands.

Transactions and balances

Transactions during the period denominated in foreign currencies have been translated at the rates of exchange ruling at the dates of the transactions. Assets and liabilities denominated in foreign currencies are translated to USD at the rates of exchange at the balance sheet date. The resulting profits or losses are dealt with in the profit and loss account.

Financial Assets

Investments in group undertakings in the financial statements of the Parent Company are carried at historical cost less accumulated impairment losses. See Note 7, *Financial Assets*, below for further information.

Associated Undertakings

The Parent Company accounts for its associated undertakings at cost, less impairment. Refer to Note 8, *Associated Undertakings*, for further discussion.

Dividend Income from Shares in Group Undertakings

Dividend income from group undertakings is recognized in the period in which it is received.

Share Premium

The difference between the proceeds received on issue of shares and the nominal value of the shares is credited to the share premium account.

3. Summary of Significant Accounting Policies (Continued)

Taxation

Corporation tax is provided on taxable profits at current rates. Deferred taxation is accounted for in respect of all timing differences at tax rates enacted or substantially enacted at the balance sheet date. Timing differences arise from the inclusion of items of income and expenditure in tax computation in periods different from those in which they are included in the financial statements. A deferred tax asset is only recognized when it is more likely than not the asset will be recoverable in the foreseeable future out of suitable taxable profits from which the underlying timing differences can be recovered.

Share Capital Presented as Equity

Equity shares issued are recognized at the proceeds received. Incremental costs directly attributable to the issue of new equity shares or options are shown in equity as a deduction, net of tax, from the proceeds.

Treasury Shares

These represent shares of Alkermes plc acquired from employees for the purchase of employee stock options or to satisfy minimum tax withholding obligations related to employee share based awards. Treasury shares are treated as a deduction from the profit and loss reserves until the shares are cancelled, reissued or disposed of. When such shares are subsequently sold or reissued, any consideration received, increases shareholders' funds.

At December 31, 2022, the Parent Company has approximately $101.0 million available to repurchase ordinary shares pursuant to a share 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. The Parent Company has not repurchased any ordinary shares under this program since September 16, 2011.

Share-Based Payments

The Parent Company and its subsidiaries operate equity-settled share-based compensation plans. The fair value of the employee services received in exchange for the grant of the options has been valued using the Black-Scholes option pricing model. In accordance with Section 26 of FRS 102 'Share-based Payments', the resulting cost for the Parent Company's employees is charged to the profit and loss account over the vesting period. The value of the charge is adjusted to reflect expected and actual levels of awards vesting. The cost for awards granted to the Parent Company's subsidiaries' employees represents additional capital contributions by the Parent Company to its subsidiaries. An additional investment in subsidiaries has been recorded in respect of those awards granted to the Parent Company's subsidiaries' employees, with a corresponding increase in the Parent Company's shareholder equity. The additional capital contribution is based on the fair value at the grant date of the awards issued, allocated over the life of the underlying grant's vesting period. Proceeds received from employees, if any, for the exercise of share-based instruments increase the share capital and share premium accounts of the Parent Company. The Parent Company has an arrangement in place with its subsidiaries whereby the subsidiary will remit an amount to the Parent Company equal to the difference between the market value of the equity and the amount paid by the employee. Amounts remitted by the subsidiaries to the Parent Company are reflected as a decrease in the Parent Company's "Investment in Subsidiaries". To the extent cash received from the vesting of restricted stock units and stock option exercises exceeds the fair value of restricted stock units and stock options on the date of grant, this amount is recorded in the Parent Company's statement of operations.

Note 16, *Share-Based Compensation*, of the 2022 Alkermes plc consolidated financial statements provides additional details of the Company's share-based compensation plans.

Contingencies

Contingent liabilities, arising as a result of past events, are not recognized as a liability because (i) it is not probable that the Parent Company will be required to transfer economic benefits in settlement of the obligation or the amount cannot be reliably measured at the end of the financial year. Possible but uncertain obligations are not recognized as liabilities but are contingent liabilities. Contingent liabilities are disclosed in the financial statements unless the probability of an outflow of resources is remote.

Contingent assets are not recognized. Contingent assets are disclosed in the financial statements when an inflow of economic benefits is probable.

3. Summary of Significant Accounting Policies (Continued)

Financial Instruments

The Parent Company has chosen to adopt Sections 11 and 12 of FRS 102 in respect of financial instruments.

Financial assets

Basic financial assets, including trade and other receivables and cash and bank balances, are initially recognized at transaction price, unless the arrangement constitutes a financing transaction, where the transaction is measured at the present value of the future receipts discounted at a market rate of interest. Such assets are subsequently carried at amortized cost using the effective interest method. At the end of each reporting period financial assets measured at amortized cost are assessed for objective evidence of impairment. If an asset is impaired the impairment loss is the difference between the carrying amount and the present value of the estimated cash flows discounted at the asset's original effective interest rate. The impairment loss is recognized in profit or loss. If there is decrease in the impairment loss arising from an event occurring after the impairment was recognized the impairment is reversed. The reversal is such that the current carrying amount does not exceed what the carrying amount would have been had the impairment not previously been recognized. The impairment reversal is recognized in profit or loss.

