

**ALKERMES PUBLIC LIMITED COMPANY**  
**DIRECTORS' REPORT AND CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Financial Year Ended December 31, 2023**  
**Registered Company Number: 498284**

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## DIRECTORS' REPORT

### For the Financial Year Ended December 31, 2023

The directors present their report (this “Directors’ Report”) and the accompanying audited consolidated financial statements and related notes of Alkermes Public Limited Company (“Alkermes plc”) for the year ended December 31, 2023. 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 accompanying 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®, ABILIFY ASIMTUFI® 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; BRIXADI®—Braeburn Inc.; BRIUMVI®—TG Therapeutics, Inc.; BUNAVAIL™—BioDelivery Sciences; CAMPRAL®—Merck Sante; CAPLYTA®—Intra-Cellular Therapies, Inc.; COPAXONE® and UZEDY®—Teva Pharmaceutical Industries Ltd.; EXTAVIA®, GILENYA®, and MAYZENT®—Novartis AG; BYANLI®, CABENUVA®, 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, income taxes and potential profitability;

- 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 acquisitions, collaborations, licensing arrangements and other significant agreements with third parties, including those related to our products and our development programs;
- our expectations regarding the impacts of new legislation, rules and regulations, the adoption of new accounting pronouncements, potential government shutdowns, or other global, political or economic instability or disruptions;
- our expectations regarding near-term changes in the nature of our market risk exposures or in our 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, and related rights or obligations;
- our expectations regarding the tax treatment and other anticipated benefits of the separation of our oncology business; 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 global biopharmaceutical company that seeks to develop innovative medicines in the field of neuroscience. We have a portfolio of proprietary commercial products for the treatment of alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder and a pipeline of clinical and preclinical candidates in development for neurological disorders. Headquartered in Dublin, Ireland, Alkermes has a research and development ("R&D") center in

Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio.

## 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
<i>ARISTADA INITIO</i>	Initiation or re-initiation of ARISTADA for the treatment of Schizophrenia	U.S.
<i>ARISTADA</i>	Schizophrenia	U.S.
<i>LYBALVI</i>	Schizophrenia; Bipolar I disorder	U.S.
<i>VIVITROL</i>	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
<i>RISPERDAL CONSTA</i>	Schizophrenia; Bipolar I disorder	Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG (“Janssen International”)	Worldwide
<i>INVEGA SUSTENNA / XEPLION</i>	INVEGA SUSTENNA: Schizophrenia; Schizoaffective disorder  XEPLION: Schizophrenia	Janssen Pharmaceutica N.V. (together with Janssen Pharmaceuticals, Inc., Janssen International and their affiliates “Janssen”)	Worldwide
<i>INVEGA TRINZA / TREVICTA</i>	Schizophrenia	Janssen	Worldwide
<i>INVEGA HAFYERA / BYANLI</i>	Schizophrenia	Janssen	Worldwide

#### *Our Key Licensed Product*

Product	Indication(s)	Licensee	Licensed Territory
<i>VUMERITY</i>	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.

In January 2024, U.S. Patent No. 11,883,394 relating to ARISTADA was granted. The patent has claims to the crystallization process of aripiprazole lauroxil and expires in 2035.

### **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.

#### *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 a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, in a single bilayer tablet. LYBALVI 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 schizophrenia?*

See the disease state description under the “ARISTADA” section in this Directors’ Report.

#### *What is bipolar I disorder?*

Bipolar 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 mood states, including extreme highs (mania) and 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 adult population in the U.S. 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.

#### *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 2022 U.S. National Survey on Drug Use and Health, an estimated 5.9 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 2022 U.S. National Survey on Drug Use and Health, an estimated 28.8 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.

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\* 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, among others, the following:

### **Products Using Our Proprietary Technologies**

#### ***INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and INVEGA HAFYERA/BYANLI***

INVEGA SUSTENNA/XEPLION (paliperidone palmitate), INVEGA TRINZA/TREVICTA (paliperidone palmitate) and INVEGA HAFYERA/BYANLI (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. BYANLI is approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION or TREVICTA. INVEGA HAFYERA/BYANLI is manufactured by Janssen.

For a discussion of legal proceedings related to certain of the patents covering INVEGA SUSTENNA and INVEGA TRINZA, see Note 21, *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 schizophrenia?*

See the disease state description under the “ARISTADA” section in this Directors’ Report.

#### *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.

### *What is schizophrenia?*

See the disease state description under the “ARISTADA” section in this Directors’ Report.

### **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. For a discussion of legal proceedings related to certain of the patents covering VUMERITY, see Note 21, *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 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 field of neuroscience 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.

#### ***ALKS 2680***

ALKS 2680 is a novel, investigational, oral, selective orexin 2 receptor (“OX2R”) agonist in development for the treatment of narcolepsy. Orexin neuropeptides are important regulators of the sleep/wake cycle through OX2R activation, and loss of orexinergic neurons in the brain is associated with excessive daytime sleepiness and cataplexy in narcolepsy. ALKS 2680 was designed to address the underlying pathology of narcolepsy with the goals of improving duration of wakefulness and providing cataplexy control. Once-daily oral administration of ALKS 2680 is currently being evaluated in a phase 1 study in healthy volunteers and people living with narcolepsy type 1, narcolepsy type 2 and idiopathic hypersomnia.

### **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, including the arrangements described below.



## *Janssen*

### *INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and INVEGA HAFYERA/BYANLI*

Under an exclusive license agreement with Janssen, 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 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 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. 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. In November 2021, we received notice from Janssen of partial termination of the license agreement, following which Janssen ceased paying us royalties related to U.S. sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA. 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. In May 2023, the arbitral tribunal (the "Tribunal") in the arbitration proceedings issued a final award (the "Final Award") that served to reinstate the Janssen royalties and required payment by Janssen of back royalties and interest for amounts owed but not yet paid since the effective date of the partial termination. The Final Award also provided, among other things, that we were entitled to royalty revenues from Janssen related to net sales of INVEGA SUSTENNA through August 20, 2024, INVEGA TRINZA through the second quarter of 2030 (but no later than May 2030 when the license agreement expires) and INVEGA HAFYERA through May 2030 (when the license agreement expires).

### *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 at our Wilmington, Ohio facility 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 31% and 15% of our consolidated revenues for the years ended December 31, 2023 and 2022, 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, 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 an agreed 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. In December 2023, we announced entry into a definitive agreement to sell our research and development and manufacturing facility in Athlone, Ireland (the "Athlone Facility") where VUMERITY is manufactured, which transaction is expected to close in mid-2024. In connection with the sale of the Athlone Facility, we have agreed to enter into a subcontracting arrangement with the purchaser of the Athlone Facility for the manufacture of VUMERITY through the manufacturing transition period.

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 8% and 10% of our consolidated revenues for the years ended December 31, 2023 and 2022, 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 the Athlone Facility 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 manufacture 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.

In December 2023, we announced that we entered into a definitive agreement to sell the Athlone Facility to Novo Nordisk (“Novo”) and that we plan to enter into subcontracting arrangements to continue certain development and manufacturing activities currently performed at the Athlone Facility for a period of time after the closing of the transaction, which may continue through the end of 2025. Such transaction is subject to various uncertainties and risks, including, without limitation, satisfaction of the conditions to closing of the transaction on the anticipated timeline, potential negative impacts on our relationships with current suppliers or licensees, diversion of management and employee attention from daily business operations, and risks inherent in the transition to subcontracting arrangements. 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 the Athlone Facility that are marketed by third parties, including FAMPYRA and VUMERITY. This facility has been inspected by U.S., Irish, Brazilian, Turkish, Libyan, Saudi Arabian, 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 the Athlone 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 our products or components of our products for clinical use.

### **Research & Development**

We devote significant resources to R&D programs. We focus our R&D efforts on developing novel therapeutics in areas of high unmet medical need. Our R&D efforts include, but are not limited to, areas such as pharmaceutical formulation, analytical chemistry, process development, engineering, scale-up and drug optimization/delivery. Please see the section entitled “Results of Operations” in this Directors’ Report.

### **Permits and Regulatory Approvals**

We hold various permits, registrations, approvals and/or licenses in respect of our manufacturing and related activities. The primary licenses held in this regard are FDA Registrations of Drug Establishment, and licenses from the Drug Enforcement Administration of the U.S. Department of Justice (“DEA”). We also hold various authorizations, licenses and certificates from the Health Products Regulatory Authority in Ireland (“HPRA”), including an Investigational Medicinal Products Manufacturers Authorization (No. IMP074/00002) in respect of our offices located in Dublin, Ireland; and a Manufacturers Authorization (No. M1067), an Investigational Medicinal Products Manufacturers Authorization (No. IMP074/00001) and Certificates of Good Manufacturing Practice Compliance of a Manufacturer (Ref. 2014/7828/IMP074 and 2014/7828/M1067) in respect of the Athlone Facility. Due to certain U.S. state law requirements, we also hold state licenses to cover distribution activities conducted in certain states where required.

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 support this authorization as needed, including 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 115 individuals. VIVITROL is primarily sold to pharmaceutical wholesalers, pharmacies, specialty distributors and treatment providers. Product sales of VIVITROL during the year ended December 31, 2023 to Cardinal Health, McKesson Corporation and AmerisourceBergen Corporation (“AmerisourceBergen”) represented approximately 27%, 23% and 16%, respectively, of total VIVITROL gross sales.

Our sales force for ARISTADA, ARISTADA INITIO and LYBALVI in the U.S. consists of approximately 360 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, 2023 to Cardinal Health, AmerisourceBergen and McKesson Corporation represented approximately 46%, 24% and 23%, respectively, of total ARISTADA and ARISTADA INITIO gross sales. Product sales of LYBALVI during the year ended December 31, 2023 to Cardinal Health, McKesson Corporation and AmerisourceBergen represented approximately 36%, 31% and 29%, 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/or royalty revenues. In some cases, these competitors may be 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 manufacture and/or 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 Pharmathen S.A., which underpins aripiprazole formulations in development, and technology underpinning Teva Pharmaceuticals Industries Ltd.'s (together with its affiliates, "Teva") once every two weeks injectable microsphere formulation, each for the treatment of schizophrenia.

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.; ABILIFY ASIMTUFII (aripiprazole), a once-every-two months 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; RYKINDO (risperidone), a once-every-two-weeks injectable formulation of risperidone developed by Luye Pharma Group; UZEDY (risperidone) extended-release injectable suspension, for subcutaneous use, developed and marketed by MedinCell S.A. and Teva; and generic versions of branded injectable products.

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. Other pharmaceutical companies are developing products for the treatment of schizophrenia that, if approved by the FDA, would compete with LYBALVI.

In the treatment of bipolar disorder, LYBALVI and RISPERDAL CONSTA compete with antipsychotics such as oral aripiprazole; REXULTI; LATUDA; VRAYLAR; ABILIFY MAINTENA; ABILIFY ASIMTUFII; CAPLYTA; RYKINDO; risperidone; quetiapine; olanzapine; ziprasidone and clozapine. Other pharmaceutical companies are developing products for the treatment of bipolar disorder that, if approved by the FDA, would compete with LYBALVI.

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; ZUBSOLV (buprenorphine and naloxone) marketed by Orexo US, Inc.; and BRIXADI (buprenorphine) extended-release injection for subcutaneous use (CIII), marketed by Braeburn Inc. VIVITROL also competes with methadone, oral naltrexone and generic versions of SUBUTEX and SUBOXONE sublingual tablets. Other pharmaceutical companies are developing products that have shown promise in treating opioid dependence that, if approved by the FDA, would compete with VIVITROL.

In the treatment of MS, VUMERITY competes with AVONEX, TYSABRI, TECFIDERA, and PLEGRIDY from Biogen; OCREVUS from Genentech; BETASERON from Bayer HealthCare Pharmaceuticals; COPAXONE from Teva; 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 BRIUMVI (ublituximab-xiiv) 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, and 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 from 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
11,883,394	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*

We have a number of patents and pending patent applications covering our microsphere technology throughout the world, which, to some extent, cover VIVITROL.

We own one unexpired Orange-Book listed U.S. patent covering VIVITROL, which expires in the U.S. in 2029. Pursuant to the terms of a confidential settlement and license agreement entered into in August 2023 with Teva, we granted Teva a non-exclusive, royalty-free, non-transferable, non-sublicensable limited license under the remaining patent covering VIVITROL to market and sell a generic version of VIVITROL in the U.S. beginning on January 15, 2027 (the “First Entry Date”), or earlier under certain circumstances. 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 on the earlier of the First Entry Date, sometime in 2028 or earlier under certain circumstances.

***INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and INVEGA HAFYERA/BYANLI***

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 and INVEGA TRINZA, see Note 21, *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. For a discussion of legal proceedings related to patents covering VUMERITY, see Note 21, *Commitments and Contingent Liabilities* in the “Notes to Consolidated Financial Statements” in this Directors’ Report.

***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
11,793,805	LYBALVI	2031
11,707,466	LYBALVI	2041

***ALKS 2680***

We have U.S. patent protection that extends to 2041, several U.S. patent applications, and a number of corresponding non-U.S. counterparts, that cover ALKS 2680.



### ***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 technologies, 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 IP 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 Application:* All available data from animal pharmacology and toxicology studies are included in an Investigational New Drug application (“IND”) submitted to the FDA and are reviewed by the FDA prior to commencement of first-in-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 subjects. In certain cases where human clinical data from ex-U.S. studies are available prior to submitting the IND, these data would also be included in the IND for review by the FDA prior to commencing clinical trials in the U.S. In addition, information pertaining to the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product are included in the IND to support identification, quality, purity, and strength of the investigational drug product.

*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, 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 intended patient population and seek to assess the efficacy of the drug for targeted indications, to determine dose-response and the optimal dose range and to gather additional information relating to the safety profile.
- 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 chemistry, manufacturing and controls (“CMC”) of the product as well as the 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 mechanisms 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 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 EU 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, in January 2016, CMS released the final Medicaid covered outpatient drug regulation, which became effective in April 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 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”) and its Irish equivalent, which prohibits 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 in May 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 disclosures, securities trading regulations and U.S. and Irish or EU 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 environmental matters, including 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 LYBALVI. We also earn manufacturing and/or royalty revenues on net sales of products commercialized by our licensees, the most significant of which in 2023 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 2023, our net income from continuing operations was \$519.2 million, as compared to net loss from continuing operations of \$33.2 million in 2022. The increase in net income from continuing operations was primarily due to increases of \$142.4 million in product sales, net, \$411.4 million in manufacturing and royalty revenue and \$99.6 million in income tax benefit, partially offset by increases of \$34.9 million in cost of goods manufactured and sold and \$99.0 million in selling, general and administrative expenses. The increase in manufacturing and royalty revenue primarily relates to the successful outcome of the arbitration proceedings in respect of the long-acting INVEGA products. These items are discussed in further detail within the “Results of Operations” section below.

### *Business Update*

On November 15, 2023, we completed the separation of our oncology business into Mural Oncology plc (“Mural”), a new, independent, publicly-traded company (the “Separation”). The Separation was effected by means of a distribution of all of the outstanding ordinary shares of Mural to our shareholders (the “Distribution”), in which each of our shareholders received one ordinary share, nominal value \$0.01 per share, of Mural for every ten ordinary shares, par value \$0.01 per share, of Alkermes held by such shareholder as of the close of business on November 6, 2023, the record date for the Distribution. The effective time of the Distribution was 12:01 a.m. Eastern time on November 15, 2023 (the “Separation Date”). In connection with the Separation, we entered into a separation agreement with Mural that, among other things, sets forth the principal terms of the Separation and the Distribution, and a number of other ancillary agreements. The Separation and related agreements are more fully described in Note 3, *Discontinued Operations*, in the “Notes to Consolidated Financial Statements” in this Directors’ Report.

On December 14, 2023, we announced that we entered into a definitive agreement to sell the Athlone Facility to Novo and plan to enter into subcontracting arrangements to continue certain development and manufacturing activities currently performed at the Athlone Facility for a period of time after the closing of the transaction, which arrangements may continue through the end of 2025. The transaction is subject to various uncertainties and risk, including, without limitation, satisfaction of the conditions to closing of the transaction on the anticipated timeline, potential negative impacts on our relationships with current suppliers or licensees or diversion of management and employee attention from daily business operations, and risks inherent in the transition to subcontracting arrangements. The transaction is expected to close in mid-2024, subject to certain closing conditions.

## Results of Operations

As a result of the Separation, the historical results of our oncology business have been reflected as discontinued operations in our accompanying consolidated financial statements through the Separation Date. Prior period results of operations and balance sheet information have been recast to reflect this presentation.

### Product Sales, Net

Our product sales, net, consist of sales of VIVITROL, ARISTADA and ARISTADA INITIO, and 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 these products during the years ended December 31, 2023 and 2022:

(In millions, except for % of Sales)	Year Ended December 31,			
	2023	% of Sales	2022	% of Sales
Product sales, gross	\$ 1,855.4	100.0 %	\$ 1,548.9	100.0 %
Adjustments to product sales, gross:				
Medicaid rebates	(426.4)	(23.0) %	(344.0)	(22.2) %
Chargebacks	(189.1)	(10.2) %	(157.2)	(10.2) %
Product discounts	(137.7)	(7.4) %	(124.1)	(8.0) %
Medicare Part D	(74.4)	(4.0) %	(68.1)	(4.4) %
Other	(107.8)	(5.8) %	(77.9)	(5.0) %
Total adjustments	(935.4)	(50.4) %	(771.3)	(49.8) %
Product sales, net	\$ 920.0	49.6 %	\$ 777.6	50.2 %

VIVITROL product sales, gross, increased by 13%, which was primarily due to an increase of 5% in the number of VIVITROL units sold and a 6% increase in the selling price of VIVITROL that went into effect in January 2023. ARISTADA and ARISTADA INITIO product sales, gross, increased by 11%, 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 January 2023. LYBALVI product sales, gross, increased by 102%, which was primarily due to an increase of 97% in the number of units sold and increases of 6% and 3% in the selling price of LYBALVI that went into effect in November 2022 and July 2023, respectively.

The following table compares product sales, net earned during the years ended December 31, 2023 and 2022:

(In millions)	Year Ended December 31,		
	2023	2022	Change
VIVITROL	\$ 400.4	\$ 379.5	\$ 20.9
ARISTADA and ARISTADA INITIO	327.7	302.1	25.6
LYBALVI	191.9	96.0	95.9
Product sales, net	\$ 920.0	\$ 777.6	\$ 142.4

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. Pursuant to the terms of a confidential settlement and license agreement entered into in August 2023 with Teva, we granted Teva a non-exclusive, royalty-free, non-transferable, non-sublicensable limited license under the remaining patent covering VIVITROL to market and sell a generic version of VIVITROL in the U.S. beginning on the First Entry Date, or earlier under certain circumstances. Under the terms of a settlement and license agreement entered into in July 2019 with 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 on the earlier of the First Entry Date, sometime in 2028 or earlier under certain circumstances.

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 2041, 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 market in the U.S., as ARISTADA and ARISTADA INITIO continue to gain market share in the U.S., and as we continue to grow sales of LYBALVI in the U.S.



## 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 other 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 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, 2023 and 2022:

(In millions)	Year Ended December 31,		Change
	2023	2022	
Manufacturing and royalty revenues:			
Long-acting INVEGA products	\$ 486.1	\$ 115.7	\$ 370.4
VUMERITY	129.3	115.5	13.8
RISPERDAL CONSTA	37.3	49.9	(12.6)
Other	90.7	50.9	39.8
Manufacturing and royalty revenues	<u>\$ 743.4</u>	<u>\$ 332.0</u>	<u>\$ 411.4</u>

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.

