2022 IRISH STATUTORY ACCOUNTS

AVADEL PHARMACEUTICALS PLC

Directors' Report and Consolidated Financial Statements

For the Financial Year Ended 31 December 2022

AVADEL PHARMACEUTICALS PLC
TABLE OF CONTENTS

DIRECTORS' REPORT

For the Financial Year Ended 31 December 2022

(dollars in thousands, except share data and where indicated)

Overview

The directors present their report on the audited consolidated financial statements for the financial year ended 31 December 2022, which are set out on pages 62 to 96, and audited parent Company financial statements for the financial year ended 31 December 2022, which are set out on pages 97 to 114.

The directors have elected to prepare the Irish statutory consolidated financial statements of Avadel Pharmaceuticals plc in accordance with Section 279 of the Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position, and profit or loss may be given by preparing the financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of part 6 of the Companies Act 2014.

The directors have elected to prepare the Avadel Pharmaceuticals plc parent Company financial statements in accordance with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* (Generally Accepted Accounting Practice in Ireland) and the Companies Act 2014.

Basis of Presentation

The accompanying consolidated financial statements reflect the consolidated financial position of the parent Company ("Avadel Pharmaceuticals plc" or "the Company") and its subsidiaries (Avadel Pharmaceuticals plc and all its subsidiaries, hereinafter referred to as "Avadel", "the Group", "us", "we", or "our") as an independent, publicly-traded Group.

Trademarks and Trade Names

Avadel owns or has rights to use trademarks and trade names that it uses in conjunction with the operation of its business. One of the more important trademarks that it owns or has rights to use that appears in this Directors' Report is "Avadel," which is a registered trademark or the subject of pending trademark applications in the United States ("U.S.") and other jurisdictions. Solely for convenience, we only use the ™ or ® symbols the first time any trademark or trade name is mentioned. Such references are not intended to indicate in any way that we will not assert, to the fullest extent permitted under applicable law, our rights to our trademarks and trade names. Each trademark or trade name of any other Group appearing in this Directors' Report is, to our knowledge, owned by such other Group.

Forward-Looking Statements

We have made forward-looking statements in this Directors' Report that are based on the director's beliefs and assumptions and on information currently available to the directors. Forward-looking statements include, but are not limited to, information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, potential growth opportunities, potential operating performance improvements, the effects of competition and the effects of future legislation or regulations. Forward-looking statements include all statements that are not historical facts and can be identified by the use of forward-looking terminology such as the words "believe," "expect," "plan," "intend," "project," "anticipate," "estimate," "predict," "potential," "continue," "may," "should" or the negative of these terms or similar expressions.

Forward-looking statements involve risks, uncertainties and assumptions. Actual results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any forward-looking statements.

The principal risks and uncertainties included in this Directors' Report could cause our results to differ materially from those expressed in forward-looking statements. There may be other risks and uncertainties that we are unable to predict at this time or that we currently do not expect to have a material adverse effect on our business.

These forward-looking statements are made as of the 31 December 2022. We expressly disclaim any obligation to update these forward-looking statements other than as required by law.

Principal Activities

Avadel Pharmaceuticals plc and its subsidiaries (Nasdaq: AVDL) is a biopharmaceutical company. Our lead product, LUMRYZ, formally known as FT218, is an extended-release formulation of sodium oxybate indicated to be taken once at

bedtime for the treatment of cataplexy or excessive daytime sleepiness ("EDS") in adults with narcolepsy. On 1 May 2023, LUMRYZ was approved by the U.S. Food and Drug Administration ("FDA"). We are primarily focused on the commercial launch of LUMRYZ.

Outside of LUMRYZ, the Group continues to evaluate opportunities to expand its product portfolio. As of the date of this report, the Group does not have any other commercialized products in its portfolio.