Financial assets are derecognized when (a) the contractual rights to the cash flows from the asset expire or are settled, (b) substantially all the risks and rewards of the ownership of the asset are transferred to another party or (c) control of the asset has been transferred to another party who has the practical ability to unilaterally sell the asset to an unrelated third party without imposing additional restrictions.

Financial liabilities

Basic financial liabilities, including trade and other payables and loans from fellow group companies, are initially recognized at transaction price, unless the arrangement constitutes a financing transaction, where the debt instrument is measured at the present value of the future receipts discounted at a market rate of interest.

Trade creditors are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Trade creditors are classified as current liabilities if payment is due within one year or less. If not, they are presented within creditors amounts falling due after more than one year.

Financial liabilities are derecognized when the liability is extinguished, that is when the contractual obligation is discharged, cancelled or expires.

Cash and Cash Equivalents

Cash and cash equivalents includes cash in hand, deposits held at call with banks, other short term highly liquid investments with original maturities of three months or less. Bank overdrafts are shown within borrowings in current liabilities. Cash and cash equivalents are initially measured at transaction price and subsequently measured at amortized cost. Bank deposits which have original maturities of more than three months are not cash and cash equivalents and are presented as current asset investments.

4. Loss for the Financial Year

In accordance with section 304 (2) of the Companies Act and Section 341 of the Companies Act, the Parent Company is availing of the exemption from presenting its individual profit and loss account to the Company's 2023 annual general meeting of shareholders and from filing it with the Registrar of Companies. The Parent Company's net loss for the financial years ended December 31, 2022 and 2021, determined in accordance with Irish GAAP, was $8.0 million and $5.6 million, respectively.

5. Critical Accounting Judgments and Estimation Uncertainty

The preparation of the Parent Company's financial statements requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, turnover and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Parent Company evaluates its estimates and judgments and methodologies, including those related to the carrying value of investments in subsidiaries and measurement of share-based compensation. The Parent 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. The key judgement identified by the Parent Company's board of directors relates to the impairment of the Parent Company's investments in its subsidiaries. Consequently, the Parent Company assesses at each reporting date whether there is any indication that an investment in a subsidiary has been impaired. If such indication exists, the Parent Company is required to undertake a review for impairment and estimate the recoverable amount of the asset.

6. Employees and Directors

The Parent Company had no employees during the year. The Parent Company's directors are not employees but are remunerated for their service by the Parent Company. See Note 24, *Directors' Remuneration* of the notes to the consolidated financial statements for a summary of their remuneration.

7. Financial Assets

Financial assets relate to investments in subsidiaries.

	(In thousands)
Balance—January 1, 2021, at cost	$ 2,118,764
Capital contribution in respect of share-based payment plans	80,939
Reduction—equity recharge from subsidiaries	(50,416)
Balance—December 31, 2021, at cost	$ 2,149,287
Capital contribution in respect of share-based payment plans	90,842
Reduction—equity recharge from subsidiaries	(59,795)
Balance—December 31, 2022, at cost	$ 2,180,334

The Parent Company's only direct subsidiary is Alkermes Ireland Holdings Limited ("AIHL") of which it owns 100%. AIHL is a holding company incorporated in the Republic of Ireland with a registered office located at Connaught House, 1 Burlington Road, Dublin 4, Ireland D04 C5Y6. See Note 26, *Subsidiaries*, in the consolidated financial statements for the list of direct subsidiaries.

8. Associated Undertakings

In May 2014, the Parent 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, 2022, the Parent Company's total contribution in Fountain was equal to €7.4 million, and its commitment represents approximately 7% of the partnership's total funding. The Parent Company is accounting for its investment in Fountain under the cost method. At December 31, 2022 and 2021, the Parent Company's investment is equal to $5.2 million and $5.2 million, respectively, which is included within "Associated undertakings" in the accompanying balance sheets.

	(In thousands)
Balance—January 1, 2021, at cost	$ 4,859
Contribution to associated undertakings	784
Foreign exchange	(408)
Balance—December 31, 2021, at cost	$ 5,235
Contributions to associated undertakings	695
Distributions from associated undertakings	(485)
Foreign exchange	(277)
Balance—December 31, 2022, at cost	$ 5,168

9. Debtors

(In thousands)	December 31, 2022	December 31, 2021
Amounts falling due within one year		
Prepaid expenses and other current assets	$ 2,941	$ 4,303
Intercompany notes and loans receivable	182,269	891,030
	$ 185,210	$ 895,333
Amounts falling due after one year		
Intercompany loans receivable	790,000	—
Total	$ 975,210	$ 895,333

The Parent Company's intercompany notes and loans receivable due within one year consisted of the following:

Borrower	Maturity	Interest Rate	December 31, 2022	December 31, 2021
			(in thousands)	
Daravita Pharma Ireland Limited	Repayable upon demand	None	$ 3,600	$ 3,600
Alkermes Finance Ireland No.3 Limited	Repayable upon demand	Variable	178,669	137,430
Alkermes Pharma Ireland Limited	July 8, 2022	7.00%	—	300,000
Alkermes Pharma Ireland Limited	September 27, 2022	7.00%	—	450,000
Total			$ 182,269	$ 891,030

The Parent Company's intercompany loans receivable with a maturity greater than one year consisted of the following loans:

Borrower	Maturity	Interest Rate	December 31, 2022	December 31, 2021
			(in thousands)	
Alkermes Pharma Ireland Limited	July 8, 2027	7.00%	$ 300,000	$ —
Alkermes Pharma Ireland Limited	September 12, 2027	7.00%	450,000	—
Alkermes Pharma Ireland Limited	September 12, 2027	7.00%	40,000	—
Total			$ 790,000	$ —

10. Creditors

(In thousands)	December 31, 2022	December 31, 2021
Amounts falling due within one year		
Accrued expenses	$ 720	$ 1,079
Trade creditors	108	45
Intercompany payables	25,916	12,152
Total	$ 26,744	$ 13,276

Trade and other creditors are payable at various dates in the next three months in accordance with the suppliers' usual and customary credit terms. Intercompany payables are amounts due to subsidiaries related to transactions in the normal course of business, are interest free and are expected to be repaid in the next three months.

11. Share Capital

(In thousands, except per share amounts)	December 31, 2022	December 31, 2021
Authorized:		
40,000 ordinary shares of €1 par value	$ 40,000	$ 40,000
50,000,000 preferred shares of $0.01 par value	500,000	500,000
450,000,000 ordinary shares of $0.01 par value	4,500,000	4,500,000
Share Capital	$ 5,040,000	$ 5,040,000

Issued Ordinary Shares (par value, $0.01 per share) (Value in thousands)	Number	Value
Balance at January 1, 2021	162,269,220	$ 1,620
Issuance of ordinary shares under employee stock plans	3,521,329	38
Balance at December 31, 2021	165,790,549	1,658
Issuance of ordinary shares under employee stock plans	3,160,644	32
Balance at December 31, 2022	168,951,193	$ 1,690

See Note 15, *Share Capital Presented as Equity*, to the Consolidated Financial Statements for additional information regarding equity shareholder's funds.

12. Reserves

The Parent Company's reserves consisted of the following:

- Share premium—includes amounts received by the Parent Company for the excess of the fair value over par value for the issuance of its common stock; the excess of the fair value over the cost of employee share options; and the par value of shares received from employees for the purchase of share options.
- Profit and loss account—includes the Parent Company's accumulated net income or loss.
- Treasury shares—includes shares of Alkermes plc acquired from employees for the purchase of employee stock options or to satisfy minimum tax withholding obligations related to employee share based awards. Treasury shares are treated as a deduction from the profit and loss reserves until the shares are cancelled, reissued or disposed of. When such shares are subsequently sold or reissued, any consideration received, increases shareholders' funds.
- Other reserves—includes a share-based payment reserve, which represents the share-based compensation expense for the cost of the awards granted to the Parent Company's subsidiaries' employees less amounts remitted to the Parent Company, equal to the fair value of the Parent Company's ordinary shares on the date options are exercised or RSU's vest, less the proceeds received.

13. Related Party Transactions

The Parent Company has not disclosed any other related party transactions as it has availed of the exemption available under the provisions of FRS 102 Section 33.1A "Related Party Disclosures" which exempts disclosure of transactions entered into between two or more members of a group, provided that any subsidiary which is a party to the transaction is wholly owned by a member of that group.

14. Contingencies

From time to time, the Parent Company may be subject to legal proceedings and claims in the ordinary course of business. On a quarterly basis, the Parent 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 Parent Company would accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on the Parent Company's best estimates based on available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, the Parent Company may reassess the potential liability related to these matters and may revise these estimates, which could result in material adverse adjustments to the Parent Company's operating results. At December 31, 2022, there were no potential losses from claims, asserted or unasserted, or legal proceedings the Parent Company felt were probable of occurring (at December 31, 2021: none).

15. Auditors' Remuneration

Remuneration, including expenses, for the statutory audit and other services carried out for the Parent Company by the Parent Company's auditors was as follows:

	Year Ended	
(In thousands)	December 31, 2022	December 31, 2021
Audit of the Parent Company's individual financial statements	$ 25	$ 25
Other assurance services	—	—
Tax advisory services	—	—
Other non-audit services	—	—
Total	$ 25	$ 25

See Note 25, *Auditors' Remuneration,* to the Consolidated Financial Statements for additional information regarding fees paid to PricewaterhouseCoopers and its affiliated firms by the Parent Company.

16. Approval of the Financial Statements

The financial statements were approved and authorized for issue by the Parent Company's board of directors on April 6, 2023 and were signed on its behalf on that day.