In November 2021, we received notice from Janssen of partial termination of our license agreement under which we provided Janssen with rights to, and know-how, training and technical assistance in respect of, our NanoCrystal technology, which was used to develop the long-acting INVEGA products. The partial termination became effective in February 2022, at which time Janssen ceased paying us royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA. Accordingly, we ceased recognizing royalty revenue related to sales of these products in February 2022. 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. In May 2023, the Tribunal issued the Final Award, which concluded the arbitration proceedings.

The Final Award provided that we were due back royalties of \$195.4 million, inclusive of \$8.1 million in late-payment interest, related to 2022 U.S. net sales of the long-acting INVEGA products, which we received from Janssen in the second quarter of 2023, and are entitled to 2023 and future royalty revenues from Janssen related to net sales of INVEGA SUSTENNA through August 20, 2024, INVEGA TRINZA through the second quarter of 2030 (but no later than May 2030 when the license agreement expires) and INVEGA HAFYERA through May 2030 (when the license agreement expires).

Following issuance of the Final Award, we recognized royalty revenues related to the back royalties for 2022, as described above, and resumed recognizing royalty revenue related to ongoing U.S. sales of the long-acting INVEGA products. Royalty revenues related to the long-acting INVEGA products increased by \$370.4 million during 2023, as compared to 2022, primarily due to the receipt of the back royalties and late-payment interest described above and a full year of royalty revenue related to worldwide net sales of the long-acting INVEGA products of approximately \$290.7 million, as compared to royalty revenue of \$115.7 million during 2022. Janssen's worldwide net sales of the long-acting INVEGA products were \$4,115.0 million during 2023, as compared to \$4,140.0 million during 2022.

We expect royalty revenues from net sales of the long-acting INVEGA products to decrease in the near-term, as the royalty revenues related to net sales of INVEGA SUSTENNA are expected to end on August 20, 2024, which could have a significant impact on our INVEGA SUSTENNA royalty revenues during 2024. 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 21, *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 receive a 15% royalty on worldwide net sales of VUMERITY manufactured and packaged by us, subject to increases in such royalty rate 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. Manufacturing revenue from VUMERITY increased by \$10.4 million during 2023, primarily due to an increase in the number of bulk batches made available to Biogen. Royalty revenue related to VUMERITY increased by \$3.4 million during 2023, due to an increase in end-market net sales of VUMERITY, which were \$576.3 million during 2023, as compared to \$553.4 million during 2022.

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. We expect revenues from RISPERDAL CONSTA to continue to decrease over time as patents covering RISPERDAL CONSTA expire in markets where end-market net sales of RISPERDAL CONSTA occur. We are aware of potential generic and other competition to RISPERDAL CONSTA that may lead to reduced unit sales and increased pricing pressure. The decrease in revenue from RISPERDAL CONSTA during 2023 was primarily due to decreases of \$6.6 million in manufacturing revenue and \$6.1 million in royalty revenue. The decrease in manufacturing revenue was primarily due to a decrease in the number of U.S. batches made available to Janssen and a 7% decrease in the rest of world average selling price of the product. The decrease in royalty revenue was primarily due to expirations of the patents covering RISPERDAL CONSTA, which expired in the U.S. in January 2023 and expired in the EU in 2021.

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,		Change
	2023	2022 <sup>(1)</sup>	
Cost of goods manufactured and sold	\$ 253.0	\$ 218.1	\$ 34.9

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.

The increase in cost of goods manufactured and sold during 2023 was primarily due to an increase of \$8.0 million in the cost of goods manufactured for VUMERITY and increases of \$15.5 million, \$13.3 million and \$6.2 million, respectively, in the cost of goods sold for VIVITROL, LYBALVI and ARISTADA, partially offset by a decrease of \$2.0 million in the cost of goods manufactured for RISPERDAL CONSTA. The increase related to VUMERITY was primarily due to increased manufacturing activity, as described above. The increases related to LYBALVI and ARISTADA were primarily due to the increases in sales activity, as described above. The increase in the cost of goods sold related to VIVITROL was due to an increase in sales activity, as described above, and an increase in costs related to out-of-specification batches. These increases were partially offset by decreases in cost of goods manufactured for RISPERDAL CONSTA, primarily due to a decrease in U.S. batches made available to Janssen, as described above, and in the cost of goods manufactured for certain legacy products that we manufacture due to a decrease in sales of such products.

### *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 preclinical activities performed by contract research organizations, 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 development programs or our products or technologies in general.

The following table sets forth our external R&D expenses for the years ended December 31, 2023 and 2022 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,		Change
	2023	2022 <sup>(1)</sup>	
<b>External R&amp;D expenses:</b>			
Development programs:			
ALKS 2680	\$ 31.3	\$ 15.7	\$ 15.6
LYBALVI	15.4	23.1	(7.7)
Other external R&D expenses	51.7	57.4	(5.7)
Total external R&D expenses	98.4	96.2	2.2
<b>Internal R&amp;D expenses:</b>			
Employee-related	128.3	129.7	(1.4)
Occupancy	12.3	12.4	(0.1)
Depreciation	9.6	10.7	(1.1)
Other	22.2	23.7	(1.5)
Total internal R&D expenses	172.4	176.5	(4.1)
Research and development expenses	\$ 270.8	\$ 272.7	\$ (1.9)

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.

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 increase in expenses related to ALKS 2680 during 2023 was primarily due to an increase in early-stage development expenses, including chemistry manufacturing and controls expenses and spend on a phase 1b proof-of-concept study, which was initiated in the second quarter of 2023. The decrease in expenses related to LYBALVI during 2023 was primarily due to decreased spend on certain ongoing long-term safety and tolerability studies as they near completion, partially offset by increased spend on the pediatric study related to the product. The decrease in other external R&D expenses was primarily due to the termination of the ALKS 1140 clinical development program in the second quarter of 2022.

### ***Selling, General and Administrative Expenses***

(In millions)	Year Ended December 31,		Change
	2023	2022 <sup>(1)</sup>	
Selling and marketing expense	\$ 487.5	\$ 392.2	\$ 95.3
General and administrative expense	202.3	198.6	3.7
Selling, general and administrative expense	\$ 689.8	\$ 590.8	\$ 99.0

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.

The increase in selling and marketing expense during 2023 was primarily due to a \$72.1 million increase in marketing spend related to the launch of the direct-to-consumer campaign for LYBALVI. Employee-related expenses also increased by \$25.2 million, primarily related to a 5% increase in sales and marketing headcount and an increase in employee travel as our in-person activities increased.

The increase in general and administrative expense during 2023 was primarily due to an increase in salaries and benefits of \$7.6 million and an increase in our branded prescription drug fee of \$2.1 million, partially offset by a decrease in professional services fees of \$2.4 million, primarily due to decreased legal expenses.

### ***Amortization of Acquired Intangible Assets***

(In millions)	Year Ended December 31,		Change
	2023	2022	
Amortization of acquired intangible assets	\$ 35.7	\$ 36.4	\$ (0.7)

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 accompanying consolidated balance sheet at December 31, 2023 is expected to be approximately \$2.0 million in the year ending December 31, 2024.

### ***Other Income (Expense), Net***

(In millions)	Year Ended December 31,		Change
	2023	2022	
Interest income	\$ 30.9	\$ 7.6	\$ 23.3
Interest expense	(23.0)	(13.0)	(10.0)
Change in the fair value of contingent consideration	—	(2.6)	2.6
Other (expense) income, net	(0.5)	2.1	(2.6)
Total other income (expense), net	\$ 7.4	\$ (5.9)	\$ 13.3

Interest income consists primarily of interest earned on our available-for-sale investments. Interest expense consists of interest incurred on our 2026 Term Loans. The increases in interest income and interest expense were primarily due to increases in interest rates over the past twelve months, due to the rising interest rate environment during the year.

The change in the fair value of contingent consideration was due to the determination during 2022 that it was unlikely we would collect any further contingent consideration proceeds under our agreements with Baudax Bio, Inc. (“Baudax”) in effect at the time, and accordingly, we reduced the fair value of the contingent consideration to zero, as discussed in Note 8, *Fair Value*, in the “Notes to Consolidated Financial Statements” in this Directors’ Report.

### ***Income Tax Benefit (Provision)***

(In millions)	Year Ended December 31,		Change
	2023	2022 <sup>(1)</sup>	
Income tax benefit (provision)	\$ 97.6	\$ (2.0)	\$ 99.6

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.

The income tax benefit in 2023 was primarily attributable to the partial release of the valuation allowance maintained against certain Irish deferred tax assets, partially offset by taxes on income earned in the U.S. and Ireland. The income tax provision in 2022 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 \$797.0 million at December 31, 2023. 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 \$70.8 million of income taxes would be payable on the repatriation of the unremitted earnings to Ireland.

As of December 31, 2023, we had \$1.3 billion of Irish NOL carryforwards, \$14.6 million of U.S. federal NOL carryforwards, \$43.2 million of state NOL carryforwards, \$9.7 million of federal R&D credits and \$31.0 million of state tax credits which will either expire on various dates through 2043 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.

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 has transposed the corporate minimum tax rules into Irish legislation with effect as of January 1, 2024.

## Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	December 31, 2023			December 31, 2022		
	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	\$ 317.8	\$ 139.7	\$ 457.5	\$ 208.4	\$ 84.1	\$ 292.5
Investments—short-term	187.6	128.4	316.0	207.6	108.4	316.0
Investments—long-term	18.0	21.9	39.9	70.3	61.3	131.6
Total cash and investments	<u>\$ 523.4</u>	<u>\$ 290.0</u>	<u>\$ 813.4</u>	<u>\$ 486.3</u>	<u>\$ 253.8</u>	<u>\$ 740.1</u>
Outstanding borrowings—short and long-term	<u>\$ 290.7</u>	<u>\$ —</u>	<u>\$ 290.7</u>	<u>\$ 293.3</u>	<u>\$ —</u>	<u>\$ 293.3</u>

At December 31, 2023, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized		Allowance for Credit Losses	Estimated Fair Value
		Gains	Losses		
Investments—short-term available-for-sale	\$ 315.8	\$ 1.4	\$ (1.2)	\$ —	\$ 316.0
Investments—long-term available-for-sale	38.7	—	(0.6)	—	38.1
Investments—long-term held-to-maturity	1.8	—	—	—	1.8
Total	<u>\$ 356.3</u>	<u>\$ 1.4</u>	<u>\$ (1.8)</u>	<u>\$ —</u>	<u>\$ 355.9</u>

### Sources and Uses of Cash

We generated \$401.4 million and \$21.0 million of cash from operating activities during the years ended December 31, 2023 and 2022, 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 our financial statements were issued. Subject to market conditions, interest rates and other factors, we may pursue opportunities to obtain additional financing in the future, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures. In addition, the 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. 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.

Information about our cash flows, by category, is presented in the accompanying consolidated statements of cash flows. The discussion of our cash flows that follows does not include the impact of any adjustments to remove discontinued operations and is stated on a total company consolidated basis. The following table summarizes our cash flows for the years ended December 31, 2023 and 2022:

(In millions)	Year Ended December 31,	
	2023	2022
Cash and cash equivalents, beginning of period	\$ 292.5	\$ 337.5
Cash flows provided by operating activities	401.4	21.0
Cash flows provided by (used in) investing activities	53.3	(64.4)
Cash flows used in financing activities	(289.7)	(1.6)
Cash and cash equivalents, end of period	<u>\$ 457.5</u>	<u>\$ 292.5</u>

### *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. Operating cash flow is derived by adjusting our net income (loss) for non-cash operating items such as depreciation, amortization and share-based compensation and 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.

Cash flows provided by operating activities during 2023 were \$401.4 million and primarily consisted of net income of \$355.8 million, adjusted for non-cash items, including share-based compensation of \$100.9 million and depreciation and amortization of \$74.9 million, partially offset by changes in working capital of \$36.7 million and deferred income taxes of \$99.9 million. During 2023, net income included receipt of \$195.4 million from Janssen, inclusive of \$8.1 million in late-payment interest, related to 2022 U.S. net sales of the long-acting INVEGA products following the successful outcome of the arbitration proceedings in respect of such products.

Cash flows provided by operating activities during 2022 were \$21.0 million and primarily consisted of net loss of \$139.2 million, adjusted for non-cash items including share-based compensation of \$94.3 million, depreciation and amortization of \$77.9 million, change in the fair value of contingent consideration of \$2.6 million and changes in working capital of \$12.8 million, partially offset by deferred income taxes of \$32.8 million.

### *Investing Activities*

Cash flows provided by investing activities during 2023 were primarily due to \$101.1 million in net sales of investments, offset by the purchase of \$48.0 million of property, plant and equipment. Cash flows used in investing activities during 2022 were primarily due to \$28.0 million in net purchases of investments and the purchase of \$38.3 million of property, plant and equipment.

We expect to spend approximately \$35.0 million during the year ending December 31, 2024 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*

Cash flows used in financing activities during 2023 primarily related to \$275.0 million in cash distributed to Mural in connection with the Separation and \$28.5 million of employee taxes paid related to the net share settlement of equity awards, partially offset by \$16.8 million of cash that we received upon exercises of employee stock options. Cash flows used in financing activities during 2022 primarily related to \$18.2 million of employee taxes paid related to the net share settlement of equity awards and \$3.0 million of principal payments on our 2026 Term Loans, partially offset by \$19.6 million of cash that we received upon exercises of employee stock options.

### ***Borrowings***

At December 31, 2023, our borrowings consisted of \$291.8 million outstanding under the 2026 Term Loans. The 2026 Term Loans bear interest at SOFR plus a credit spread adjustment applicable to the interest period and an applicable margin of 2.5% with a 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 7, *Long-Term Debt*, in the “Notes to Consolidated Financial Statements” in this Directors’ Report for a discussion of our outstanding term loans.

### ***Discontinued Operations***

Net loss from discontinued operations consists of the results of our oncology business and is reported as a separate component of income. For additional information, please refer to Note 3, *Discontinued Operations*, in the “Notes to Consolidated Financial Statements” in this Directors’ Report.

### **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. In connection with our acquisition of Rodin Therapeutics, Inc. (“Rodin”) in



November 2019, we may become obligated to make up to \$825.0 million in future milestone payments to the former shareholders of Rodin, \$200.0 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, 2023, 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 36% and 61% of our investments at December 31, 2023 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, 2023, our borrowings consisted of \$291.8 million outstanding under the 2026 Term Loans. The 2026 Term Loans mature on March 12, 2026. In June 2023, we amended the 2026 Terms Loans to transition the interest rate available for borrowings thereunder from a LIBOR-based interest rate to an interest rate based on SOFR and to make other conforming and mechanical changes. The 2026 Term Loans bear interest at the one-, three- or six-month SOFR rate of our choosing plus a credit spread adjustment applicable to the interest period and an applicable margin of 2.50% with a floor of 0.5%.

We are currently using the one-month SOFR rate, which was 5.47% at December 31, 2023. A 10% increase in the one-month SOFR rate would have increased the amount of interest we owed by approximately \$2.3 million. At December 31, 2022, a 10% increase in the one-month LIBOR rate, which was the rate in use at the time, would have increased the amount of interest we owed by approximately \$1.3 million.

### **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, 2023, 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 \$10.3 million, as compared to a reduction in revenues of approximately \$1.1 million for the year ended December 31, 2022.

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, 2023, 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 \$7.7 million, as compared to an increase in our expenses of approximately \$7.5 million in the year ended December 31, 2022.

## **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 public filings with the U.S. Securities and Exchange Commission (the "SEC"). If any events described by the following risks actually occur, they could materially adversely affect our business, financial condition, cash flows or results of operations. This could cause the market price of our ordinary shares to decline.*

### **Risks Related to Our Business and Our Industry**

***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 revenue from sales by our licensees of our licensed products and third-party products incorporating our proprietary technologies. We also earn manufacturing revenues for products that we currently manufacture on behalf of other parties. 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. 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, INVEGA HAFYERA/BYANNLI, and CABENUVA. While we ultimately prevailed in arbitration proceedings related to, among other things, this partial termination and Janssen's royalty and other obligations under the license agreement, the announcement of the partial termination, expectations regarding the loss of royalty revenues, actual delays in receipt of royalty revenues that resulted from such termination, and the ultimate announcement of the resumption of payment of such royalty revenues, caused the market price of our ordinary shares to fluctuate significantly.

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 technologies obsolete or noncompetitive. For a detailed discussion of the competition that we face with respect to our current marketed products, technologies 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 approvals 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 new significant

warnings or restrictions on use;

- our continued ability to engage third parties to manufacture, 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 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 and 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;
- exchange rate valuations and fluctuations;
- U.S. and global political changes, conflicts and/or instability, public health matters, economic conditions and/or any related changes in applicable laws and regulations, that may impact resources and markets for 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 the Drug Price Negotiation Program applicable to Medicare Parts D and B and those provisions that impose new manufacturer financial liability on all drugs in Medicare

Part D beginning in 2025, and require companies to pay rebates to Medicare for drug prices that increase faster than inflation. The Drug Price Negotiation Program is subject to ongoing litigation, the outcome of which is difficult to predict.

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 payment support programs could become the target of similar 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, including those located in or near areas of conflict or areas impacted by political, environmental, public health or economic events;

- 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 timelines;
- an inability to recruit and enroll clinical trial participants at the expected rate or at all, or to adequately follow participants following treatment;
- safety or tolerability issues;
- an inability to manufacture or obtain sufficient quantities of materials used for clinical trials; and
- unforeseen governmental or regulatory issues or concerns, including those of the FDA and other regulatory agencies, that may impact the strategies for, and design, timelines or feasibility of, our clinical development programs.

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. 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, 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 sufficient safety and efficacy or a sufficiently favorable benefit/risk profile 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 our clinical trials or during clinical trials of other product candidates in the same class could lead to requirements that trials be repeated or extended, or that a development 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 a prolonged U.S. government shutdown, or other global 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.

***Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or other events could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely is subject to the impacts of political events, which are inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may increase the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA and the SEC to timely review and process our submissions, which could have a material adverse effect on our business.

***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; global disruptions such as the COVID-19 pandemic and ongoing conflicts in various regions of the world; 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 currently rely on the Athlone Facility 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 or otherwise, 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.

In addition, in December 2023 we announced entry into a definitive agreement to sell the Athlone Facility to Novo and plans to enter into subcontracting arrangements to continue certain development and manufacturing activities currently performed at the Athlone Facility for a period of time after the closing of the transaction, which may continue through the end of 2025. Such transaction is subject to various uncertainties and risk, including, without limitation, satisfaction of the conditions to closing of the transaction on the anticipated timeline, potential negative impacts on our relationships with current suppliers or licensees or diversion of management and employee attention from daily business operations, and risks inherent in the transition to subcontracting arrangements. Any interruption or delay in supply, whether resulting from issues with equipment, materials, personnel, manufacturing processes, or internal or external quality audits or reviews, or issues related to the sale of the Athlone Facility and related subcontracting arrangements, could result in delays in meeting our contractual obligations and could damage our reputation and relationships with our licensees, and result in potential loss of 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 related to the labor market, 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 support 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 COVID-19 pandemic and ongoing conflicts in various regions in the world, 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 these wholesalers experience prolonged business disruptions, 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 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 Act (the “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 licensed products or 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 our 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.