LUMRYZ

Our lead product LUMRYZ was approved by the United States ("U.S.") Food and Drug Administration ("FDA") in May 2023 for the treatment of cataplexy or EDS in adults with narcolepsy. In approving LUMRYZ, the FDA approved a risk evaluation and mitigation strategy ("REMS") for LUMRYZ to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in narcolepsy outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of the drug. Under this REMS, healthcare providers must be specially certified, pharmacies, practitioners, or health care settings that dispense the drug must be specially certified and the drug must be dispensed to patients with documentation of safe use conditions. Additionally, with its approval, the FDA also granted seven years of orphan drug exclusivity to LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy due to a finding of clinical superiority of LUMRYZ relative to currently marketed oxybate treatments. In particular, FDA found that LUMRYZ makes a major contribution to patient care over currently marketed, twice-nightly oxybate treatments by providing a once-nightly dosing regimen that avoids nocturnal arousal to take a second dose. We are advancing our preparations for the commercial launch of LUMRYZ. For example, on March 15, 2023, we were notified by the FDA that we are permitted to conduct certain pre-launch activities including the importation of foreign manufactured product under the Pre-launch Activities Importation Request ("PLAIR") Program.

With respect to clinical data generated for LUMRYZ, we conducted a Phase 3 clinical trial of LUMRYZ (the "REST-ON trial"), which was a randomized, double-blind, placebo-controlled study that enrolled 212 patients who received at least one dose of LUMRYZ or placebo, and was conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient's last visit was completed at the end of the first quarter of 2020, and positive top line data from the REST-ON trial was announced on 27 April 2020. Patients who received 9 g of once-at-bedtime LUMRYZ, the highest dose administered in the trial, demonstrated statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test ("MWT"), clinical global impression-improvement ("CGI-I"), and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g, also demonstrated statistically significant and clinically meaningful improvement on all three co-primary endpoints compared to placebo. We observed the 9 g dose of once-at-bedtime LUMRYZ to be generally well-tolerated. Adverse reactions commonly associated with sodium oxybate were observed in a small number of patients (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3% and enuresis 9%), and 3.9% of the patients who received 9 g of LUMRYZ discontinued the trial due to adverse reactions.

In January 2018, the FDA granted LUMRYZ orphan drug designation for the treatment of narcolepsy, which made LUMRYZ eligible for certain development and commercial incentives, including potential U.S. market exclusivity for up to seven years. With the approval of LUMRYZ on May 1, 2023, the FDA also granted seven years of orphan drug exclusivity to LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy. That orphan exclusivity will continue until May 1, 2030. Additionally, thirteen LUMRYZ-related U.S. patents have been issued having expiration dates spanning from mid-2037 to early-2042, and there are additional patent applications currently in development and/or pending at the U.S. Patent and Trademark Office ("USPTO"), as well as foreign patent offices.

In July 2020, we announced that the first patient was dosed in our open-label extension ("OLE")/switch study of LUMRYZ as a potential treatment for cataplexy or EDS in patients with narcolepsy ("RESTORE"). The RESTORE study is examining the long-term safety and maintenance of efficacy of LUMRYZ in patients with narcolepsy who participated in the REST-ON study, as well as dosing and preference data for patients switching from twice-nightly sodium oxybate to once-at-bedtime LUMRYZ, regardless of whether they participated in REST-ON. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study.

New secondary endpoints from the REST-ON trial were presented at the American Academy of Neurology, beginning 17 April 2021. The first poster described LUMRYZ improvements in disturbed nocturnal sleep ("DNS"), defined in REST-ON as the number of shifts from stages N1, N2, N3, and rapid eye movement ("REM") sleep to wake and from stages N2, N3, and REM sleep to stage N1. LUMRYZ also decreased the number of nocturnal arousals as measured on polysomnography. Improvements in DNS were further supported by post-hoc analyses demonstrating increased time in deep sleep (N3, also known as slow wave sleep), and less time in N1. A second poster described the statistically significant improvements in the Epworth Sleepiness

Scale ("ESS"), both the quality of sleep and the refreshing nature of sleep, and a decrease in sleep paralysis. These clinically relevant improvements were observed for all doses, beginning at week 3, for the lowest 6 g dose, compared to placebo. LUMRYZ did not demonstrate significant improvement for hypnagogic hallucinations compared to placebo.