## **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 and other legal proceedings, which are 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. In addition, in August 2023, we settled Paragraph IV litigation proceedings with Teva (described in more detail below) by granting Teva a license to market and sell a generic version of VIVITROL in the U.S. beginning on January 15, 2027, or earlier under certain circumstances. Ultimately, the outcome of such litigation and other proceedings, or any settlement arrangements 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. In August 2023, we entered into a confidential settlement and license agreement (the "Settlement Agreement") with Teva to resolve the proceedings between the parties. Pursuant to the terms of the Settlement Agreement, we granted Teva a non-exclusive, royalty-free, non-transferable, non-sublicensable limited license to market and sell a generic version of VIVITROL in the U.S. beginning on January 15, 2027, or earlier under certain circumstances.

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 or settle any such legal proceedings or disputes on favorable terms. 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 any 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, IP 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 or litigation that request that the FDA refuse to approve, delay or withdraw approval of, or impose additional approval requirements on our marketing applications. If successful, such petitions can significantly delay, or even prevent, the approval of the marketing application in question or cause such marketing application approval to be withdrawn. 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, violations related to anti-corruption and anti-bribery laws, 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.

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. 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.

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 their initiatives that restrict covered entities’ ability to purchase products at the 340B program price for shipment through an unlimited number of contract pharmacies. Based on the outcome of litigation related to this topic or for other reasons, we may implement, and other pharmaceutical manufacturers have implemented, similar restrictions. The outcome of pending judicial proceedings and the potential impact on the way in which manufacturers extend discounts to covered entities through contract pharmacies remain uncertain and one or more negative legal rulings, or the passage of legislation in respect of this topic, may materially adversely impact our results of operations if we were to impose limitations on contract pharmacy arrangements.

We have obligations to report the average sales price for certain of our drugs to the Medicare program. In addition, we are required to report the best price for our drugs, as defined under the Medicaid Drug Rebate Program, to CMS. Statutory or regulatory changes or changes in CMS guidance could affect the average sales price or best price calculations for our products and the resulting Medicare payment rate or rebates we owe to state Medicaid programs. Such changes 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 be able to maintain profitability on a sustained basis.*

At December 31, 2023, our accumulated deficit was \$1.3 billion, which was primarily the result of net losses incurred from continuing operations from 1987, the year Alkermes, Inc., was founded, through December 31, 2022, partially offset by net income from continuing operations over certain fiscal periods, including net income earned during the year ended December 31, 2023.

Our ability to maintain profitability on a sustained basis will depend on our ability to continue to grow and diversify our revenue and to 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, the long-acting INVEGA products, 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 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 programs, 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, including the costs and availability of raw materials or components of our products;
- the costs of doing business with third-party vendors, including suppliers, manufacturers, packagers and distributors;
- the scope and costs of our commercial activities, including our investment in direct-to-consumer campaigns and other initiatives;
- the cost of possible business development activities, including licenses or acquisitions of technologies, compounds or product rights or the potential acquisition of other assets, including equipment, facilities, businesses or entire companies;
- 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 of compliance with new regulations applicable to us, including those related to the measurement, reporting and assurance of environmental performance data; and
- the costs associated with recruiting, compensating and retaining a highly-skilled workforce in an environment where competition for highly-skilled employees is intense.

***We have broad discretion regarding use of our cash and cash equivalents and we may not allocate our cash in ways that ultimately increase the value of our ordinary shares.***

We have broad discretion in the allocation of our cash and cash equivalents and we may not allocate our cash in ways that ultimately increase the value of our ordinary shares. We could make capital allocation decisions to utilize such funds in a way that our shareholders do not agree with or that do not ultimately generate shareholder value in the manner they, or we, anticipate or at all. If our cash and cash equivalents are not deployed effectively or do not generate shareholder value, we may fail to achieve expected financial results or other business objectives, which could have a material negative impact on our financial condition, results of operations or the market price of our ordinary shares.

***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 of 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 U.S. Internal Revenue Code of 1986, as amended (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 becomes impaired, we could have to take significant charges against earnings.***

At December 31, 2023, we had \$83.0 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 has been impaired. Any reduction or impairment of the value of goodwill will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders’ equity in future periods.

***Our effective tax rate may increase.***

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

***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, which could have a material adverse effect on our business, financial condition, cash flows and results of operations. In December 2023, the IRS issued Notice 2024-12 that provided clarity on the application of Section 174 of the Code (“Section 174”). On this basis, we adjusted our estimate of expenses that should be capitalized and amortized which resulted in lower taxable income for the year ended December 31, 2023.

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 has transposed the corporate minimum tax rules into Irish legislation with effect as of January 1, 2024. As such, we expect a material increase in our tax expense and a material decrease in cash flows provided from operations, which could have a material adverse effect on our business, financial condition, cash flows and results of operations.

***Our deferred tax assets may not be realized.***

As of December 31, 2023, we had \$100.6 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 operating events (including clinical program progression), 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 \$100.6 million an amount of \$33.0 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.

As of December 31, 2023, we had \$94.7 million of net deferred tax assets in Ireland including \$87.5 million relating to net operating losses (“NOL”). The NOLs can be carried forward, without time limit, against trading income of the same trade in future accounting periods. The disposition of the Athlone Facility may result in (i) a significant change to the existing trade such that the same trade is no longer continued, and (ii) a complete discontinuance of the existing trade and the commencement of a new trade. We do not believe that the disposition would amount to a significant change or a discontinuance of our existing trade; however, the Irish Tax Authority could assert a contrary position, in which case we could become involved in tax controversy with the Irish Tax Authority regarding possible additional tax liabilities. If we were to be unsuccessful in resolving any such tax controversy in our favor, we could be liable for significant tax liabilities which would materially adversely affect our financial condition, cash flows 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.

***If the separation of our oncology business completed in November 2023 does not ultimately qualify as a transaction that is generally tax-free for U.S. federal and Irish tax purposes as we anticipate, we and/or our shareholders could be subject to significant tax liabilities.***

In connection with the separation of our oncology business into Mural Oncology plc completed in November 2023, we sought and received a private letter ruling from the IRS (the “IRS Ruling”) and an opinion from our U.S. tax advisor (the “U.S. Tax Opinion”) regarding U.S. federal income tax consequences of the separation, including that, among other things, the separation would be expected to generally qualify as tax-free for U.S. federal income tax purposes under Sections 368(a)(1)(D) and 355 of the Code. The IRS Ruling and/or the U.S. Tax Opinion were based on and relied on, among other things, certain facts, assumptions, representations, and undertakings from us and Mural Oncology plc, 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 Mural Oncology plc 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 the 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 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 separation, we sought and received an opinion from our Irish tax advisor (the “Irish Tax Opinion”) regarding the Irish tax consequences of the separation. The Irish Tax Opinion was based on and relied 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.

***Our level of indebtedness, and the interest-rate transition to SOFR, 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 London Interbank Offered Rate (“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”). In June 2023, we amended the 2026 Term Loans to transition the interest rate available for borrowings thereunder from a LIBOR-based interest rate to an interest rate based on SOFR and to make other confirming and mechanical changes. 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. As of December 31, 2023, our borrowings consisted of \$291.8 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 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.

***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 financing 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 disappplied by approval of the company's shareholders. In June 2023, our shareholders authorized our board of directors to allot and issue ordinary shares in an amount equal to approximately 20% of our issued ordinary share capital (as of May 15, 2023), and to issue ordinary shares for cash on a non-pre-emptive basis in an amount equal to approximately 20% of our issued share capital (as of May 15, 2023) under certain specified circumstances; however, these share issuance authorities were granted for eighteen months only, at which point they will 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 if needed, 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.

Even if we are able to finance potential transactions without seeking any external financing, expenditure of a significant amount of cash on such transactions may require difficult capital allocation decisions and may limit our ability to pursue other important business and strategic objectives, may significantly impact our financial condition and profitability and limit our potential to return capital to shareholders. As a result of these and other potential impacts, the market price of our ordinary shares may fluctuate significantly.

***Currency exchange rates may affect revenues and expenses.***

We conduct a large portion of our business in international markets. For example, we derive all of our XEPLION, TREVICTA and BYANLI revenues from sales in countries other than the U.S., and these sales are denominated in non-U.S. dollar ("USD") currencies. We also incur substantial operating costs in Ireland and face exposure to changes in the exchange ratio of the USD and the euro arising from expenses and payables at our Irish operations that are settled in Euro. Our efforts to mitigate the impact of fluctuating currency exchange rates may not be successful. As a result, currency fluctuations among our reporting currency, USD, and the currencies in which we do business will affect our results of operations, often in unpredictable ways. See "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, 2023, the closing price of our ordinary shares on the Nasdaq Global Select Market ranged from \$23.37 to \$33.63 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 and sustain profitability, the outcomes of business development transactions in which we may participate, our capital allocation decisions, and other factors, including the risk factors 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.

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.

In recent years, we engaged in extensive dialogue with principals of Elliot Investment Management L.P. and Sarissa Capital Offshore Master Fund LP and their affiliates, resulting in negotiation of settlement arrangements in 2020 and 2021 pursuant to which directors were elected to our board of directors and a contested election in 2023. The extensive interactions and activities related to our engagement with activist shareholders required the expenditure of time, energy and expense by management and our board of directors and diverted employee and management attention from business operations.

Any future activist shareholder interactions, 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, proprietary business information of ours and that of our suppliers and partners, as well as personally identifiable information of persons who use our medicines, clinical trial participants and employees. 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, the expansion of remote work, and the increased use of artificial intelligence presents new and increased 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 crime). 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, or those of our partners and third-party providers, 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.***

In the ordinary course of business, we may process personal data and other sensitive information, including proprietary and confidential business data, trade secrets, IP, data we collect about trial participants in connection with clinical trials, patient data and sensitive third-party data. Our data processing activities subjects us 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, federal and state consumer protection laws, and state health information privacy laws (for example, the California Consumer Privacy Act of 2018 and the California Privacy Rights Act of 2020), govern the collection, use, disclosure, and protection of personal information. Such federal and state laws and regulations may require businesses to provide specific disclosures and implement processes to permit individuals to exercise certain privacy rights, which in each case could increase our potential liability, increase our compliance costs, and affect our ability to collect and use personal information. The privacy regulation landscape is rapidly evolving, and any changes to existing legislation or adoption of new state or federal regulations may further complicate compliance efforts and further increase legal risk and compliance costs for us and the third parties upon whom we rely. In addition, each of these current and potential future laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and the third parties upon whom we rely. 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 adopt 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

***A future pandemic, epidemic or outbreak of an infectious disease, may materially and adversely affect our business, financial condition and results of operations.***

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. For example, the COVID-19 pandemic, which impacted the operation of healthcare systems, global travel, supply and labor markets and other business and economic activity worldwide, had 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—were adversely impacted as a result of COVID-19-related restrictions, labor shortages and other developments that transpired, many of which contributed to limited access to, or reduced willingness to access, healthcare providers and locations where injectable medications may be administered.

In addition, the COVID-19 pandemic disrupted, to varying degrees, 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. Any prolonged material disruption to the third parties on which we rely could negatively impact our ability to conduct our clinical development, manufacturing or other business activities 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 also impacted, at various stages of the pandemic, the regulatory agencies with which we interact in the development, manufacture, regulatory review and commercialization of our medicines, including the FDA, the HPRC and other regulatory agencies. Any disruptions to these agencies can 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.

Although the acute COVID-19 public health emergency has lapsed, we will continue to monitor its long-term impacts, including impacts on market practices and on the labor market, and adjust our policies and practices as needed to mitigate any adverse impacts to our business operations and financial condition. We will also work with our internal teams and the third-parties on which we rely to assess, and seek to mitigate, the potential impacts on our business operations and financial condition of any future outbreaks of contagious diseases or other adverse public health developments that may emerge from time to time.

***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.

***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 IP, 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.

### **Going Concern**

Our 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, our board of directors has taken account of current and anticipated trading performance, recognizing the impact of the current macroeconomic environment, together with the current and anticipated levels of net debt and the availability of the committed borrowing facilities. Our forecasts and projections, taking account of reasonably possible changes in trading performance, show that we should be able to operate within the level of our current facilities. After making enquiries, our board of directors has 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 potential 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 believe we can benefit from our core competencies and global infrastructure. We plan to allocate resources to support products that are fast-growing, and present high-margin opportunities in areas for which we have developed or may be able to develop a competitive advantage. In fiscal year 2024, as we are now a pure-play, profitable neuroscience company, we expect that we will continue our work to develop innovative medicines for people living with difficult-to-treat psychiatric and neurological disorders, which may lead to the acquisition or divestiture of assets and/or businesses.

In December 2023, we announced that we entered into a definitive agreement to sell the Athlone Facility to Novo and that we plan to enter into subcontracting arrangements to continue certain development and manufacturing activities currently performed at the Athlone Facility for a period of time after the closing of the transaction, which may continue through the end of 2025. See Note 1, *Description of Business* within the "Notes to Consolidated Financial Statements" in this Directors' Report for additional information regarding such planned transaction.

### **Accounting Records**

Our 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 our 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 documents are available on the Investors page of the Company's website at [www.alkermes.com](http://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, 2023 are set out below.

<b><u>Directors</u></b>	<b><u>Date of Service as a Director or Secretary</u></b>
Emily Peterson Alva	(Reappointed June 29, 2023)
Shane M. Cooke	(Reappointed June 29, 2023)
David A. Daglio, Jr.	(Reappointed June 14, 2021)
Richard B. Gaynor, M.D.	(Reappointed June 29, 2023)
Cato T. Laurencin, M.D., Ph.D.	(Reappointed June 29, 2023)
Brian P. McKeon	(Reappointed June 29, 2023)
Richard F. Pops	(Reappointed June 29, 2023)
Nancy L. Snyderman, M.D.	(Reappointed June 14, 2021)
Frank A. Wilson	(Reappointed June 14, 2021)
Christopher I. Wright, M.D., Ph.D.	(Reappointed June 29, 2023)
Nancy J. Wysenski	(Resigned effective December 8, 2023)

## **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)

	<b>Number</b>	<b>Value</b>
January 1, 2023	4,574,184	\$ 160,862
Acquired during the year	1,015,034	28,474
December 31, 2023	<u>5,589,218</u>	<u>\$ 189,336</u>

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, 2023, the shares acquired represented 3.2% of the total ordinary shares issued and outstanding of the Company (at December 31, 2022: 2.7%).

## **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, 2022: none). We anticipate that we will generally retain earnings 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 26, *Directors' Remuneration*, of the accompanying consolidated financial statements. The interests of the directors and secretary in office at January 1 and December 31, 2023 in the ordinary share capital of Alkermes plc are shown in the table below.

	Ordinary Shares <sup>(1)</sup> At December 31, 2023			Ordinary Shares <sup>(1)</sup> At January 1, 2023		
	Shares	Options <sup>(2)</sup>	Restricted Share Units <sup>(2)</sup>	Shares	Options	Restricted Share Units
<b>Directors</b>						
Emily Peterson Alva	19,722	65,112	9,975	12,311	51,105	13,548
Shane M. Cooke	96,977	363,699	6,104	94,118	458,838	5,957
David A. Daglio, Jr.	99,696	72,092	10,637	90,724	57,949	14,847
Richard B. Gaynor, M.D.	20,356	140,039	6,104	15,829	124,563	5,957
Cato T. Laurencin, M.D., Ph.D.	15,169	52,006	10,267	7,479	43,693	14,120
Brian P. McKeon	29,696	72,092	10,637	20,724	57,949	14,847
Richard F. Pops	1,052,881	3,073,016	608,762	968,299	3,027,897	587,462
Nancy L. Snyderman, M.D.	20,783	165,233	6,104	16,256	149,263	5,957
Frank A. Wilson	20,356	140,039	6,104	15,829	124,563	5,957
Christopher I. Wright, M.D., Ph.D.	7,269	43,627	12,706	—	30,041	16,039
Nancy J. Wysenski	36,237	184,613	—	27,071	234,513	5,957
<b>Company Secretary</b>						
David J. Gaffin	127,950	780,975	171,860	97,766	675,057	155,180

- (1) All interests declared are in the ordinary shares of \$0.01 par value of Alkermes plc.
- (2) The options and restricted share units outstanding as of December 31, 2023 reflect adjustments made to outstanding awards in connection with the Separation (and in accordance with the Company's equity compensation plans) in order to preserve the intrinsic value associated with the awards prior to and following the Separation.

## **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 2023.

## **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 28, *Subsidiaries*, to the accompanying 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 2024 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 32-54 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 11 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 governance 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 Corporate Governance page of the Investors section of the Company's website at [www.alkermes.com](http://www.alkermes.com). Our most recently published Corporate Responsibility Report is available on the Responsibility section of the Company's website at [www.alkermes.com](http://www.alkermes.com). All references to such report and policies in this Non-Financial Statement refer to the versions of such policies and reports available on our website as of the date of this Directors' Report.

### **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 maintain a culture of sustainability throughout the organization and work collaboratively across internal stakeholder groups and functions to identify ways to reduce our environmental impact, including those related to resource use, waste management and climate change.

Alkermes is committed to operating in a manner 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.

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; human rights, 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 and Greenhouse Gas Emissions

Alkermes recognizes the serious environmental, economic and societal impacts caused by climate change. 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 and processed 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 group 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.

#### 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. We strive to reduce our generation of waste at each source and assess opportunities for circularity—a production and consumption model which involves reusing, repairing, refurbishing and recycling existing materials and products to keep materials within the economy. In addition, 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 impact. 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. In addition, we provide employees with training, support and resources to allow them to succeed in their work environments while appropriately balancing their professional and personal lives. Beyond our employee initiatives, we are committed to broader social engagement through local community support and 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 the disease areas that our medicines are designed to treat, 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 recent years, we have adapted our remote work policies to allow more flexibility to our employees. As many of our employees have adopted hybrid work models, employee engagement has remained a top priority for the Company. In 2023, we continued to enhance our internal interactive communication channels and increased the number of in-person trainings, employee town halls and social events to keep employees feeling connected, motivated, supported and informed.

### *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 and programs 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 are: Limitless, a network to support people impacted by disability or illness; Mosaic, a multicultural network; Operation Salute, a veterans’ network; Pride@Work, an LGBTQ+ and allies 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, learning 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. Beginning 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, development and engagement. Additionally, as part of our continued focus on social and racial justice, diversity and inclusion, we have held company-wide town hall conversations, sponsored social, educational and recognition events, supported mentoring and internship opportunities and enhanced our Company’s diversity education and awareness training.

We remain committed to cultivating and supporting the advancement of a diverse workforce. We have established a women’s mentoring program to provide internal resources for the continued development of our female talent pool, focused on early-stage leaders. 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 Conexión 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 onboarding 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 2023, we continued function- and site-specific mentoring programs, conducted open forums with leaders, created employee focused information resources connected to major initiatives occurring at the Company 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 and community engagement are core to our mission. We regularly engage with policymakers and leaders in the patient advocacy community to better understand their perspectives and goals and the complex care systems for individuals living with complex neurological and psychiatric disorders. Learnings from these interactions help to inform our

business activities, including with respect to clinical trials, policy and advocacy. We actively seek input from patients and advocates early in our drug development process to help identify unmet patient needs and inform our research. These engagement efforts help us design clinical trials and programs with specific patient outcomes in mind. We continue to consult with patients during the drug development process and beyond, so that patient perspectives continue to inform the development and lifecycle management of our products.

#### *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 employee volunteer support.

#### *Sponsorships*

We foster and maintain relationships with a variety of health-related and public policy organizations in our local communities.

#### *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<sup>®</sup> program has awarded more than \$5 million in funding to innovative programs that support the needs of people impacted by addiction, serious mental illness and cancer. In 2023, grants were awarded to 11 nonprofit organizations working to address the needs of people living with these complex conditions, with a focus on unmet needs in historically under-resourced or underrepresented communities with longstanding and widespread health disparities. Since 2018, our ALKERMES PATHWAYS RESEARCH AWARDS<sup>®</sup> program has provided funding to 23 researchers working to advance our understanding of diseases in the field of neuroscience.