Additional data supportive of the efficacy findings in REST-ON were presented at the 35th Annual Meeting of the Associated Professional Sleep Societies, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, also known as SLEEP 2021, beginning 10 June 2021. New data included post-hoc analyses demonstrating endpoints improvements, regardless of concomitant stimulant use, in both narcolepsy Type 1 ("NT1") or Type 2 ("NT2"). Additionally, a post-hoc analysis showed that LUMRYZ was associated with decreased body mass index compared to placebo, which may be relevant as people with narcolepsy often have co-morbid obesity. In August 2021, the primary results from the REST-ON trial were published by Kushida et al. in the journal SLEEP.

New data was presented at the American College of Chest Physicians annual meeting ("CHEST"), beginning 17 October 2021, including additional post-hoc analyses from the REST-ON trial, demonstrating a greater proportion of patients receiving LUMRYZ experienced reductions in weekly cataplexy attacks and improvement in mean sleep latency compared to placebo, as well as the results of a discrete choice experiment, indicating that the overall driver of patient preference between sodium oxybate treatments is a once-at-bedtime, versus twice-nightly, formulation.

New data was presented at World Sleep 2022 Congress in March 2022, in Rome, Italy. A total of eight posters were presented, including five new post-hoc analyses from the REST-ON trial. Most notably, the post-hoc analyses showed that LUMRYZ demonstrated improvement in subjective measures of daytime sleepiness, sleep quality and refreshing nature of sleep as early as week 1 with the 4.5 g starting dose, with even greater improvement at week 2 soon after starting the 6 g dose compared to placebo. Additional post-hoc analyses, stratified by narcolepsy type, as well as concomitant stimulant use, or without stimulants, demonstrated positive results that are generally consistent with previously reported positive endpoints from REST-ON and add to the existing body of evidence for LUMRYZ.

In addition, the results of a discrete choice experiment ("DCE") were presented, which showed that once-at-bedtime dosing, when compared to twice-nightly dosing, was the most important attribute driving both patient and clinician preference for overall oxybate product choice, as well as patient quality of life and reduction of patient anxiety/stress; dosing frequency (twice-nightly versus once-at-bedtime) was also viewed as a more important attribute as compared to other attributes assessed, including sodium content. Accompanying the DCE was a background survey for both patients and clinicians, which showed that dosing frequency was noted as a significant stressor by both patients and clinicians. The World Sleep 2022 presentations also included the first presentation of an interim safety analysis from the ongoing RESTORE study, which showed that LUMRYZ has generally been well-tolerated, with some patients receiving therapy for more than 18 months.

Additional peer-reviewed publications have included data on improvement on DNS, the first DCE and a Plain Language Summary reviewing sodium oxybate and cardiovascular health, which did not identify a signal of cardiovascular disease in the twenty years that sodium oxybate has been available. At the annual SLEEP Congress in June 2022, nine posters were presented, including five post-hoc analyses from REST-ON which support the following:

- A low number-needed-to-treat to achieve effectiveness across all three evaluated doses, as well as effect sizes, showing a moderate-to-high effect for improving MWT, ESS, and number of cataplexy attacks;
- Confirmation via various statistical methods to handle missing data that LUMRYZ improved cataplexy and EDS symptoms versus placebo;
- Confirmation of benefit for NT1 and NT2 for DNS and ESS;
- Confirmation of benefit for subgroups taking stimulants and those without stimulants for DNS and ESS; and
- Early efficacy (Week 1 and Week 2) for ESS, refreshing nature of sleep and quality of sleep.

In addition, interim data from RESTORE were presented demonstrating that a high proportion of patients switching from twice-nightly sodium oxybate formulations had difficulty in taking the second dose, with a high proportion (92.5%) stating a preference for the once-at-bedtime dosing regimen and that most participants (62%) switching from twice-nightly sodium oxybate formulations had a stable dose equal to their starting dose; participants not currently taking sodium oxybate formulations or oxybate naive reached a stable dose with 2–4 dose titrations within four weeks.