#### *United States*

We are committed to giving back to our communities. Since 2008, many of our employees have volunteered each year as part of our Alkermes in Action volunteer program. In 2023, we celebrated the 15th anniversary of this volunteer program with in-person events across our sites to support local organizations focused on education, caring for veterans, maintaining outdoor community spaces and providing for 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 housing insecurity, 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, potential 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](http://www.alkermes.com).

**Directors' Compliance Statement**

As required by Section 225(2) of the Companies Act 2014, 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 2023, 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*

March 28, 2024

## 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 (each such term as defined below) assets, liabilities and financial position and of the profit or loss of the Group for the financial year. Under that law the directors have prepared the accompanying 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 accompanying 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 this Directors' Report and Consolidated Financial Statements included on the Company's website at [www.alkermes.com](http://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 2023 and of the group's profit 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 2023;
- the Parent Company Balance Sheet as at 31 December 2023;
- the Consolidated Profit and Loss Account and Consolidated Statement of Comprehensive Profit and 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 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 requirements.

### **Our audit approach**

#### *Overview*

	<p>Overall materiality</p> <ul style="list-style-type: none"><li>• \$11.1 million (2022: \$8.1 million) - Consolidated financial statements.</li><li>• Based on c. 5% of profit before tax from continuing operations, adjusted for the non-recurring back royalties and associated interest (2022: c. 0.75% of turnover).</li><li>• \$29.5 million (2022: \$31.6 million) - Parent company financial statements.</li><li>• Based on c. 1% of net assets.</li></ul> <p>Performance materiality</p> <ul style="list-style-type: none"><li>• \$8.3 million (2022: \$6.1 million) - Consolidated financial statements.</li><li>• \$22.1 million (2022: \$23.7 million) - Parent company financial statements.</li></ul>
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	<p>Audit scope</p> <ul style="list-style-type: none"> <li>• The group has one reportable segment consisting of two primary geographic reporting components – United States (“US”) and Ireland.</li> <li>• We conducted full scope audits on both reporting components.</li> </ul>
	<p>Key audit matters</p> <ul style="list-style-type: none"> <li>• Rebate Accruals - Medicaid Drug Rebate Program.</li> <li>• Tax-Free Determination of the Separation of the Oncology Business.</li> </ul>

### *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.

<b><i>Key audit matter</i></b>	<b><i>How our audit addressed the key audit matter</i></b>
<p><b><i>Rebate Accruals - Medicaid Drug Rebate Program</i></b></p> <p>Refer to Note 2 "Summary of significant accounting policies - Turnover from Contracts with Customers" and Note 18 "Provisions for liabilities" to the consolidated financial statements.</p> <p>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.</p> <p>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, 2023, total accrued Medicaid rebates amounted to \$213.8 million of which a significant amount related to the Medicaid Drug Rebate Program.</p> <p>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.</p> <p>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.</p>	<p>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.</p> <p>We assessed the appropriateness of management’s methodology used to determine the accruals for the Medicaid Drug Rebate Program.</p> <p>We assessed the reasonableness of management’s estimate of the rebate accruals for the Medicaid Drug Rebate Program by:</p> <p>(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;</p> <p>(ii) comparing the independent estimate to management’s estimate; and</p> <p>(iii) testing rebate claims processed by the Company.</p> <p>We considered the historical accuracy of the accrual for the Medicaid Drug Rebate Program.</p>

<i>Key audit matter</i>	<i>How our audit addressed the key audit matter</i>
<p><i>Tax-Free Determination of the Separation of the Oncology Business</i></p> <p>Refer to Note 1 “Description of Business” and Note 3 “Discontinued Operations” to the consolidated financial statements.</p> <p>The group completed the separation of its oncology business which was affected by means of a distribution of shares in Mural Oncology plc to the company's shareholders.</p> <p>Management determined that the separation and related distribution qualified as tax-free for U.S. federal income tax purposes, which required significant judgement by management.</p> <p>In making such determinations, management applied U.S. federal tax law to relevant facts and circumstances and obtained:</p> <p>(i) a favourable private letter ruling from the IRS;</p> <p>(ii) an external tax opinion; and</p> <p>(iii) other tax advice related to the understanding and application of tax laws and regulations relevant to this transaction.</p> <p>If the separation and distribution were to fail to qualify for tax-free treatment for U.S. federal income tax purposes, the Company and/or its shareholders could be subject to significant liabilities.</p> <p>We determined the Tax-Free Determination of the Separation of the Oncology Business to be a key audit matter due to the significant judgement by management with regards to interpretation of the facts and the application of tax laws and regulations in concluding that the divestiture qualifies as a tax-free transaction.</p>	<p>We tested the effectiveness of controls relating to the key judgements in management’s evaluation of the tax treatment of the transaction.</p> <p>We assessed the reasonableness of management’s judgements and evaluation of the tax treatment of the transaction by:</p> <p>(i) evaluating the information used in management’s determination, such as tax rulings from relevant taxing authorities and supporting information, the external tax opinion, and relevant tax laws and regulations, and</p> <p>(ii) evaluating the reasonableness of management’s position that the transaction qualifies for tax-free treatment. Professionals with specialised skill and knowledge were used to assist in evaluating the transaction, the application of tax laws and regulations, the private letter ruling and tax opinion, and related representations from management.</p>

### *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 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 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 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:

	<i>Consolidated financial statements</i>	<i>Parent company financial statements</i>
<i>Overall materiality</i>	\$11.1 million (2022: \$8.1 million).	\$29.5 million (2022: \$31.6 million).
<i>How we determined it</i>	c. 5% of profit before tax from continuing operations, adjusted for the non-recurring back royalties and associated interest (2022: c. 0.75% of turnover).	c. 1% of net assets.
<i>Rationale for benchmark applied</i>	In the current year, given the separation of the oncology business and the resumption of royalty revenue from Janssen related to the U.S. sales of the long acting INVEGA products we believe profit before tax from continuing operations adjusted for non-recurring back royalties and associated interest is the most appropriate benchmark. In the prior year, we deemed turnover to be an appropriate benchmark having regard to the volatility in the loss before tax in prior years.	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 \$11.1 million (2022: \$8.1 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 \$8.3 million (group audit) and \$22.1 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 \$0.83 million (group audit) (2022: \$0.61 million) and \$1.5 million (parent company audit) (2022: \$1.6 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 and 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; and
- Considering available financing and maturity profile and the covenants attaching to long term debt to assess liquidity for the going concern assessment period.

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 2023 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).

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## **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 64, 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:

- Inquiries with the Audit & Risk Committee, management and Chief Legal Officer including any 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 auditor, 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 by challenging assumptions made by management in its significant accounting estimates and judgements, particularly in relation to the key audit matters;
- 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.

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](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.

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## **Other required reporting**

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### **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.

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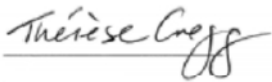
### **Other exception reporting**

#### *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  
28 March 2024

- The maintenance and integrity of the Alkermes Plc 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,	
		2023	2022
		(In thousands, except per share amounts)	
Product sales, net	4	\$ 919,998	\$ 777,552
Manufacturing and royalty turnover	4	743,388	331,983
License turnover		—	2,000
Research and development turnover		19	260
Total turnover		1,663,405	1,111,795
Cost of sales		253,037	218,068
Gross profit from continuing operations		1,410,368	893,727
Research and development expense		270,806	272,702
Selling, general and administrative expense		689,751	590,751
Amortization of acquired intangible assets	6	35,689	36,363
Operating profit (loss) from continuing operations		414,122	(6,089)
Interest income		30,854	7,629
Interest expense	7	(23,032)	(13,040)
Change in the fair value of contingent consideration	8	—	(2,642)
Other income, net		(425)	2,122
Total other (expense) income, net		7,397	(5,931)
Profit (loss) before income taxes from continuing operations		421,519	(12,020)
Income tax benefit (provision)	9	97,638	(2,024)
Profit (loss) after income taxes from continuing operations		519,157	(14,044)
Discontinued operations, net of tax		(163,400)	(125,115)
Net profit (loss)		\$ 355,757	\$ (139,159)
<b>EARNINGS (LOSS) PER ORDINARY SHARE:</b>			
Earnings (loss) per share from continuing operations - basic	10	\$ 3.12	\$ (0.09)
Earnings (loss) per share from discontinued operations - basic	10	\$ (0.98)	\$ (0.76)
Earnings (loss) per share - basic	10	\$ 2.14	\$ (0.85)
Earnings (loss) per share from continuing operations - diluted	10	\$ 3.06	\$ (0.09)
Earnings (loss) per share from discontinued operations - diluted	10	\$ (0.96)	\$ (0.76)
Earnings (loss) per share - diluted	10	\$ 2.10	\$ (0.85)
<b>WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:</b>			
Basic	10	166,223	163,742
Diluted	10	169,730	163,742

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

**ALKERMES PLC**  
**CONSOLIDATED STATEMENT OF COMPREHENSIVE PROFIT AND LOSS**

	<u>Year Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
	<u>(In thousands, except per share amounts)</u>	
NET PROFIT (LOSS)	\$ 355,757	\$ (139,159)
Unrealized (losses) gains on marketable securities:		
Unrealized (losses) gains, net of tax	7,779	(7,166)
Unrealized (losses) gains on marketable securities	7,779	(7,166)
COMPREHENSIVE PROFIT (LOSS)	<u>\$ 363,536</u>	<u>\$ (146,325)</u>

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



**ALKERMES PLC**  
**CONSOLIDATED BALANCE SHEET**

	<u>Notes</u>	<u>December 31, 2023</u>	<u>December 31, 2022</u>
(In thousands, except share and per share amounts)			
<b>ASSETS</b>			
<i>Fixed Assets</i>			
Intangible assets—Goodwill	6	\$ 83,027	\$ 83,027
Intangible assets—Intellectual property	6	1,991	37,680
Assets related to discontinued operations—long-term	3	—	37,763
Assets held for sale—long-term		—	93,871
Tangible assets	11, 12	318,403	320,458
Financial assets	6, 15	47,444	139,482
Total fixed assets		<u>450,865</u>	<u>712,281</u>
<i>Current Assets</i>			
Stock	13	186,406	181,418
Debtors	14	631,201	459,490
Assets related to discontinued operations	3	—	2,324
Assets held for sale		94,260	—
Investments	15	316,022	315,992
Cash at bank and in-hand		457,469	292,473
Total current assets		<u>1,685,358</u>	<u>1,251,697</u>
TOTAL ASSETS		<u>\$ 2,136,223</u>	<u>\$ 1,963,978</u>
<b>LIABILITIES AND RESERVES</b>			
<i>Capital and Reserves</i>			
Called-up share capital presented as equity	16	\$ 1,726	\$ 1,690
Share premium		365,494	642,530
Profit and loss account		13,809	(341,948)
Treasury shares	16	(189,336)	(160,862)
Other reserves		1,010,993	902,343
Total equity		<u>1,202,686</u>	<u>1,043,753</u>
<i>Provisions for liabilities</i>	18	287,322	265,612
<i>Liabilities related to discontinued operations—long-term</i>	3	—	13,542
<i>Creditors</i>			
Debt	7, 12	372,185	379,435
Creditors	19	274,030	255,792
Liabilities related to discontinued operations		4,542	5,844
Total for creditors		<u>646,215</u>	<u>641,071</u>
TOTAL LIABILITIES		<u>\$ 2,136,223</u>	<u>\$ 1,963,978</u>

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

The consolidated financial statements were approved by the board and signed on its behalf on March 28, 2024 by:

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

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

**ALKERMES PLC**  
**CONSOLIDATED STATEMENT OF CASH FLOWS**

	<u>Year Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
	(In thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Loss after tax	\$ 355,757	\$ (139,159)
Adjustments to reconcile net loss to after tax to cash flows from operating activities:		
Depreciation and amortization	74,927	77,862
Share-based compensation expense	100,905	94,254
Deferred income taxes	(99,902)	(32,795)
Change in the fair value of contingent consideration	—	2,642
Other non-cash charges	6,329	5,531
Changes in assets and liabilities, excluding the effect of acquisitions:		
Trade receivables	(44,510)	25,250
Contract assets	8,223	4,434
Stock	(2,712)	(31,021)
Prepaid expenses and other assets	(34,847)	(5,328)
Right-of-use assets	15,387	16,569
Creditors	34,535	30,433
Contract liabilities	(5,926)	(7,129)
Operating lease liabilities	(16,147)	(33,225)
Other long-term liabilities	9,334	12,726
Cash flows provided by operating activities	<u>401,353</u>	<u>21,044</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Additions to property, plant and equipment	(48,048)	(38,255)
Proceeds from the sale of equipment	354	—
Proceeds from contingent consideration	—	1,273
Return of Fountain Healthcare Partners II, L.P. investment	—	485
Purchases of investments	(254,471)	(309,671)
Sales and maturities of investments	355,522	281,627
Cash flows provided by (used in) investing activities	<u>53,357</u>	<u>(64,541)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Cash transferred to Mural Oncology plc at separation	(275,000)	—
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	16,760	19,630
Employee taxes paid related to net share settlement of equity awards	(28,474)	(18,204)
Proceeds from the issuance of long-term debt	—	—
Principal payments of long-term debt	(3,000)	(3,000)
Payment made in connection with debt refinancing	—	—
Cash flows used in financing activities	<u>(289,714)</u>	<u>(1,574)</u>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>164,996</b>	<b>(45,071)</b>
<b>CASH AND CASH EQUIVALENTS—Beginning of period</b>	<b>292,473</b>	<b>337,544</b>
<b>CASH AND CASH EQUIVALENTS—End of period</b>	<b>\$ 457,469</b>	<b>\$ 292,473</b>
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>		
Cash paid for interest	\$ 22,748	\$ 13,563
Cash paid for taxes	\$ 44,243	\$ 20,749
Non-cash investing and financing activities:		
Purchased capital expenditures included in creditors	\$ 2,645	\$ 2,950

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

**ALKERMES PLC**

**CONSOLIDATED RECONCILIATION OF MOVEMENT IN SHAREHOLDERS' FUNDS**

<b>(In thousands)</b>	<b>Share Capital</b>	<b>Share Premium</b>	<b>Profit and Loss Account</b>	<b>Treasury Shares</b>	<b>Other Reserves</b>	<b>Total</b>
BALANCE — January 1, 2022	\$ 1,658	\$ 622,932	\$ (202,789)	\$ (142,658)	\$ 814,333	\$ 1,093,476
Net loss	—	—	(139,159)	—	—	(139,159)
Other comprehensive income	—	—	—	—	(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 for the purchase of stock options or 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
Net income	—	—	355,757	—	—	355,757
Distribution of Mural Oncology plc	—	(293,760)	—	—	—	(293,760)
Other comprehensive income	—	—	—	—	7,779	7,779
Share-based payment reserve	—	—	—	—	100,871	100,871
Shares issued under employee stock plans	36	16,724	—	—	—	16,760
Receipt of Alkermes' shares to satisfy minimum tax withholding obligations related to share-based awards	—	—	—	(28,474)	—	(28,474)
BALANCE — December 31, 2023	<u>\$ 1,726</u>	<u>\$ 365,494</u>	<u>\$ 13,809</u>	<u>\$ (189,336)</u>	<u>\$ 1,010,993</u>	<u>\$ 1,202,686</u>

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

## ALKERMES PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 1. DESCRIPTION OF BUSINESS

Alkermes plc (together with its consolidated subsidiaries, the “Company”) is a global biopharmaceutical company that seeks to develop innovative medicines in the field of neuroscience. The Company has a portfolio of proprietary commercial products for the treatment of alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder and a pipeline of clinical and preclinical candidates in development for neurological disorders. Headquartered in Dublin, Ireland, the Company has a research and development (“R&D”) center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio.

On November 15, 2023, the Company completed the separation of its oncology business into Mural Oncology plc (“Mural”), a new, independent, publicly-traded company (the “Separation”). The Separation was effected by means of a distribution of all of the outstanding ordinary shares of Mural to the Company’s shareholders (the “Distribution”), in which each of the Company’s shareholders received one ordinary share, nominal value \$0.01 per share, of Mural for every ten ordinary shares, par value \$0.01 per share, of the Company (the “Distribution Ratio”) held by such shareholder as of the close of business on November 6, 2023, the record date for the Distribution (the “Record Date”). The historical results of the oncology business have been reflected as discontinued operations in the Company’s consolidated financial statements through November 15, 2023 (the “Separation Date”). For additional information related to the Separation, see Note 3, *Discontinued Operations* in these “Notes to Consolidated Financial Statements” in this Directors’ Report.

On December 14, 2023 the Company announced that it entered into a definitive agreement to sell its development and manufacturing facility located in Athlone, Ireland (the “Athlone Facility”) to Novo Nordisk (“Novo”) and plans to enter into subcontracting arrangements to continue certain development and manufacturing activities currently performed at the Athlone Facility for a period of time after the closing of the transaction, which arrangements may continue through the end of 2025. Such transaction is expected to close in mid-2024, subject to certain closing conditions. At December 31, 2023, the Company had classified the assets described under the related asset purchase agreement as “Assets held for sale” within the accompanying consolidated balance sheet.

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, 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

## ALKERMES PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

##### *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. Columns and rows within tables may not sum due to rounding.

##### *Reclassification*

The Company has presented its former oncology business as discontinued operations in its consolidated financial statements for all periods presented. See Note 3, *Discontinued Operations* in these “Notes to Consolidated Financial Statements” in this Directors’ Report for additional information. Additionally, as a result of the planned sale of the Athlone Facility, the Company has classified the assets described under the related asset purchase agreement as held for sale. The Company’s historical financial statements and footnotes have been recast accordingly.

##### *Discontinued Operations*

The Company determined that the separation of its oncology business in November 2023 met the criteria for classification of the oncology business as discontinued operations in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 205, *Discontinued Operations*. Accordingly, the consolidated financial statements have been updated to present the assets and liabilities associated with the oncology business as discontinued operations as of December 31, 2022 on the accompanying consolidated balance sheets, and the results of the oncology business as discontinued operations through the Separation Date for the years ended December 31, 2023 and 2022 in the consolidated statements of profit (loss).

##### *Assets Held for Sale*

In connection with the planned sale of the Athlone Facility, the Company reviewed FASB ASC 805, *Business Combinations* and, based on the definitions therein, has determined that the Athlone Facility constitutes a business. Accordingly, the assets associated with the planned sale of the Athlone Facility have been classified as “Assets held for sale” within the accompanying consolidated balance sheets as of December 31, 2023 and 2022.

##### *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, 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 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 at bank and in-hand at cost plus accrued interest, which the Company believes approximates their market value. The Company considers as 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

*Investments*

The Company has investments in various types of securities, consisting primarily of 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, 2023, 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, 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) the Company has determined that it is more likely than not that it 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 "Investments—long-term," in the accompanying consolidated balance sheets.

*Fair Value of Financial Instruments*

The Company's financial assets and liabilities are recorded at fair value and are classified as Level 1, 2 or 3 within the fair value hierarchy, as described in the accounting standards for fair value measurement. At December 31, 2023, the Company's financial assets consisted of cash equivalents and investments and are classified within the fair value hierarchy as follows:

- *Level 1*—these valuations are based on a market approach using quoted prices in active markets for identical assets. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 1 inputs at December 31, 2023 included U.S. treasury securities, marketable securities classified as cash equivalents and a fixed term deposit account; and
- *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, 2023 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.

The carrying amounts reflected in the accompanying 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 statement of profit (loss).

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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

***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.

When some, but not all, of a reporting unit is to be disposed of, the accounting for that reporting unit's goodwill will depend on whether the disposal group constitutes a business. If the disposal group constitutes a business, the Company attributes a portion of the reporting unit's goodwill to the disposal group based on the relative fair values of: (i) the disposal group; and (ii) the portion of the reporting unit that will be retained.

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 accompanying 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

*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.

*Turnover from Contracts with Customers*

The Company recognizes turnover in accordance with FASB 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<sup>®</sup>, ARISTADA<sup>®</sup> and ARISTADA INITIO<sup>®</sup> and LYBALVI<sup>®</sup>, 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 revenues recognized will not occur in a future period. Actual amounts may ultimately differ from the Company’s estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment. The following are the Company’s significant categories of sales discounts and allowances:

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



## ALKERMES PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

- *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. To date, actual product returns have not differed materially from the Company's estimates; 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. To date, actual Medicare Part D rebates have not differed materially from the Company's estimates.

#### Collaborative Arrangements

The Company has entered into collaborative arrangements 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<sup>®</sup>/XEPLION<sup>®</sup>, INVEGA TRINZA<sup>®</sup>/TREVICTA<sup>®</sup>, INVEGA HAFYERA<sup>®</sup>/BYANLI<sup>®</sup> (the "long-acting INVEGA products") and RISPERDAL CONSTA<sup>®</sup>, and Biogen Swiss Manufacturing GmbH (together with its affiliates, "Biogen") related to VUMERITY<sup>®</sup>. 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. Substantially all of the manufacturing turnover is recognized at a point in time when control of the product passes to the licensee. 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 revenues and estimated manufacturing turnover is reconciled and adjusted for in the period in which they become known, which is generally within the same quarter. The differences 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. 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.

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Certain of the Company's royalty turnover is 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 differences between the Company's actual and estimated royalty turnover have not been material to date.

*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 (expense) income, net" in the consolidated statements of profit (loss) account. During the years ended December 31, 2023 and 2022, the Company recorded a loss of \$0.5 million and a gain of \$0.7 million, respectively, on foreign currency translation.

*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 debtors, 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 debtors from the Company's customers exceeding 10% of the total in each category as of, and for the years ended, December 31, 2023 and 2022:

Customer	Year Ended December 31,			
	2023		2022	
	Receivables	Turnover	Receivables	Turnover
Janssen	23%	31%	*	15%
Biogen	9%	11%	19%	13%
Cardinal Health	24%	20%	24%	24%
AmerisourceBergen	16%	12%	18%	14%
McKesson	14%	14%	12%	16%

\* Indicates receivables for the customer did not exceed 10% of the Company's total trade receivable 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 revenues by geographic location for the years ended December 31, 2023 and 2022, as determined by the location of the customer, are as follows:

(In thousands)	Year Ended December 31,	
	2023	2022
Turnover by region:		
U.S.	\$ 1,491,939	\$ 931,991
Ireland	1,179	1,829
Rest of world	170,287	177,975

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The location of the Company's assets are as follows:

(In thousands)	December 31,	
	2023	2022 <sup>(1)</sup>
Assets by region:		
Current assets:		
U.S.:		
Assets related to discontinued operations	\$ —	\$ 2,324
Other current assets	867,588	700,240
Ireland:		
Assets held for sale	\$ 94,260	\$ —
Other current assets	523,658	427,742
Rest of world	—	—
Long-term assets:		
U.S.:		
Assets related to discontinued operations	\$ —	\$ 37,763
Other	432,870	499,038
Ireland:		
Intangible assets	\$ 1,991	\$ 37,680
Assets held for sale	—	93,871
Goodwill	83,027	83,027
Other	132,829	82,293

(1) Prior period amounts have been retrospectively adjusted to reflect assets related to discontinued operations related to the Separation and assets held for sale related to the planned sale of the Athlone Facility.

**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 preclinical 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 development programs or the Company's products or technologies in general.

**Selling, General and Administrative Expenses**

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

Advertising costs are expensed as incurred. During the years ended December 31, 2023 and 2022, advertising costs totaled \$127.6 million and \$41.4 million, respectively.

**Share-Based Compensation**

The Company's share-based compensation programs permit grants of 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"), the Company's employees may, at the discretion of the plan administrator, become eligible in certain circumstances set forth in the Plans for accelerated vesting of certain awards granted to them under the Plans. In such circumstances, if there are no effective future service requirements for such employees, the remaining fair value of any such accelerated awards would be expensed as of the date of acceleration.

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Time-Based Stock Options

Except as otherwise provided in the applicable Plan or award certificate, 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: (i) 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; and (ii) stock option grants to new non-employee directors expire ten years from the grant date and generally vest over a three-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:

	<u>Year Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
Expected option term	5 - 8 years	5 - 8 years
Expected stock volatility	40 % - 44 %	43 % - 51 %
Risk-free interest rate	3.34 % - 4.75 %	1.83 % - 4.26 %
Expected annual dividend yield	—	—

Time-Based Restricted Stock Unit Awards

Except as otherwise provided in the applicable Plan or award certificate, 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 that the final outcome of the performance criteria is determined.

## ALKERMES PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

##### Conversion and modification of equity awards outstanding at Separation date

In connection with the Separation, and in accordance with the provisions of the Alkermes Stock Option and Incentive Plans (as defined in Note 17, *Share-based Compensation*) and the terms of that certain employee matters agreement, dated as of November 13, 2023, as amended, by and between the Company and Mural (the “Employee Matters Agreement”), outstanding stock options, RSUs and performance-based RSUs were adjusted (an equitable adjustment) in order to preserve the intrinsic value of such awards immediately before and immediately after the Separation Date. Based upon the terms and the methodology set forth in the Employee Matters Agreement, one conversion ratio was calculated for awards held by current and former employees of the Company (the “Alkermes Conversion Ratio”), a second conversion ratio was calculated for stock options held by employees who transferred to Mural in connection with the Separation and a third conversion ratio was calculated for RSUs held by employees who transferred to Mural in connection with the Separation (the “Mural Conversion Ratios”).

Following the application of the Alkermes Conversion Ratio to applicable awards that were outstanding immediately before the Separation Date, the Company compared the fair value of such awards to the fair value of the awards that were outstanding immediately after the Separation Date, as adjusted, to determine whether the Company would recognize an incremental fair value adjustment related to the awards. Following this calculation, it was determined that no incremental fair value resulted from the application of the Alkermes Conversion Ratio.

Following the application of the applicable Mural Conversion Ratios to applicable awards that were outstanding immediately before the Separation Date, Mural compared the fair value of such awards to the fair value of the awards that were outstanding immediately after the Separation Date, as adjusted, to determine whether an incremental fair value adjustment was required. Following this calculation, it was determined that the fair value of the post-conversion awards held by employees who transferred to Mural increased immediately following the Separation, resulting in an incremental fair value charge as of the Separation Date. In accordance with FASB ASC 718, *Compensation—Stock Compensation*, the Company recognized a charge within share-based compensation expense of \$1.6 million, which represented the incremental fair value related to stock option awards that had vested prior to the Separation Date.

##### ***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 Profit (Loss)***

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

## ALKERMES PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

##### *Earnings (Loss) Per Share*

Basic earnings (loss) per ordinary share from continuing operations is calculated based upon net profit (loss) from continuing operations available to holders of ordinary shares divided by the weighted average number of ordinary shares outstanding. Basic loss per ordinary share from discontinued operations is calculated based upon net loss from discontinued operations available to holders of ordinary shares, divided by the weighted average number of ordinary shares outstanding. For the calculation of diluted earnings (loss) per ordinary share from continuing operations and discontinuing operations, the Company utilizes the treasury stock method and adjusts the weighted average number of ordinary shares outstanding for the potential dilutive effect of outstanding ordinary share equivalents such as stock options and RSUs.

##### *Segment Information*

The Company operates as one business segment, which is the business of developing, manufacturing and commercializing medicines designed to address unmet medical needs of patients in major therapeutic areas. The Company's chief decision maker, the Chairman and Chief Executive Officer, reviews the Company's operating results on an aggregate basis and manages the Company's operations as a single operating unit.

##### *Employee Benefit Plans*

###### 401(k) Plan

The Company maintains a 401(k) retirement savings plan (the "401(k) Plan"), which covers substantially all of its U.S.-based employees. Eligible employees may contribute up to 100% of their eligible compensation, subject to certain Internal Revenue Service ("IRS") limitations. The Company matches 100% of employee contributions up to the first 5% of employee pay, up to IRS limits. Employee and Company contributions are fully vested when made. During the years ended December 31, 2023 and 2022, the Company contributed \$15.0 million and \$14.4 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, 2023 and 2022, the Company contributed \$5.6 million and \$5.1 million, respectively, in contributions to the Defined Contribution Plan.

##### *New Accounting Pronouncements*

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

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosure*, which requires disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items to reconcile to segment profit or loss and the title and position of the Company's chief operating decision maker. The amendments in this guidance also expand the interim segment disclosure requirements. All disclosure requirements under this guidance are required for public entities with a single reportable segment. This ASU became effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted and the amendments in this guidance are required to be applied on a retrospective basis. The Company is currently evaluating the potential impact this ASU will have on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, to enhance the transparency and decision usefulness of income tax disclosures in order to provide information to assist key stakeholders in better assessing how the Company's operations and related tax risks and tax planning and operational opportunities affect the Company's tax rate and prospects for future cash flows. This ASU becomes effective for public companies for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. This guidance will be applied on a prospective basis. The Company is currently evaluating the impact this ASU will have on its consolidated financial statements and related disclosures.

**ALKERMES PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. DISCONTINUED OPERATIONS**

***Mural Oncology Separation***

On November 15, 2023, the Company completed the Separation. In connection with the Separation, the Company entered into a separation agreement with Mural, dated as of November 13, 2023, that, among other things, sets forth the Company's agreements with Mural regarding the principal actions taken or to be taken in connection with the Separation, including the Distribution. The separation agreement identified those assets to be transferred to, liabilities to be assumed by and contracts to be assigned to Mural, including the operating lease for the office and laboratory space at 852 Winter Street in Waltham, Massachusetts, as part of the Separation, and it provided for when and how such transfers, assumptions and assignments were to occur. The purpose of the separation agreement was to provide Mural and the Company with those assets necessary to operate their respective businesses and to retain or assume the respective liabilities related to those assets.

Under the terms of the separation agreement, the Company granted Mural a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to IP controlled by the Company as of the date of the Distribution to allow Mural to use such IP for the oncology business, and Mural granted the Company a perpetual, worldwide, non-exclusive, royalty-free, fully paid-up license (or, as the case may be, sublicense) to IP transferred to Mural as part of the Separation for the Company's use outside of the oncology business.

Each of Mural and the Company agreed to releases with respect to pre-Distribution claims, and cross-indemnities with respect to post-Distribution claims, that are principally designed to place financial responsibility for the obligations and liabilities allocated to Mural under the separation agreement with Mural, and financial responsibility for the obligations and liabilities allocated to the Company under the separation agreement with the Company. The Company and Mural are also each subject to mutual six-month employee non-solicitation and non-hire restrictions, subject to certain customary exceptions, and certain confidentiality restrictions and information sharing obligations.

The transfer of assets and liabilities to Mural was effected through a contribution in accordance with the separation agreement, as summarized below:

(In thousands)	November 15, 2023
<b>ASSETS</b>	
<i>Fixed Assets</i>	
Intangible assets—Goodwill	\$ 7,800
Tangible assets	24,609
Total fixed assets	32,409
<i>Current Assets</i>	
Debtors	1,799
Cash at bank and in-hand	275,000
Total Assets	\$ 309,208
<b>LIABILITIES</b>	
<i>Creditors</i>	
Debt	\$ 15,448
Net Assets Transferred to Mural	\$ 293,760

The Company determined that the Separation and related Distribution qualified as tax-free for U.S. federal income tax purposes, which required significant judgment by management. In making such determinations, the Company applied U.S. federal tax law to relevant facts and circumstances and obtained: (i) a favorable private letter ruling from the IRS; (ii) a tax opinion; and (iii) other external tax advice related to the concluded tax treatment. If the Separation and Distribution were to ultimately fail to qualify for tax-free treatment for U.S. federal income tax purposes, the Company and/or its shareholders could be subject to significant liabilities, which could have material adverse impacts on the Company's business, financial condition, results of operations and cash flows in future reporting periods. Furthermore, other than taxes recorded on the transfer of IP, the Company determined that the Separation and related Distribution qualified as tax-free for Irish tax purposes, which required significant judgment by management. In making such determinations, the Company applied Irish tax law to relevant facts and circumstances and obtained: (i) a tax opinion; and (ii) other external tax advice related to the concluded tax treatment. If the Separation and Distribution were to ultimately fail to qualify for tax-free treatment for Irish tax purposes, the Company and/or its shareholders could be subject to significant liabilities, which could have material adverse impacts on the Company's business, financial condition, results of operations and cash flows in future reporting periods.



**ALKERMES PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. DISCONTINUED OPERATIONS (Continued)**

In connection with the Separation, the Company also entered into a tax matters agreement with Mural, dated as of November 13, 2023. The tax matters agreement governs the Company’s and Mural’s respective rights, responsibilities and obligations with respect to taxes (including taxes arising in the ordinary course of business and taxes, if any, incurred as a result of any failure of the Distribution, together with certain related transactions, to qualify as tax-free for U.S. federal income tax purposes), tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings, and assistance and cooperation in respect of tax matters.

In connection with the Separation, the Company also entered into the Employee Matters Agreement. The Employee Matters Agreement, as amended, governs the Company’s, Mural’s and their respective subsidiaries’ and affiliates’ rights, responsibilities and obligations after the Separation with respect to, employment, benefits and compensation matters relating to employees and former employees (and their respective dependents and beneficiaries) who are or were associated with the Company, including those who became employees of Mural in connection with the Separation; the allocation of assets and liabilities generally relating to employees, employment or service-related matters and employee benefit plans; other human resources, employment and employee benefits matters; and the treatment of equity-based awards granted by the Company prior to the Separation.

The Company entered into two transition services agreements with Mural. On November 13, 2023, Alkermes, Inc., a wholly-owned subsidiary of the Company (“Alkermes US”), and Mural Oncology, Inc., a wholly-owned subsidiary of Mural (“Mural US”), entered into one transition services agreement, pursuant to which the Company and its subsidiaries will provide, on an interim, transitional basis, various services to Mural and its subsidiaries, and a second transition services agreement, pursuant to which Mural and its subsidiaries will provide certain services to the Company and its subsidiaries, in each case for a term of two years, unless earlier terminated in accordance with the terms of the applicable agreement. As of December 31, 2023, the Company had an immaterial amount of accounts receivable and accounts payable due from and to Mural related to such transition services agreements.

***Discontinued Operations***

The results of the oncology business and transaction costs related to the Separation have been reflected as “Loss from discontinued operations, net of taxes” in the consolidated statement of profit (loss) account through the Separation Date. Prior periods have been recast to reflect this presentation. The transaction costs related to the Separation were \$36.0 million during 2023 and \$1.4 million during 2022, and primarily relate to professional fees for separation activities within the finance, tax, legal and information technology functions. As of December 31, 2022, the assets and liabilities associated with the oncology business are classified as “Assets held for discontinued operations” and “Liabilities related to discontinued operations” in the accompanying consolidated balance sheet.

The following table summarizes expenses of the discontinued operations for the years ended December 31, 2023 and 2022:

(In thousands)	Year Ended December 31,	
	2023	2022
Operating expenses from discontinued operations		
Cost of goods manufactured	\$ 39	\$ 40
Research and development	116,177	121,140
Selling, general and administrative	48,587	14,996
Total operating expenses from discontinued operations	164,803	136,176
Operating loss from discontinued operations	(164,803)	(136,176)
Income tax benefit from discontinued operations	1,403	11,061
Net loss and comprehensive loss from discontinued operations	\$ (163,400)	\$ (125,115)



ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. DISCONTINUED OPERATIONS (Continued)

There were no assets and \$4.5 million of liabilities related to the Separation as of December 31, 2023. All assets were transferred to Mural as of the Separation Date. The \$4.5 million of liabilities classified as “Liabilities related to discontinued operations” in the accompanying consolidated balance sheet relates to bonus amounts accrued for employees that transferred to Mural during 2023 through the Separation Date that will be paid by the Company, in accordance with the terms of the Employee Matters Agreement. The following table summarizes the assets and liabilities related to Mural that have been classified as assets and liabilities from discontinued operations in our accompanying consolidated balance sheet as of December 31, 2022:

(In thousands)	December 31, 2022	
<b>ASSETS</b>		
<i>Fixed Assets</i>		
Intangible assets—Goodwill	\$	7,800
Tangible assets		28,933
Total fixed assets		<u>36,733</u>
<i>Current Assets</i>		
Debtors		3,354
Total Assets	\$	<u>40,087</u>
<b>LIABILITIES</b>		
<i>Creditors</i>		
Debt	\$	19,386
Total liabilities	\$	<u>19,386</u>

The following table summarizes the significant non-cash items and capital expenditures of the discontinued operations that are included in the consolidated statements of cash flows for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
(In thousands)		
<b>OPERATING ACTIVITIES:</b>		
Depreciation	\$ 2,319	\$ 1,539
Share-based compensation expense	8,188	6,577
Right-of-use assets	3,803	5,909
Operating lease liabilities	(3,938)	(5,920)
<b>INVESTING ACTIVITIES:</b>		
Additions of tangible assets	\$ (1,798)	\$ (5,510)

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. TURNOVER FROM CONTRACTS WITH CUSTOMERS

During the years ended December 31, 2023 and 2022, the Company recorded product sales, net, as follows:

(In thousands)	Year Ended December 31,	
	2023	2022
VIVITROL	\$ 400,419	\$ 379,478
ARISTADA and ARISTADA INITIO	327,690	302,052
LYBALVI	191,889	96,022
Total product sales, net	<u>\$ 919,998</u>	<u>\$ 777,552</u>

During the years ended December 31, 2023 and 2022, the Company recorded manufacturing and royalty turnover from its collaborative arrangements as follows:

(In thousands)	Year Ended December 31, 2023		
	Manufacturing Turnover	Royalty Turnover	Total
Long-acting INVEGA products <sup>(1)</sup>	\$ —	\$ 486,101	\$ 486,101
VUMERITY	42,886	86,440	129,326
RISPERDAL CONSTA	36,123	1,153	37,276
Other	63,489	27,196	90,685
	<u>\$ 142,498</u>	<u>\$ 600,890</u>	<u>\$ 743,388</u>

(In thousands)	Year Ended December 31, 2022		
	Manufacturing Turnover	Royalty Turnover	Total
Long-acting INVEGA products <sup>(1)</sup>	\$ —	\$ 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
	<u>\$ 112,374</u>	<u>\$ 219,609</u>	<u>\$ 331,983</u>

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

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 the long-acting INVEGA products. When the partial termination became effective in February 2022, Janssen ceased paying royalties related to sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA. Accordingly, the Company ceased recognizing royalty turnover related to sales of these products in February 2022. 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. In May 2023, the arbitral tribunal (the “Tribunal”) in the arbitration proceedings issued a final award (the “Final Award”) which concluded the arbitration proceedings. The Final Award provided, among other things, that the Company was due back royalties of \$195.4 million, inclusive of \$8.1 million in late-payment interest related to 2022 U.S. net sales of the long-acting INVEGA products, which amount the Company received from Janssen in the second quarter of 2023, and is entitled to 2023 and future royalty turnover from Janssen related to net sales of INVEGA SUSTENNA through August 20, 2024, INVEGA TRINZA through the second quarter of 2030 (but no later than May 2030 when the license agreement expires) and INVEGA HAFYERA through May 2030 (when the license agreement expires).