Additional peer-review publications have included a relative bioavailability pharmacokinetics ("PK") study and a Plain Language Summary of the primary REST-ON trial results.

We believe LUMRYZ has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standards of care for cataplexy or EDS in patients with narcolepsy.

Our Drug Delivery Technologies

We own drug delivery technologies that address formulation challenges, potentially allowing the development of differentiated drug products for administration in various forms (e.g., capsules, tablets, sachets or liquid suspensions for oral use; or injectables for subcutaneous administration) that could be applied to a broad range of drugs (novel, already-marketed, or off-patent).

A brief discussion of each of our drug delivery technologies is set forth below.

- MICROPUMP. Our MICROPUMP technology allows for the development of modified release solid, oral dosage formulations of drugs. MICROPUMP-carvedilol and MICROPUMP-aspirin formulations have been approved in the U.S. Further, a version of our MICROPUMP technology is being employed in our LUMRYZ product.

- LIQUITIME. Our LIQUITIME technology allows for development of modified release oral products in a liquid suspension formulation, which may make such formulations particularly well suited for children and/or patients having issues swallowing tablets or capsules. Although we own this technology, we are currently not pursuing any commercial pharmaceutical drug development opportunities using it.

- MEDUSA. Our MEDUSA technology allows for the development of modified-release injectable dosage formulations of drugs (e.g., peptides, polypeptides, proteins, and small molecules). Although we own this technology, we are currently not pursuing any commercial pharmaceutical drug development opportunities using it.

Corporate Information

The Group was incorporated in Ireland on 1 December 2015 as a private limited company, and re-registered as an Irish public limited company on 21 November 2016 (Company registration number: 572535). The address of our registered office is 10 Earlsfort Terrace, Dublin 2, Ireland.

We currently have five direct wholly-owned subsidiaries: (a) Avadel US Holdings, Inc., (b) Flamel Ireland Limited, which conducts business under the name Avadel Ireland, (c) Avadel Investment Company Limited, (d) Avadel Finance Ireland Designated Activity Company and (e) Avadel France Holding SAS. Avadel US Holdings, Inc., a Delaware corporation, is the holding entity of (i) Avadel Legacy Pharmaceuticals, LLC, (ii) Avadel Management Corporation, and (iii) Avadel CNS Pharmaceuticals LLC. Avadel Finance Ireland Designated Activity Company is the holding entity of Avadel Finance Cayman Limited. Flamel Ireland Limited (operating under the trade name Avadel Ireland) is an Irish corporation. Avadel France Holding SAS is the holding entity of Avadel Research SAS. A complete list of the Group's subsidiaries can be found in *Note 23: Subsidiary Undertakings* in the Notes to the consolidated financial statements.

Dividends

No dividends have been paid in the current or preceding period. We currently do not anticipate paying any cash dividends for the foreseeable future, as we intend to retain earnings to finance R&D, acquisitions and the continued operation and expansion of our business. The recommendation, declaration and payment of any dividends in the future by us will be subject to the sole discretion of our board of directors and will depend upon many factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with certain of our debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay dividends in the future, there can be no assurance that we will continue to pay such dividends.

Share Capital

For the changes in share capital, see *Note 14: Called-up Share Capital and Reserves*.

Share Repurchase Program

As of 31 December 2022, the Group does not hold any of its own shares.

Business Review and Key Performance Indicators

The Group reported a loss after taxation of $137,464 and a loss after taxation of $77,329 for fiscal 2022 and 2021, respectively.

	Fiscal Year		2022 vs. 2021	
	2022	2021	$	%
Research and development costs	$ (20,700)	$ (17,104)	$ (3,596)	(21.0)%
Distribution and administrative expenses	(74,516)	(68,495)	(6,021)	(8.8)%
Restructuring (expense) income	(3,345)	53	(3,398)	(6,411.3)%
Operating loss	(98,561)	(85,546)	(13,015)	(15.2)%
Investment and other (expense) income, net	(824)	1,706	(2,530)	(148.3)%
Interest expense	(12,342)	(9,942)	(2,400)	(24.1)%
Foreign exchange gain	288	637	(349)	54.8 %
Loss on ordinary activities before taxation	(111,439)	(93,145)	(18,294)	(19.6)%
Taxation (charge) credit	(26,025)	15,816	(41,841)	(264.5)%
Loss after taxation	$ (137,464)	$ (77,329)	$ (60,135)	77.8 %

Research and Development Cost

R&D cost increased $3,596 or 21.0% during the year ended 31 December 2022 as compared to the same period in 2021. This change is driven by a $4,800 increase in active pharmaceutical ingredient purchases in the current year, offset by a $1,000 reduction in clinical studies spend.

Distribution and Administrative Expenses

Distribution and administrative expenses increased $6,021 or 8.8% during the year ended 31 December 2022 as compared to the same prior year. This increase was driven primarily by higher legal costs of approximately $11,400 and debt issuance costs of approximately $5,450 related to the Exchange Transaction. The increase in selling, general and administrative expense was offset by lower commercial activities of approximately $7,800, and lower medical affairs activities of $2,400.

Restructuring (expense) income

Restructuring expense was $3,345 for the year ended December 31, 2022 as compared to restructuring income of $53 for the same period in 2021. Restructuring expense was driven by the 2022 Corporate Restructuring Plan, which was announced in June 2022. See *Note 24: Restructuring Costs* to our audited consolidated financial statements.

Investment and Other (Expense) Income, net

Investment and other (expense) income on our marketable securities was $(824) for the year ended 31 December 2022 as compared to $1,706 for the year ended 31 December 2021. The decrease in investment and other (expense) income, net was driven by $1,700 more of realized losses for the year ended December 31, 2022 as compared to the prior period, as well as $1,000 less of interest income earned for the year ended December 31, 2022 as compared to the prior period.

Interest Expense

Interest expense of $12,342 and $9,942 for the years ended 31 December 2022 and 2021, respectively, is related to interest on the February 2023 Notes. Included in these amounts are coupon interest expense of $6,405 and $6,469 for each period, respectively, and the amortization of debt issuance costs and debt discount of $6,052 and $1,248 for each period, respectively. Current period interest expense also included a $203 gain on the early extinguishment of $8,875 aggregate principal amount of the February 2023, which reduced total interest reported for the period. See *Note 13: Long-Term Debt* to our audited consolidated financial statements for further details. Interest expense for the years ended December 31, 2022 and 2021 also included $88 and $2,225, respectively, of additional interest expense owed as a result of not removing a restrictive legend from the 2023 Notes 365 days following original issuance of the 2023 Notes on February 16, 2018.

Foreign Exchange Gain

We recorded a foreign exchange gain of $288 for the year ended 31 December 2022 compared to a foreign exchange gain of $637 for the year ended 31 December 2021. The foreign exchange gain in the current year and prior year is a result of a decrease in the Euro foreign exchange rate.

Taxation

In 2022, income tax charge was $26,025, with an effective tax rate of (23.4)%, as compared to income tax credit of $15,816, with an effective tax rate of 17.0%, in 2021. The change in the effective tax rate for the year ended December 31, 2022 is primarily driven by the valuation allowances recorded against our deferred tax assets during the period. The effective tax rate for 2021 was impacted by the geographic mix of earnings.

	Fiscal Year		2022 vs 2021	
Balance Sheet Data:	**2022**	**2021**	**$**	**%**
Cash at bank and in hand	$ 73,981	$ 50,708	$ 23,273	45.9 %
Investments	22,518	106,513	(83,995)	(78.9)%
Debtors	16,898	70,271	(53,373)	(76.0)%
Creditors	(147,910)	(164,824)	16,914	(10.3)%
Provision for liabilities	(6,020)	(4,197)	(1,823)	43.4 %
Shareholders' Funds	$ (21,145)	$ 78,244	$ (99,389)	(127.0)%

Cash at bank and in hand

Cash at bank and in hand increased $23,273 driven by net proceeds from the sale of marketable securities of $83,828 and net proceeds from the sale and issuance of ADSs under the ATM program of $25,318 offset by the use of cash in operating activities of $70,304.