Following issuance of the Final Award, the Company recognized royalty turnover related to the back royalties noted above and resumed recognizing royalty turnover related to ongoing U.S. sales of the long-acting INVEGA products. During 2023, the Company recorded \$486.1 million in royalty turnover from sales of the long-acting INVEGA products, including \$195.4 million related to back royalties and associated interest related to net sales of the long-acting INVEGA in the U.S. in 2022 and resumed recognizing royalty turnover related to worldwide net sales of the long-acting INVEGA products of approximately \$290.7 million, as compared to royalty turnover of \$115.7 million during 2022.

## ALKERMES PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 4. TURNOVER FROM CONTRACTS WITH CUSTOMERS (Continued)

In October 2022 and November 2022, an arbitration panel found that the Company must return to Acorda Therapeutics, Inc. (“Acorda”) \$16.5 million (inclusive of prejudgment interest and administrative fees) and \$1.8 million (inclusive of prejudgment interest), respectively, previously paid by Acorda under a license agreement between the Company and Acorda. These amounts represented a portion of the royalty turnover paid to the Company by Acorda since July 2020 related to AMPYRA. The Company paid Acorda the aggregate \$18.3 million in the fourth quarter of 2022. In addition, during the three months ended June 30, 2022, the Company had recorded \$3.2 million of royalty turnover related to AMPYRA as the Company believed that it had met the necessary revenue recognition criteria under 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 turnover within “Manufacturing and royalty turnover” in the consolidated statements of profit (loss) account. The amounts related to such arbitration ruling were included as part of “Other” within the manufacturing and royalty turnover table above for the year ended December 31, 2022. As a result of the arbitration ruling, the Company has no contractual obligation to manufacture and supply AMPYRA or contractual right to receive future manufacturing or royalty turnover related to AMPYRA. Refer to Note 21, *Commitments and Contingent Liabilities* within the “Notes to Consolidated Financial Statements” in this Directors’ Report for information regarding additional legal proceedings related to the arbitration with Acorda.

#### 5. 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 turnover the Company has earned in the years ended December 31, 2023 and 2022 is summarized in Note 4, *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/BYANLI

Under an exclusive license agreement with Janssen, 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 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, 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 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.

In November 2021, the Company received notice from Janssen of partial termination of the license agreement, following which Janssen ceased paying the Company royalties related to U.S. sales of INVEGA SUSTENNA, INVEGA TRINZA and INVEGA HAFYERA. 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. In May 2023, the Tribunal in the arbitration proceedings issued a Final Award that served to reinstate the Janssen royalties and required payment by Janssen of back royalties and interest for amounts owed but not yet paid since the effective date of the partial termination. The Final Award also provided, among other things, that the Company was entitled to royalty revenues from Janssen related to net sales of INVEGA SUSTENNA through August 20, 2024, INVEGA TRINZA through the second quarter of 2030 (but no later than May 2030 when the license agreement expires) and INVEGA HAFYERA through May 2030 (when the license agreement expires).

## ALKERMES PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 5. COLLABORATIVE ARRANGEMENTS (Continued)

##### RISPERDAL CONSTA

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

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

The Company exclusively manufactures RISPERDAL CONSTA at its Wilmington, Ohio facility 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.

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. COLLABORATIVE ARRANGEMENTS (Continued)

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 an agreed 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.

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.

6. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consists of the following:

(In thousands)	Goodwill <sup>(1)</sup>	Intangible Assets—Intellectual Property				Total
		Collaboration Agreements	NanoCrystal Technology	OCR Technology	Other	
<b>Cost:</b>						
At January 1, 2023	\$ 83,027	\$ 465,590	\$ 74,600	\$ 42,560	\$ 1,000	\$ 583,750
At December 31, 2023	\$ 83,027	\$ 465,590	\$ 74,600	\$ 42,560	\$ 1,000	\$ 583,750
<b>Accumulated Depreciation:</b>						
At January 1, 2022	\$ —	\$ (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)
Expensed during the year	—	(29,703)	(5,521)	(429)	(36)	(35,689)
At December 31, 2023	\$ —	\$ (465,590)	\$ (73,556)	\$ (42,560)	\$ (53)	\$ (581,759)
<b>Net Book Amount:</b>						
At December 31, 2023	\$ 83,027	\$ —	\$ 1,044	\$ —	\$ 947	\$ 1,991
At December 31, 2022	\$ 83,027	\$ 29,703	\$ 6,565	\$ 429	\$ 983	\$ 37,680

- (1) In connection with the sale of the Athlone Facility, certain of the Company’s goodwill has been classified as “Assets held for sale” in the accompanying consolidated balance sheets at December 31, 2023 and 2022. In addition, certain prior period amounts have been retrospectively adjusted to reflect the portion of goodwill allocated to Mural as part of the Separation and is classified as “Assets held for discontinued operations” in the accompanying consolidated balance sheet at December 31, 2022.

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 \$35.7 million and \$36.4 million of amortization expense related to its finite-lived intangible assets during the years ended December 31, 2023 and 2022, respectively. The Company’s intangible assets included within its accompanying consolidated balance sheets at December 31, 2023 are expected to be fully amortized in the year ending December 31, 2024.

The Company performed its annual goodwill impairment test as of October 31, 2023. The Company performed a quantitative impairment test and based on the weight of all available evidence, determined that the fair value of the reporting unit exceeded its carrying value. As part of the assessment performed as of October 31, 2023, it was determined that a portion of the Company’s goodwill should be allocated to Mural, as a portion of the IP that transferred to Mural was owned by the reporting unit to which the Company’s goodwill was assigned. In connection with the completion of the Separation, the Company recorded a reduction in goodwill of \$7.8 million in the accompanying consolidated balance sheet.

**ALKERMES PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**6. GOODWILL AND INTANGIBLE ASSETS (Continued)**

In addition, in connection with the planned sale of the Athlone Facility, the Company reviewed FASB ASC 805, *Business Combinations* and determined that the Athlone Facility constitutes a business and, accordingly, \$2.0 million of the Company's goodwill was allocated to the Athlone Facility and is classified as "Assets held for sale" within the accompanying consolidated balance sheets as of December 31, 2023 and 2022.

**7. LONG-TERM DEBT**

Long-term debt consists of the following:

(In thousands)	December 31, 2023	December 31, 2022
2026 Term Loans, due March 12, 2026	\$ 290,730	\$ 293,270
Less: current portion	(3,000)	(3,000)
Long-term debt	<u>\$ 287,730</u>	<u>\$ 290,270</u>

The Company's outstanding term loans mature on March 12, 2026 (the "2026 Term Loans"). In June 2023, the Company amended the 2026 Terms Loans to transition the interest rate available for borrowings thereunder from a London Interbank Offered Rate ("LIBOR")-based interest rate to an interest rate based on the Secured Overnight Financing Rate ("SOFR") and to make other conforming and mechanical changes. The 2026 Term Loans bear interest at SOFR plus a credit spread adjustment applicable to the interest period and an applicable margin of 2.50% with a floor of 0.5%.

The 2026 Term Loans have an incremental facility capacity in the amount of \$175.0 million plus additional potential amounts, provided that the 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, 2023.

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

Year Ending December 31:	
2024	\$ 3,000
2025	3,000
2026	285,750
Total	<u>\$ 291,750</u>

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.

**8. 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, 2023	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents	\$ 34,316	\$ 34,316	\$ —	\$ —
U.S. government and agency debt securities	218,869	181,041	37,828	—
Corporate debt securities	131,224	—	131,224	—
Non-U.S. government debt securities	3,996	—	3,996	—
Total	<u>\$ 388,405</u>	<u>\$ 215,357</u>	<u>\$ 173,048</u>	<u>\$ —</u>

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. FAIR VALUE (Continued)

	December 31, 2022	Level 1	Level 2	Level 3
<b>Assets:</b>				
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	—
Total	<u>\$ 465,639</u>	<u>\$ 188,496</u>	<u>\$ 277,143</u>	<u>\$ —</u>

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, 2023. At December 31, 2023, the Company had no investments with fair values that were determined using Level 3 inputs.

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.

In April 2015, the Company sold its Gainesville, GA manufacturing facility, the related manufacturing and royalty revenue associated with certain products manufactured at the facility, and the rights to IV/IM and parenteral forms of Meloxicam to Recro Pharma, Inc. ("Recro") and Recro Gainesville LLC (such transaction the "Gainesville Transaction"). The Gainesville Transaction included in the purchase price contingent consideration tied to low double digit royalties on net sales of the IV/IM and parenteral forms of Meloxicam and any other product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of the Company's IP to which Recro was provided a right of use, through license or transfer, pursuant to the Gainesville Transaction (such products, the "Meloxicam Products"), and milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products.

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

In Baudax's Quarterly Report on Form 10-Q for the period ended September 30, 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. 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 reduced 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 11, *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 the U.S. Food and Drug Administration ("FDA") acknowledged the discontinuation of sale of ANJESO via listing in the Orange Book.

The estimated fair value of the Company's long-term debt under the 2026 Term Loans, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and which may not be representative of actual values that could have been, or will be, realized in the future, was \$291.0 million and \$278.9 million at December 31, 2023 and 2022, respectively.



ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. INCOME TAXES

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

(In thousands)	Year Ended December 31,	
	2023	2022 <sup>(1)</sup>
Current income tax benefit (provision):		
U.S. federal	\$ 981	\$ (11,169)
U.S. state	(722)	(4,401)
Rest of world	—	—
Deferred income tax benefit (provision):		
U.S. federal	(10,192)	10,536
U.S. state	507	3,010
Ireland	107,064	—
Total income tax benefit (provision)	<u>\$ 97,638</u>	<u>\$ (2,024)</u>

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.

The income tax benefit in 2023 was primarily due to the partial release of the valuation allowance maintained against certain Irish deferred tax assets, partially offset by taxes on income earned in the U.S. and Ireland. The income tax provision in 2022 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.

In December 2023, the IRS issued Notice 2024-12 that provided clarity on the application of Section 174. On this basis, the Company adjusted its estimate of expenses that should be capitalized and amortized, resulting in lower taxable income and an elimination of the foreign derived intangible income ("FDII") deduction for the year ended December 31, 2023.

The income tax benefit associated with the Company's oncology business, and the tax impact of the Separation, are discussed in further detail in Note 3, *Discontinued Operations*, in these "Notes to Consolidated Financial Statements" in this Directors' Report. The tax benefits included within discontinued operations were \$1.4 million and \$11.1 million for the years ended December 31, 2023 and 2022, respectively.

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 \$797.0 million at December 31, 2023. 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 \$70.8 million of income taxes would be payable on the repatriation of the unremitted earnings to Ireland.

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

(In thousands)	Year Ended December 31,	
	2023	2022 <sup>(1)</sup>
Ireland	\$ 411,767	\$ (13,090)
U.S.	9,752	1,070
Profit (loss) before benefit (provision) for income taxes	<u>\$ 421,519</u>	<u>\$ (12,020)</u>

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.



ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. INCOME TAXES (Continued)

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

(In thousands)	December 31, 2023	December 31, 2022 <sup>(1)</sup>
Deferred tax assets:		
Net operating loss carryforwards	\$ 195,658	\$ 238,128
Tax credits	49,206	66,464
Accrued expenses and reserves	56,083	51,362
Share-based compensation	37,727	39,333
Bonus accrual	27,116	22,932
Other	5,582	6,543
Less: valuation allowance	(129,296)	(268,067)
Total deferred tax assets	242,076	156,695
Deferred tax liabilities:		
Tangible assets	(44,019)	(41,169)
Other	(2,716)	(1,502)
Total deferred tax liabilities	(46,735)	(42,671)
Net deferred tax assets	\$ 195,341	\$ 114,024

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.

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

(In thousands)	Balance at Beginning of Period <sup>(1)</sup>	(Additions) / Reductions <sup>(2)</sup>	Balance at End of Period <sup>(1)</sup>
Deferred tax asset valuation allowance for the year ended December 31, 2022	\$ (251,506)	\$ (20,011)	\$ (271,517)
Deferred tax asset valuation allowance for the year ended December 31, 2023	\$ (271,517)	\$ 142,221	\$ (129,296)

(1) Inclusive of continuing and discontinued operations for all periods other than the balance at December 31, 2023.

(2) (Additions) reductions represent continuing and discontinued operations. The reduction during the year ended December 31, 2023 primarily relates to the partial release of the valuation allowance maintained against certain Irish net deferred tax assets. The additions in 2022 relate primarily to Irish net operating losses ("NOLs").

The Company regularly assesses the need for a valuation allowance against its deferred tax assets. In making such assessment, the Company considers both positive and negative evidence related to the likelihood of realization of the deferred tax assets to determine, based on the weight of available evidence, whether it is more-likely-than-not that some or all of the deferred tax assets will not be realized. During the year ended December 31, 2023, the Company: (i) achieved a favorable outcome in its arbitration with Janssen (as described in Note 4, *Turnover from Contracts with Customers* in these "Notes to Consolidated Financial Statements" in this Directors' Report); (ii) successfully completed the Separation; and (iii) recorded significant pre-tax income due to multiple factors, including the growth of its proprietary revenues and items (i) and (ii) above. As a result, the Company's main operating subsidiary in Ireland recorded cumulative income during the year ended December 31, 2023 and the three-year period ended December 31, 2023. On this basis and other positive factors (such as anticipated future earnings) and negative factors (such as the potential decrease in certain manufacturing and royalty revenues), the Company has concluded that it is more-likely-than-not that certain Irish deferred tax assets will be realized. Of the \$271.5 million valuation allowance maintained as of December 31, 2022, the Company released \$143.9 million during the year ended December 31, 2023. At December 31, 2023, the Company maintained a valuation allowance of \$27.3 million against certain U.S. state deferred tax assets and \$102.0 million against certain Irish deferred tax assets, as the Company has determined that it is more-likely-than-not that these deferred tax assets will not be realized and some may be abandoned.

If the Company incurs losses in the U.S. or in Ireland in the future, the evaluation of the recoverability of the deferred tax assets could change and a valuation allowance against such deferred tax assets may be required in part or in whole. The Company will continue to monitor the need for a valuation allowance against its deferred tax assets on a quarterly basis.

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. INCOME TAXES (Continued)

As of December 31, 2023, the Company had \$1.3 billion of Irish NOL carryforwards, \$14.6 million of U.S. federal NOL carryforwards, \$43.2 million of state NOL carryforwards, \$9.7 million of federal R&D credits and \$31.0 million of state tax credits which will either expire on various dates through 2043 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 \$14.6 million of U.S. federal NOL carryforwards and \$6.3 million of state NOL carryforwards, acquired as part of the acquisition of Rodin Therapeutics, Inc. ("Rodin"), each of which are subject to a \$0.5 million annual limitation.

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,	
	2023	2022 <sup>(1)</sup>
Statutory tax rate	12.5 %	12.5 %
Profit (loss) from continuing operations before income taxes at statutory rate	\$ 52,690	\$ (1,497)
Share-based compensation	4,177	4,347
Foreign rate differential <sup>(2)</sup>	4,701	521
Change in valuation allowance	(142,424)	(1,292)
Intercompany amounts <sup>(3)</sup>	(16,551)	(1,694)
Irish rate differential <sup>(4)</sup>	235	4,926
Uncertain tax positions	(234)	602
Non-deductible lobbying expenses	705	775
U.S. state income taxes, net of U.S. federal benefit	347	1,272
Foreign derived intangible income	—	(4,530)
R&D credit	(2,823)	(2,531)
Other permanent items <sup>(5)</sup>	1,539	1,125
Income tax (benefit) provision	<u>\$ (97,638)</u>	<u>\$ 2,024</u>
Effective tax rate	(23.2) %	(16.8) %

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.

(2) Represents income or losses of U.S. subsidiaries, subject to tax at a rate other than the Irish statutory rate.

(3) Intercompany amounts include cross-territory eliminations, the pre-tax effect of which has been eliminated in arriving at the Company's accompanying consolidated profit (loss) before taxes from continuing operations. In 2023, this included a tax benefit of \$15.7 million related to the intercompany transfer of stock that was owned by the Company at December 31, 2023.

(4) Represents income or losses of Irish companies subject to tax at a rate other than the Irish statutory rate.

(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, 2021	\$ 8,372
Reductions based on the lapse of applicable statutes 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
Reductions based on tax positions related to prior periods	(1,073)
Additions based on tax positions related to the prior period	281
Additions based on tax positions related to the current period	558
Balance, December 31, 2023	<u>\$ 8,739</u>

**ALKERMES PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The unrecognized tax benefits at December 31, 2023, 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, 2023 and 2022, the Company's accrued interest and penalties related to uncertain tax positions were not material.

The Company's major taxing jurisdictions include Ireland and the U.S. (federal and state). These jurisdictions have varying statutes of limitations. In the U.S., the 2020 through 2023 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 2019 through 2023 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 February 2023, the Company submitted an appeal to the LTA against the notice of assessment received in 2022 for the year ended December 31, 2017. In the third quarter of 2023, the Company received confirmation that the LTA changed its position and agreed to the originally filed tax return, resulting in the closure of the examination of the year ended December 31, 2017. In connection with the closure, the Company received a refund of approximately €2.2 million from the LTA. As of December 31, 2023, the Company had not received a notice of assessment from the LTA in relation to the year ended December 31, 2018.

**10. PROFIT (LOSS) PER SHARE**

Basic profit (loss) per ordinary share from continuing operations is calculated based upon net profit (loss) from continuing operations available to holders of ordinary shares divided by the weighted average number of ordinary shares outstanding. Basic loss per ordinary share from discontinued operations, is calculated based upon net loss from discontinued operations available to holders of ordinary shares, divided by the weighted average number of ordinary shares outstanding. For the calculation of diluted profit (loss) per ordinary share from continuing operations and discontinuing operations, the Company utilizes the treasury stock method and adjusts the weighted average number of ordinary shares outstanding for the potential dilutive effect of outstanding ordinary share equivalents such as stock options and RSUs.

(In thousands)	Year Ended December 31,	
	2023	2022 <sup>(1)</sup>
Numerator:		
Net profit (loss) from continuing operations	519,157	(14,044)
Net (loss) from discontinued operations	(163,400)	(125,115)
Net profit (loss)	\$ 355,757	\$ (139,159)
Denominator:		
Weighted average number of ordinary shares outstanding	166,223	163,742
Effect of dilutive securities:		
Stock options	1,093	—
Restricted stock unit awards	2,414	—
Dilutive ordinary share equivalents	3,507	—
Shares used in calculating diluted profit (loss) per ordinary share	169,730	163,742

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.