Investments

Investments decreased $83,995 driven by sale of investments to fund operations. There was a net decrease of $55,580 to money market and mutual funds, a net decrease of $16,479 to corporate bonds, a net decrease of $9,471 to U.S. government securities, and a net decrease of $2,465 to other fixed-income securities. See *Note 7: Investments.*

Debtors

Debtors decreased $53,373 due to collection of an income tax receivable of $29,097 and decrease in deferred tax assets of $24,128 as a result of the Company recording a full valuation allowance. See Note *4: Taxation Credit.*

Creditors

Creditors decreased $16,914 due to the payment of the February 2023 Notes and amortization of debt issuance and debt discount costs. See *Note 13: Long-Term Debt.*

Provision for Liabilities

Provision for liabilities increased $1,823, due to amounts charged against the provision for tax liabilities. See *Note 12: Provisions for Liabilities.*

Shareholders' Funds

The decrease in Shareholders' Funds is driven by the net loss of $137,464. See the Consolidated Statement of Changes in Shareholders' (Deficit) Equity and *Note 14: Called-up Share Capital and Reserves.*

Competition and Market Opportunities

Competition

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with other pharmaceutical and biotechnology companies. Some of these competitors may also be our business partners. There can be no assurance that our competitors will not obtain patent protection or other intellectual property rights that would make it difficult or impossible for us to compete with their products. Furthermore, major technological changes can happen quickly in the pharmaceutical and biotechnology industries. Such rapid technological change, or the development by our competitors of technologically improved or differentiated products, could render our products, product candidates, or drug delivery platforms, obsolete or noncompetitive.

The pharmaceutical industry has dramatically changed in recent years, largely as a function of the growing importance of generic drugs. The growth of generics (typically small molecules) and of large molecules (biosimilars) has been accelerated by the demand for less expensive pharmaceutical products. As a result, the pricing power of pharmaceutical companies will be more tightly controlled in the future.

In addition, consolidation has reduced our pool of potential partners and acquisition opportunities within the biopharmaceutical space.

Potential competition for LUMRYZ

LUMRYZ will compete with the currently approved twice-nightly oxybate formulations, as well as a number of daytime wake promoting agents including lisdexamfetamine, detroamphetamine, methylphenidate, amphetamine, modafinil, and armodafinil, which are widely prescribed, as well as solriamfetol and pitolisant. We anticipate LUMRYZ may face competition from manufacturers of generic twice-nightly sodium oxybate formulations, who have reached settlement agreements with the current marketer, which allows for entry of an authorized generic in 2023. On 3 January 2023, Hikma Pharmaceuticals plc, announced that it launched an authorized generic version of Jazz Pharmaceuticals plc's ("Jazz") Xyrem (sodium oxybate). Hikma will have 180 days of marketing exclusivity for its authorized generic product in the U.S. and will distribute through the same specialty pharmacy that Jazz uses to dispense Xyrem.

In addition, there are other products in development that may be approved in the future that could have an impact on the narcolepsy treatment market, including, for example, reboxetine, orexin 2 receptor agonists, flecainide / modafinil combination, histamine H3 antagonists/inverse agonists, or GABAB agonists.

Intellectual Property

Parts of our product pipeline and strategic alliances utilize our drug delivery platforms and related products of which certain features are the subject of patents or patent applications. As a matter of policy, we seek patent protection of our inventions and also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and develop competitive positions.

- LUMRYZ Patents. We have been awarded thirteen LUMRYZ-related U.S. patents having expiry dates from mid-2037 to early-2042. We have a number of additional LUMRYZ-related patent applications pending at the USPTO as well as at non-U.S. patent offices.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and patent scope can be reinterpreted by the courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any of our licensed or owned patents will provide sufficient protection from competitors. Any of our licensed or owned patents may be challenged, circumvented, or invalidated by third parties. For more information, please see the information set forth under the caption "Risks Related to Our Intellectual Property – If we cannot adequately protect our intellectual property and proprietary information, we may be unable to effectively compete" in the "Principal Risks and Uncertainties".