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

(In thousands)	Year Ended December 31,	
	2023	2022
Stock options	12,422	12,777
Restricted stock unit awards	2,378	5,040
Total	14,800	17,817

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. TANGIBLE FIXED ASSETS

Tangible fixed assets consist of the following:

(In thousands)	Land and Buildings <sup>(1)</sup>	Furniture, Fixtures and Equipment <sup>(1)</sup>	Leasehold Improvements <sup>(1)</sup>	Construction in Progress <sup>(1)</sup>	Total <sup>(1)</sup>
<b>Cost:</b>					
At January 1, 2022	\$ 103,389	\$ 212,585	\$ 31,642	\$ 74,352	\$ 421,968
Additions at cost	2,224	13,423	—	3,664	19,311
Disposals	—	(3,599)	—	—	(3,599)
At December 31, 2022	<u>\$ 105,613</u>	<u>\$ 222,409</u>	<u>\$ 31,642</u>	<u>\$ 78,016</u>	<u>\$ 437,680</u>
Additions at cost	28,079	30,909	8,294	(32,225)	35,057
Disposals	—	(12,682)	(43)	—	(12,725)
Impairments	—	(2,907)	—	—	(2,907)
At December 31, 2023	<u>\$ 133,692</u>	<u>\$ 237,729</u>	<u>\$ 39,893</u>	<u>\$ 45,791</u>	<u>\$ 457,105</u>
<b>Accumulated Depreciation:</b>					
At January 1, 2022	\$ (37,936)	\$ (149,822)	\$ (4,158)	\$ —	\$ (191,916)
Charged during the year	(4,012)	(20,164)	(2,074)	—	(26,250)
Disposals	—	3,405	—	—	3,405
At December 31, 2022	<u>\$ (41,948)</u>	<u>\$ (166,581)</u>	<u>\$ (6,232)</u>	<u>\$ —</u>	<u>\$ (214,761)</u>
Charged during the year	(4,161)	(19,811)	(2,336)	—	(26,308)
Disposals	—	10,864	43	—	10,907
At December 31, 2023	<u>\$ (46,109)</u>	<u>\$ (175,528)</u>	<u>\$ (8,525)</u>	<u>\$ —</u>	<u>\$ (230,162)</u>
<b>Net Book Amount:</b>					
At December 31, 2023	<u>\$ 87,583</u>	<u>\$ 62,201</u>	<u>\$ 31,368</u>	<u>\$ 45,791</u>	<u>\$ 226,943</u>
At December 31, 2022	<u>\$ 63,665</u>	<u>\$ 55,828</u>	<u>\$ 25,410</u>	<u>\$ 78,016</u>	<u>\$ 222,919</u>

(1) In connection with the sale of the Athlone Facility, certain of the Company's property, plant and equipment has been classified as "Assets held for sale" in the accompanying consolidated balance sheets at December 31, 2023 and 2022. In addition, certain prior period amounts have been retrospectively adjusted to reflect the effects of the Separation and classified as "Assets held for discontinued operations" in the accompanying consolidated balance sheet at December 31, 2022.

Depreciation expense was \$25.7 million and \$26.3 million for the years ended December 31, 2023 and 2022, respectively. Also, during the years ended December 31, 2023 and 2022, the Company wrote off tangible assets that had an approximate carrying value of \$1.7 million and \$0.5 million, respectively, at the time of disposition.

Amounts included as construction in progress in the accompanying 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 \$30.6 million of construction in progress will be placed into service during 2024. 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 "Creditors" 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 profit (loss) account during the year ended December 31, 2022.

In December 2023, the Company determined that \$2.9 million of its construction in progress at its Wilmington, Ohio manufacturing facility had no future value and was written off through "cost of goods manufactured and sold" in the accompanying consolidated statements of operations and comprehensive income (loss) during the year ended December 31, 2023.

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. LEASES

All of the Company's leases are accounted for as operating leases. 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.

On November 13, 2023, in connection with the Separation, Alkermes US and Mural US entered into an assignment and assumption of lease agreement (the "Assignment"), pursuant to which Alkermes US assigned to Mural US an operating lease for approximately 180,000 square feet of corporate office space, administrative areas and laboratories located at 852 Winter Street in Waltham, Massachusetts (the "852 Winter Street Lease"). Under the terms of the Assignment, Mural US assumed all of Alkermes US' obligations under the 852 Winter Street Lease. In accordance with FASB ASC 842, *Leases*, as the Company can no longer access or direct the use of the asset following the Assignment, the 852 Winter Street Lease no longer meets the definition of a lease for the Company. On November 15, 2023, the effective date of the Assignment, the Company reduced its right-of-use asset and lease liability by \$14.5 million and \$15.4 million, respectively in the accompanying consolidated balance sheet.

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.

At December 31, 2023 and 2022, the operating leases held by the Company had a weighted average incremental borrowing rate of 4.4% and 5.5%, respectively, and a weighted average remaining lease term of 8.7 years and 9.6 years, respectively. During the years ended December 31, 2023 and 2022, cash paid for amounts included for the measurement of lease liabilities was \$10.3 million and \$27.0 million, respectively. The Company recorded operating lease expense of \$10.2 million and \$10.7 million for the years ended December 31, 2023 and 2022, respectively.

Right-of-use assets as of December 31, 2023 consisted of the following:

(In thousands)	Right-of-Use Assets <sup>(1)</sup>
Balance, January 1, 2022	\$ 91,401
Addition and remeasurement of operating leases in 2022	16,797
Amortization	(10,660)
Balance, December 31, 2022	\$ 97,538
Addition and remeasurement of operating leases in 2023	4,082
Amortization	(10,160)
Balance, December 31, 2023	\$ 91,460

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.

At December 31, 2023 and 2022, liabilities arising from operating leases were \$81.5 million and \$86.3 million, respectively, of which \$5.8 million and \$5.8 million fall due within one year, respectively, and \$75.7 million and \$76.3 million fall due after more than one year, respectively.

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. LEASES (Continued)

Future lease payments under non-cancelable leases as of December 31, 2023 consisted of the following:

(In thousands)	December 31, 2023
2024	\$ 10,148
2025	10,248
2026	10,319
2027	9,509
2028	9,574
Thereafter	59,665
Total operating lease payments	\$ 109,463
Less: imputed interest	(28,008)
Total operating lease liabilities	\$ 81,455

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.

13. STOCK

Stock consists of the following:

(In thousands)	December 31, 2023	December 31, 2022
Raw materials	\$ 71,416	\$ 61,064
Work in process	68,843	76,228
Finished goods <sup>(1)</sup>	46,147	44,126
Total stock	\$ 186,406	\$ 181,418

(1) At December 31, 2023 and 2022, the Company had \$33.9 million and \$30.9 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, 2023 and 2022, the Company had a provision for stock obsolescence of less than \$0.1 million and none, respectively.

14. DEBTORS

(In thousands)	December 31, 2023	December 31, 2022 <sup>(1)</sup>
<i>Amounts falling due within one year</i>		
Trade receivables	\$ 332,477	\$ 287,967
Contract assets	706	8,929
Prepaid expenses and other current assets	98,166	41,203
	\$ 431,349	\$ 338,099
<i>Amounts falling due after more than one year</i>		
Deferred tax assets	\$ 195,888	\$ 114,572
Other debtors	3,964	6,819
Total	\$ 631,201	\$ 459,490

(1) Prior period amounts have been retrospectively adjusted to reflect the effects of the Separation.

Included in trade receivable at December 31, 2023 and 2022 are unbilled receivables of \$103.1 million and \$72.0 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 each of December 31, 2023 and 2022.



ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. DEBTORS (Continued)

Contract assets include unbilled amounts that will result in a sale under certain of the Company's manufacturing contracts. The amounts included in the contract assets table below are classified as "Debtors" in the accompanying consolidated balance sheets, as they relate 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, 2022	\$ 13,363
Additions	42,218
Transferred to receivables, net	(46,652)
Contract assets at December 31, 2022	\$ 8,929
Additions	13,606
Transferred to receivables, net	(21,829)
Contract assets at December 31, 2023	<u>\$ 706</u>

15. INVESTMENTS

Investments consist of the following:

December 31, 2023	Amortized Cost	Gains	Gross Unrealized Losses		Estimated Fair Value
			Less than One Year	Greater than One Year	
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 199,708	\$ 758	\$ (36)	\$ (611)	\$ 199,819
Corporate debt securities	112,055	703	(15)	(536)	112,207
Non-U.S. government debt securities	4,004	—	—	(8)	3,996
Total short-term investments	<u>315,767</u>	<u>1,461</u>	<u>(51)</u>	<u>(1,155)</u>	<u>316,022</u>
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	19,392	—	(27)	(315)	19,050
Corporate debt securities	19,306	—	—	(289)	19,017
	<u>38,698</u>	<u>—</u>	<u>(27)</u>	<u>(604)</u>	<u>38,067</u>
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Total long-term investments	<u>40,518</u>	<u>—</u>	<u>(27)</u>	<u>(604)</u>	<u>39,887</u>
Total investments	<u>\$ 356,285</u>	<u>\$ 1,461</u>	<u>\$ (78)</u>	<u>\$ (1,759)</u>	<u>\$ 355,909</u>
<b>December 31, 2022</b>					
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	<u>320,583</u>	<u>16</u>	<u>(718)</u>	<u>(3,889)</u>	<u>315,992</u>
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
	<u>134,548</u>	<u>—</u>	<u>(2,467)</u>	<u>(2,291)</u>	<u>129,790</u>
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Total long-term investments	<u>136,368</u>	<u>—</u>	<u>(2,467)</u>	<u>(2,291)</u>	<u>131,610</u>
Total investments	<u>\$ 456,951</u>	<u>\$ 16</u>	<u>\$ (3,185)</u>	<u>\$ (6,180)</u>	<u>\$ 447,602</u>

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. INVESTMENTS (Continued)

The following table is a rollforward of the fair value of the Company's investments for the year ended December 31, 2023:

(In thousands)	Corporate Debt Securities	U.S.	Non-U.S.	Certificates of Deposit	Fair Value
		Government and Agency Debt Securities	Government Debt Securities		
Balance, January 1, 2023	\$ 204,943	\$ 202,050	\$ 38,789	\$ 1,820	\$ 447,602
Purchases	63,123	190,415	—	1,820	255,358
Maturities and redemptions	(140,563)	(179,695)	(35,250)	(1,820)	(357,328)
Amortization, accretion and inflation profit (loss), net	(847)	2,450	(300)	—	1,303
Base change in net unrealized gain (loss)	4,568	3,649	757	—	8,974
Balance, December 31, 2023	<u>\$ 131,224</u>	<u>\$ 218,869</u>	<u>\$ 3,996</u>	<u>\$ 1,820</u>	<u>\$ 355,909</u>

At December 31, 2023, 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 and backed by U.S. agencies and the U.S. government. At December 31, 2023, 97 of the Company's 231 investment securities were in an unrealized loss position and had an aggregate estimated fair value of \$135.0 million. Approximately 36% and 61% of the Company's investment securities at December 31, 2023 were 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. The primary reason for the unrealized losses in the Company's investment portfolio is that its investments are fixed-rate securities acquired in a rising interest rate environment. In making the determination whether the decline in fair value of these securities was 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.

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

(In thousands)	Year Ended December 31,	
	2023	2022
Proceeds from the sales and maturities of investments	\$ 355,522	\$ 281,627
Realized gains	\$ —	\$ —
Realized losses	\$ —	\$ 529

The Company's available-for-sale and held-to-maturity securities at December 31, 2023 had contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	\$ 207,005	\$ 205,950	\$ 1,820	\$ 1,820
After 1 year through 5 years	147,460	148,139	—	—
Total	<u>\$ 354,465</u>	<u>\$ 354,089</u>	<u>\$ 1,820</u>	<u>\$ 1,820</u>



ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. SHARE CAPITAL PRESENTED AS EQUITY

*Share Capital*

(In thousands, except per share amounts)	December 31,	
	2023	2022
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	<u>\$ 5,040,000</u>	<u>\$ 5,040,000</u>

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, 2022	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
Issuance of ordinary shares under employee stock plans	3,617,858	36
Balance at December 31, 2023	<u>172,569,051</u>	<u>\$ 1,726</u>

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. SHARE CAPITAL PRESENTED AS EQUITY (Continued)

*Share Repurchase Program*

On February 15, 2024, the Company's board of directors authorized a share repurchase program to repurchase ordinary shares of the Company in an aggregate amount of up to \$400.0 million (exclusive of any fees, commissions or other expenses related to such repurchases) from time to time (the "2024 Repurchase Program"). The timing and amount of any share repurchases under the 2024 Repurchase Program will be based on a variety of factors, including but not limited to ongoing assessments of the Company's capital needs, alternative investment opportunities, the market price of the Company's ordinary shares and general market conditions. The 2024 Repurchase Program has no set expiration date and may be suspended or discontinued at any time. The 2024 Repurchase Program terminates, and supersedes in its entirety, the Company's prior share repurchase program authorized by its board of directors in September 2011 (the "Prior Repurchase Program") under which the Company has purchased a total of 8,866,342 ordinary shares at a cost of \$114.0 million. During the years ended December 31, 2023 and 2022 the Company did not purchase any ordinary shares under the Prior Repurchase Program.

*Treasury Shares*

Treasury Shares (par value, \$0.01 per share) (Value in thousands)	Number	Value
Balance at January 1, 2022	3,853,222	\$ 142,658
Acquired during the year	720,962	18,204
Balance at December 31, 2022	4,574,184	\$ 160,862
Acquired during the year	1,015,034	28,474
Balance at December 31, 2023	<u>5,589,218</u>	<u>\$ 189,336</u>

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.

17. SHARE-BASED COMPENSATION

*Share-Based Compensation Expense*

The following table presents share-based compensation expense from continuing and discontinued operations included in the Company's accompanying consolidated profit (loss) accounts:

(In thousands)	Year Ended December 31,	
	2023	2022
Cost of goods manufactured and sold	\$ 11,353	\$ 10,284
Research and development	25,753	23,289
Selling, general and administrative	55,611	54,104
Share-based compensation expense from continuing operations	<u>92,717</u>	<u>87,677</u>
Cost of goods manufactured and sold	—	—
Research and development	3,255	4,652
Selling, general and administrative	4,933	1,925
Share-based compensation expense from discontinued operations	<u>8,188</u>	<u>6,577</u>
Total share-based compensation expense	<u>\$ 100,905</u>	<u>\$ 94,254</u>

During the years ended December 31, 2023 and 2022, \$3.2 million and \$3.3 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," and together with the 2018 Plan and the 2008 Plan, the "Alkermes Stock Option and Incentive Plans"). 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

**ALKERMES PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. SHARE-BASED COMPENSATION (Continued)**

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 June 29, 2023, 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 6.5 million. At December 31, 2023, there were 15.1 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.

In connection with the Separation and in accordance with the provisions of the Alkermes Stock Option and Incentive Plans, the Company adjusted outstanding equity awards as described in Note 2, *Significant Accounting Policies* within these "Notes to Consolidated Financial Statements" in this Directors' Report, and specifically the section entitled "Conversion and Modification of Equity Awards Outstanding at Separation Date". The incremental number of ordinary shares underlying each award that was outstanding immediately prior to the Separation is included as "Conversion Reissuance" in each of the associated tables below.

***Stock Options***

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

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 2023	17,596,961	\$ 33.32
Granted	3,479,898	\$ 27.88
Conversion Reissuance	357,146	\$ 32.26
Exercised	(772,207)	\$ 21.70
Expired	(1,334,719)	\$ 37.02
Forfeited	(1,187,176)	\$ 26.56
Outstanding, December 31, 2023	<u>18,139,903</u>	\$ 32.28
Exercisable, December 31, 2023	<u>11,054,082</u>	\$ 37.24

The weighted average grant date fair value of stock options granted during the years ended December 31, 2023 and 2022 was \$13.74 and \$12.62, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2023 and 2022 was \$6.0 million and \$11.6 million, respectively.

At December 31, 2023, there were 6.9 million stock options expected to vest, with a weighted average exercise price of \$24.46 per share, a weighted average contractual remaining life of 8.0 years and an aggregate intrinsic value of \$24.6 million. At December 31, 2023, the aggregate intrinsic value of stock options exercisable was \$29.4 million with a weighted average remaining contractual term of 4.5 years. The number of stock options expected to vest was determined by applying the pre-vesting forfeiture rate to the total 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.

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. SHARE-BASED COMPENSATION (Continued)

At December 31, 2023, there was \$33.0 million of unrecognized share-based compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 1.9 years.

*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, 2023	6,625,422	\$ 23.34
Granted	2,884,122	\$ 27.65
Conversion reissuance	110,015	\$ 24.19
Forfeited	(1,368,705)	\$ 25.17
Vested	(2,593,276)	\$ 24.31
Unvested, December 31, 2023	<u>5,657,578</u>	\$ 24.18

The weighted average grant date fair values of time-vesting RSUs granted during the years ended December 31, 2023 and 2022 were \$27.65 and \$25.27, respectively. The total fair value of time-vesting RSUs that vested during the years ended December 31, 2023 and 2022, was \$63.0 million and \$54.3 million, respectively.

At December 31, 2022, there was \$55.4 million of total unrecognized share-based compensation expense related to unvested time-vesting RSUs, which will be recognized over a weighted average remaining contractual term of 1.9 years.

*Performance-Based Restricted Stock Unit Awards*

In February 2023, 2022 and 2021, 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, 2023	1,349,634	\$ 26.05
Granted	667,565	\$ 29.91
Conversion reissuance	30,244	\$ 27.15
Forfeited	(248,711)	\$ 24.06
Vested	(252,375)	\$ 23.43
Unvested, December 31, 2023	<u>1,546,357</u>	\$ 27.95

The weighted average grant date fair values of performance-based RSUs granted during the years ended December 31, 2023 and 2022 were \$29.91 and \$30.73, respectively. The total fair value of performance-based RSUs that vested during the years ended December 31, 2023 and 2022 were \$5.9 million and none, respectively. At December 31, 2023, there was \$2.5 million of unrecognized share-based compensation expense related to performance-based RSUs granted in February 2022 and 2023, which would be recognized in accordance with the terms of the awards when the Company deems it probable that the performance criteria will be met.

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. SHARE-BASED COMPENSATION (Continued)

The Company has additional unrecognized share-based compensation expense related to performance-based RSUs that were granted in February 2021. As of December 31, 2023, the financial performance criteria for these awards were deemed not probable of being achieved. On February 8, 2024, the compensation committee of the Company's board of directors determined that the Company partially achieved the financial performance criteria. This was considered a modification in accordance with FASB ASC 718, *Compensation—Stock Compensation* and resulted in a modification charge of approximately \$6.8 million. On February 8, 2024, the compensation committee of the Company's board of directors also determined that the Company achieved the pipeline performance criteria for these awards, resulting in a \$2.6 million incremental share-based compensation expense, as it was deemed such pipeline performance criteria had been met. The share-based compensation expense related to these achievements will be recognized in 2024.

18. PROVISIONS FOR LIABILITIES

Provisions for liabilities consists of the following:

(In thousands)	Medicaid Rebates	Product Returns	Medicare Part D	Other	Total
Balance, January 1, 2022	\$ 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
Additions	426,447	36,263	74,412	51,905	589,027
Amounts utilized	(420,933)	(24,865)	(72,252)	(49,267)	(567,317)
Balance, December 31, 2023	<u>\$ 213,845</u>	<u>\$ 41,064</u>	<u>\$ 20,569</u>	<u>\$ 11,844</u>	<u>\$ 287,322</u>

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

19. CREDITORS

(In thousands)	December 31, 2023	December 31, 2022
Amounts falling due within one year		
Accrued expenses	\$ 189,913	\$ 195,388
Trade creditors	65,649	32,843
Contract liabilities	2,730	6,816
Payroll taxes	3,275	3,556
Accrued interest on long-term debt	775	952
Value added tax	190	319
Corporate tax	40	38
Other taxes	761	638
	<u>\$ 263,333</u>	<u>\$ 240,550</u>
Amounts falling due after more than one year		
Deferred tax liabilities	\$ 547	\$ 548
Contract liabilities	2,045	3,885
Uncertain tax positions	1,588	3,322
Accrued vacation	5,047	5,874
Other long-term liabilities	1,470	1,613
Total	<u>\$ 274,030</u>	<u>\$ 255,792</u>

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 payable at various dates over the coming months in accordance with the applicable statutory provisions.

**ALKERMES PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**19. CREDITORS (Continued)**

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

Contract liabilities consisted of the following:

<b>(In thousands)</b>	<b>Contract Liabilities</b>
Contract liabilities at January 1, 2022	\$ 17,830
Additions	6,769
Amounts recognized into revenue	(7,514)
Amounts recognized into other (expense) income, net	(6,384)
Contract liabilities at December 31, 2022	\$ 10,701
Reductions	(931)
Amounts recognized into revenue	(4,995)
Contract liabilities at December 31, 2023	<u>\$ 4,775</u>

**20. RESTRUCTURING**

In July 2023, in conjunction with the Company's ongoing review of operations and the Separation, the Company implemented a restructuring plan, which included the elimination of approximately 60 positions across the Company (the "Restructuring"). The Company recorded a charge of \$6.0 million during the third quarter of 2023 as a result of the Restructuring, which consisted of one-time termination benefits for employee severance, benefits and related costs, all of which are expected to result in cash expenditures, and all of which are expected to be paid within 12 months of the Restructuring. The Company recognized \$4.5 million and \$1.5 million of this expense in R&D expense and SG&A expense, respectively, in the accompanying consolidated profit (loss) account.

<b>(In thousands)</b>	
Balance, December 31, 2022	\$ —
Restructuring charge	5,969
Amounts paid during the period:	
Severance	(3,932)
Benefits	(520)
Outplacement services	(183)
Balance, December 31, 2023	<u>\$ 1,334</u>

**21. 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, 2023, there were no potential material losses from claims, asserted or unasserted, or legal proceedings that the Company determined were probable of occurring.

**INVEGA SUSTENNA ANDA Litigation**

Janssen Pharmaceutica 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"), in December 2019 against Pharmascience, Inc. ("Pharmascience"), Mallinckrodt plc, and SpecGX LLC (the "Pharmascience Lawsuit"), and in February 2022 against Accord Healthcare, Inc., Accord Healthcare, Ltd. and Intas Pharmaceuticals, Ltd ("Accord" and such lawsuit, the "Accord Lawsuit"), and in the U.S. District Court for the District of Delaware (the "DE District Court") in December

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**21. COMMITMENTS AND CONTINGENT LIABILITIES (Continued)**

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, Accord 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 was held in the Tolmar Lawsuit in October 2023. The Pharmascience Lawsuit and the Accord Lawsuit were 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, 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 (the “’693 Patent”). Requested judicial remedies include recovery of litigation costs and injunctive relief. In May 2023, the NJ District Court issued an opinion in favor of the Janssen entities on the issues of infringement and validity of the ’693 Patent and the Mylan entities filed a notice of appeal of the decision. The Company is not a party to this proceeding.

**VUMERITY ANDA Litigation**

In July 2023, Biogen Inc., Biogen Swiss Manufacturing GmbH and Alkermes Pharma Ireland Limited filed a patent infringement lawsuit in the DE District Court against Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, “Zydus”) following the filing by Zydus of an ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a generic version of VUMERITY (diroximel fumarate) delayed-release capsules for oral use, 231 mg, before expiration of the Company’s U.S. Patent Nos. 8,669,281; 9,090,558; and 10,080,733. The filing of the lawsuit triggered a stay of FDA approval of the ANDA for up to 30 months in accordance with the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”). In October 2023, Zydus filed an answer to the complaint.

**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.

**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, in January 2023, Acorda filed a petition with the U.S. District Court for the Southern District of New York (the “NY Southern District Court”) 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. In August 2023, the NY Southern District Court confirmed the final arbitral award and declined to modify the final award to increase the damages awarded thereunder. In September 2023, Acorda filed a notice of appeal of the NY Southern District Court decision to the U.S. Court of Appeals for the Federal Circuit (the “Federal Circuit”), and the Company filed a motion to transfer the appeal to the U.S. Court of Appeals for the Second Circuit. On October 10, 2023, Acorda filed an opposition to such motion. On January 18, 2024, the Federal Circuit denied without prejudice the Company’s motion to transfer the appeal and instructed the parties to brief the jurisdictional question as part of the merits appeal.

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.



**ALKERMES PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**21. COMMITMENTS AND CONTINGENT LIABILITIES (Continued)**

**Guarantees**

In connection with the Separation, the Company entered into the Assignment related to the 852 Winter Street Lease, which is described in more detail in Note 12, *Leases* in these “Notes to Consolidated Financial Statements” in this Directors’ Report. Although the Assignment transferred all of the rights, title and interest in, to and under the 852 Winter Street Lease to Mural US as of November 15, 2023, the Company ratified and reaffirmed for the remainder of the lease term its guarantor obligations under that certain Guaranty dated as of May 16, 2014 related to the 852 Winter Street Lease. Upon completion of the Separation, the Assignment was accounted for as a termination of the original lease and the Company de-recognized the right-of-use asset and lease liability related to the 852 Winter Street Lease. At December 31, 2023, the fair value of the guarantee was not material to the Company.

**22. CAPITAL EXPENDITURE COMMITMENTS**

The Company’s board of directors authorized the Company to spend \$35.0 million for capital expenditures in the year ended December 31, 2024.

**23. 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 28, *Subsidiaries*, to the consolidated financial statements.

*Trading Transactions*

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

**24. 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.

**25. EMPLOYEES**

The average number of persons employed by the Company during the years ended December 31, 2023 and 2022, respectively, was as follows:

	December 31, 2023	December 31, 2022
Manufacturing	798	790
Research and development	359	434
Selling, general and administrative	994	985
Total	2,151	2,209



**ALKERMES PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**25. EMPLOYEES (Continued)**

Employee costs included in profit and loss during the years ended December 31, 2023 and 2022 consisted of the following:

(In thousands)	December 31, 2023	December 31, 2022
Wages and salaries	\$ 431,918	\$ 401,975
Share-based compensation	100,905	94,254
Social insurance costs <sup>(1)</sup>	70,870	65,117
Defined contribution plan contributions	23,100	21,417
<b>Total</b>	<b>\$ 626,793</b>	<b>\$ 582,763</b>

(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, 2023 and 2022, the Company capitalized \$3.1 million and \$2.8 million, respectively, as part of its tangible fixed assets and \$87.4 million and \$81.7 million, respectively, as part of its stock.

**26. 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, 2023	December 31, 2022
<b>Managerial Services:</b>		
Emoluments	\$ 2,594	\$ 2,289
Benefits under long term incentive schemes	4,260	1,298
Company contribution to 401(k) plan	17	15
<b>Total</b>	<b>\$ 6,871</b>	<b>\$ 3,602</b>
<b>Director Services:</b>		
Fees paid in cash	\$ 984	\$ 1,022
<b>Total</b>	<b>\$ 984</b>	<b>\$ 1,022</b>

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, 2023 was \$0.1 million (December 31, 2022: \$5.1 million). The Company considers its directors to be key management personnel.

Retirement benefits are accruing to 1 director (2022: 1 director) under the 401(k) contribution plan in connection with Managerial Services, as noted above.

**ALKERMES PLC**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**27. AUDITORS' REMUNERATION**

Total auditors' remuneration, including expenses, accrued and paid to PricewaterhouseCoopers and its affiliated firms for the years ended December 31, 2023 and 2022, respectively, were as follows:

(In thousands)	December 31, 2023	December 31, 2022
Audit and review of group financial statements <sup>(1)</sup>	\$ 3,554	\$ 2,587
Audit-related fees <sup>(2)</sup>	2,348	109
Tax fees <sup>(3)</sup>	1,803	1,140
All other fees <sup>(4)</sup>	7	27
<b>Total</b>	<b>\$ 7,712</b>	<b>\$ 3,863</b>

- (1) Consists of fees for services related to the audit of the Company's annual consolidated financial statements, the audit of discontinued operations related to the separation of our oncology business, statutory audits and review of our quarterly consolidated financial statements, including review of our internal controls over financial reporting, and other engagements during the fiscal year. Included in these amounts for 2023 and 2022 are expenses of approximately \$17 thousand and \$22, respectively.
- (2) Consists of audit-related fees associated with the separation of the Company's 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 separation of the Company's oncology business. No expenses are included in these amounts for the years ended December 31, 2023 or 2022.
- (4) Consists of fees for access to certain PricewaterhouseCoopers online accounting resources.

Total fees paid to PricewaterhouseCoopers Ireland in respect of the audit of the Company financial statements were \$0.6 million and \$0.5 million during the years ended December 31, 2023 and 2022, respectively. In addition, PricewaterhouseCoopers Ireland received \$0.4 million and less than \$0.1 million for tax advisory services during the years ended December 31, 2023 and 2022, respectively.

**28. 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	900 Winter Street, Waltham, MA 02451 United States	100%
Alkermes, Inc.	Manufacturing and R&D	900 Winter Street, Waltham, MA 02451 United States	100%
Alkermes Controlled Therapeutics, Inc.	Non-Operating	900 Winter Street, Waltham, MA 02451 United States	100%
Rodin Therapeutics, Inc.	R&D	900 Winter Street, Waltham, MA 02451 United States	100%

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

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

29. PRIOR YEAR RECONCILIATION TO ANNUAL REPORT

Following the issuance of the Company's 2021 Annual Report on Form 10-K ("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 (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 2023 Directors' Report and Consolidated Financial Statements, the Company adjusted its consolidated profit (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 (LOSS) ACCOUNT

	Year Ended December 31, 2022		
	As Reported on Form 10-K (1)	Subsequent Event Adjustment	As reported in Alkermes Plc Directors' Report and Consolidated Financial Statements
<b>(In thousands, except per share amounts)</b>			
Total turnover	\$ 1,111,795	\$ —	\$ 1,111,795
Operating loss from continuing operations	(6,089)	—	(6,089)
Interest income	7,629	—	7,629
Interest expense	(13,040)	—	(13,040)
Change in the fair value of contingent consideration	(21,750)	(19,108)	(40,858)
Other income, net	2,122	—	2,122
Loss before income taxes from continuing operations	(31,128)	(19,108)	(50,236)
Income tax provision from continuing operations	(2,024)	—	(2,024)
Loss after income taxes from continuing operations	(33,152)	(19,108)	(52,260)
Loss from discontinued operations, net of tax	(125,115)	—	(93,118)
Net loss	<u>\$ (158,267)</u>	<u>\$ (19,108)</u>	<u>\$ (145,378)</u>
<b>LOSS PER ORDINARY SHARE:</b>			
From continuing operations—basic and diluted	\$ (0.20)	\$ (0.12)	\$ (0.32)
From discontinued operations—basic and diluted	\$ (0.76)	\$ —	\$ (0.57)
Net loss—basic and diluted	<u>\$ (0.97)</u>	<u>\$ (0.12)</u>	<u>\$ (0.89)</u>
<b>WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:</b>			
Basic and diluted	<u>163,742</u>	<u>163,742</u>	<u>163,742</u>

ADJUSTED CONSOLIDATED BALANCE SHEET

	December 31, 2022		
	As Reported on Form 10-K (1)	Subsequent Event Adjustment	As reported in Alkermes Plc Directors' Report and Consolidated Financial Statements
<b>(In thousands)</b>			
Debtors	\$ 459,490	\$ —	\$ 459,490
Total assets	<u>\$ 1,963,978</u>	<u>\$ —</u>	<u>\$ 1,963,978</u>
Profit and loss account	(341,948)	—	(341,948)
Total equity	1,043,753	—	1,043,753
Total liabilities	920,225	—	920,225
Total liabilities and equity	<u>\$ 1,963,978</u>	<u>\$ —</u>	<u>\$ 1,963,978</u>

**ALKERMES PLC**  
**PARENT COMPANY BALANCE SHEET**

(In thousands)	Note	December 31, 2023	December 31, 2022
<b>ASSETS</b>			
<i>Fixed Assets</i>			
Financial assets	7	\$ 2,192,562	\$ 2,180,334
Associated undertakings	8	5,459	5,168
Total fixed assets		<u>2,198,021</u>	<u>2,185,502</u>
<i>Current Assets</i>			
Debtors	9	705,026	975,210
Cash at bank and in-hand		60,562	34,649
TOTAL ASSETS		<u>\$ 2,963,609</u>	<u>\$ 3,195,361</u>
<b>EQUITY SHAREHOLDERS' FUNDS AND LIABILITIES</b>			
<i>Creditors</i>			
Creditors—amounts falling due after one year	10	\$ 110,000	\$ —
Creditors—amounts falling due within one year	10	16,623	26,744
Total for creditors		<u>126,623</u>	<u>26,744</u>
<i>Equity Shareholders' Funds</i>			
Share capital, \$0.01 par value	11	1,726	1,690
Share premium	12	655,718	638,965
Profit and loss account	12	1,370,263	1,791,079
Treasury shares	12	(189,336)	(160,862)
Other reserves	12	998,615	897,745
Total equity shareholders' funds		<u>\$ 2,836,986</u>	<u>\$ 3,168,617</u>
TOTAL EQUITY SHAREHOLDERS' FUNDS AND LIABILITIES		<u>\$ 2,963,609</u>	<u>\$ 3,195,361</u>

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

The Parent Company financial statements were approved by the Parent Company's board and signed on its behalf on March 28, 2024 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, 2022	\$ 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 for the purchase of share options or 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
Net loss	—	—	(40,816)	—	—	(40,816)
Share-based payment reserve	—	—	—	—	100,870	100,870
Shares issued under employee stock plans	36	16,753	—	—	—	16,789
Distribution of Mural Oncology plc	—	—	(380,000)	—	—	(380,000)
Receipt of Alkermes' shares to satisfy minimum tax withholding obligations related to share based awards	—	—	—	(28,474)	—	(28,474)
BALANCE—December 31, 2023	<u>\$ 1,726</u>	<u>\$ 655,718</u>	<u>\$ 1,370,263</u>	<u>\$ (189,336)</u>	<u>\$ 998,615</u>	<u>\$ 2,836,986</u>

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

## ALKERMES PLC

### NOTES TO THE PARENT COMPANY 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 merged 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. For this reason, the going concern basis continues to be adopted in the preparation of the Parent Company’s financial statements.

NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)

**3. Summary of Significant Accounting Policies (Continued)**

***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.

## NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)

**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.

On February 15, 2024, the Parent Company's board of directors authorized a share repurchase program to repurchase ordinary shares of the Company in an aggregate amount of up to \$400.0 million (exclusive of any fees, commissions or other expenses related to such repurchases) from time to time (the "2024 Repurchase Program"). The timing and amount of any share repurchases under the 2024 Repurchase Program will be based on a variety of factors, including but not limited to ongoing assessments of the Company's capital needs, alternative investment opportunities, the market price of the Company's ordinary shares and general market conditions. The 2024 Repurchase Program has no set expiration date and may be suspended or discontinued at any time. The 2024 Repurchase Program terminates, and supersedes in its entirety, the Company's prior share repurchase program authorized by its board of directors in September 2011 (the "Prior Repurchase Program") under which the Company has purchased a total of 8,866,342 ordinary shares at a cost of \$114.0 million. During the years ended December 31, 2023 and 2022 the Company did not purchase any ordinary shares under the Prior Repurchase Program.

***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 17, *Share-Based Compensation*, of the 2023 Alkermes plc consolidated financial statements provides additional details of the Company's share-based compensation plans.



## NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)

**3. Summary of Significant Accounting Policies (Continued)*****Contingencies***

Contingent liabilities, arising as a result of past events, are not recognized as a liability because 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.

***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 2024 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, 2023 and 2022, determined in accordance with Irish GAAP, was \$40.8 million and \$8.0 million, respectively.

ALKERMES PLC

NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)

**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 judgment 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 26, *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, 2022, 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
Capital contribution in respect of share-based payment plans	95,520
Reduction—equity recharge from subsidiaries	(83,292)
Balance—December 31, 2023, at cost	\$ 2,192,562

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 28, *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, 2023, 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, 2023 and 2022, the Parent Company’s investment is equal to \$5.4 million and \$5.2 million, respectively, which is included within “Associated undertakings” in the accompanying balance sheets.

	(In thousands)
Balance—January 1, 2022, at cost	\$ 5,235
Contribution to associated undertakings	695
Distributions from associated undertakings	(485)
Foreign exchange	(277)
Balance—December 31, 2022, at cost	\$ 5,168
Contributions to associated undertakings	97
Foreign exchange	194
Balance—December 31, 2023, at cost	\$ 5,459

ALKERMES PLC

NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)

9. Debtors

(In thousands)	December 31, 2023	December 31, 2022
<i>Amounts falling due within one year</i>		
Prepaid expenses and other current assets	\$ 77	\$ 2,941
Intercompany notes and loans receivable	59,949	182,269
	<u>\$ 60,026</u>	<u>\$ 185,210</u>
<i>Amounts falling due after one year</i>		
Intercompany loans receivable	645,000	790,000
Total	<u>\$ 705,026</u>	<u>\$ 975,210</u>

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

Borrower	Maturity	Interest Rate	December 31,	
			2023	2022
(In thousands)				
Daravita Pharma Ireland Limited	Repayable upon demand	None	\$ 3,600	\$ 3,600
Alkermes Finance Ireland No.3 Limited	Repayable upon demand	Variable	56,349	178,669
Total			<u>\$ 59,949</u>	<u>\$ 182,269</u>

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,	
			2023	2022
(in thousands)				
Alkermes Pharma Ireland Limited	July 8, 2027	7.00%	\$ 130,000	\$ 300,000
Alkermes Pharma Ireland Limited	September 12, 2027	7.00%	450,000	450,000
Alkermes Pharma Ireland Limited	September 12, 2027	7.00%	65,000	40,000
Total			<u>\$ 645,000</u>	<u>\$ 790,000</u>

10. Creditors

(In thousands)	December 31, 2023	December 31, 2022
<i>Amounts falling due within one year</i>		
Accrued expenses	\$ 2,167	\$ 720
Trade creditors	50	108
Intercompany payables	14,406	25,916
Total	<u>\$ 16,623</u>	<u>\$ 26,744</u>

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.

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

Holder	Maturity	Interest Rate	December 31,	
			2023	2022
(in thousands)				
Alkermes Pharma Ireland Limited	November 14, 2027	4.69%	\$ 110,000	\$ —
Total			<u>\$ 110,000</u>	<u>\$ —</u>

**ALKERMES PLC**

**NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)**

**11. Share Capital**

<b>(In thousands, except per share amounts)</b>	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Authorized:</b>		
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
<b>Share Capital</b>	<b>\$ 5,040,000</b>	<b>\$ 5,040,000</b>
<b>Issued Ordinary Shares (par value, \$0.01 per share)</b>		
<b>(Value in thousands)</b>	<b>Number</b>	<b>Value</b>
Balance at January 1, 2022	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
Issuance of ordinary shares under employee stock plans	3,617,858	36
Balance at December 31, 2023	<u>172,569,051</u>	<u>\$ 1,726</u>

See Note 16, *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.

**ALKERMES PLC**

**NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)**

**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, 2023, there were no potential losses from claims, asserted or unasserted, or legal proceedings the Parent Company felt were probable of occurring (at December 31, 2022: 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:

(In thousands)	Year Ended	
	December 31, 2023	December 31, 2022
Audit of the Parent Company's individual financial statements	\$ 25	\$ 25
Other assurance services	—	—
Tax advisory services	—	—
Other non-audit services	—	—
<b>Total</b>	<b>\$ 25</b>	<b>\$ 25</b>

See Note 27, *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 and were signed on its behalf on March 28, 2024.