Supplies and Manufacturing

We attempt to maintain multiple suppliers in order to mitigate the risk of shortfall and inability to supply market demand. Nevertheless, for LUMRYZ, we currently rely on one supplier for sourcing active pharmaceutical ingredients ("API").

The API in LUMRYZ, sodium oxybate, is a Schedule I controlled substance in the U.S., and LUMRYZ is anticipated to be a Schedule III controlled substance in the U.S. per current federal regulations. As a result, LUMRYZ is subject to regulation by the U.S. Drug Enforcement Administration ("DEA") under the Controlled Substances Act ("CSA"), and its manufacturing and distribution are highly restricted. Quotas from the DEA are required in order to manufacture and primary package sodium oxybate and LUMRYZ in the U.S. Similar rules, restrictions and controls apply to LUMRYZ in relevant jurisdictions outside of the U.S.

The API for LUMRYZ is currently manufactured by a single source contract manufacturing organization ("CMO") in the U.S. The drug product for commercial lots is manufactured outside of the U.S. by a single source CMO. We will continue to outsource the production of LUMRYZ to current good manufacturing practices ("cGMP") -compliant, DEA and FDA-audited CMOs pursuant to supply agreements and have no present plans to acquire manufacturing facilities. We are establishing, and may continue to establish, additional CMOs for the manufacture LUMRYZ, including drug product manufacturing in the U.S.

Principal Risks and Uncertainties

An investment in Avadel involves a high degree of risk. You should carefully consider the risks described below, as well as the other information included in the Directors' Report and accompanying financial statements, before making an investment decision. Avadel's business, financial condition, results of operations and cash flows could be materially adversely affected by any of these risks. The market or trading price of Avadel's securities could decline due to any of these risks.

The principal risks and uncertainties described below reflect the Board's assessment of the principal risks and uncertainties facing the company as of 29 March 2023. These risks and uncertainties should be read in the context of the matters described in the "Events Since the Balance Sheet Date" section of this directors' report below.

Risks Related to Our Lead Product Candidate, Future Product Candidates Clinical Development and Commercialization

We cannot be certain that our lead product candidate or future product candidates will receive marketing approval. Without marketing approval, we will not be able to commercialize our lead product candidate or future product candidates.

We have devoted significant financial resources and business efforts to the development of our lead product candidate. We cannot be certain that our lead product candidate or future product candidates will receive marketing approval.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the U.S. and by comparable regulatory authorities in other countries. We are not permitted to market our lead product candidate or future product candidates in the U.S. until we receive approval of an NDA by the FDA. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. An NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. For example, we submitted an NDA to the FDA for LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy in December 2020 through the Section 505(b)(2) regulatory pathway. In February 2021, the FDA assigned LUMRYZ a PDUFA target action date of 15 October 2021. In October 2021, the FDA notified us that its review was still ongoing and action would not be taken by the PDUFA date. On 24 May 2022, we were notified by the FDA that the LUMRYZ NDA patent statement pertaining to the REMS Patent was deemed inappropriate. As such, the FDA requested the Group add a certification to the REMS Patent to its NDA. On 29 June 2022, we announced that we had submitted a Paragraph IV patent certification pertaining to the REMS Patent to LUMRYZ's NDA. On 15 July 2022, Jazz filed a patent infringement suit in the U.S. District Court for the District of Delaware ("the Delaware Court") asserting that LUMRYZ will infringe at least one claim of that patent. The filing of that lawsuit triggered a regulatory stay on FDA approval of LUMRYZ. On 18 July 2022, we received tentative approval from the FDA for LUMRYZ for the treatment of cataplexy or EDS in adults suffering from narcolepsy. On 18 November 2022, pursuant to a motion requesting same as well as briefing and arguments of the parties, the Delaware Court issued an order requiring Jazz to request delisting of the REMS Patent from FDA's Orange Book. Jazz appealed the Delaware Court's decision to the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit"), which resulted in a stay of the Delaware Court's order pending appeal. On 24 February 2023, the Federal Circuit issued an opinion affirming the Delaware Court's decision and ordered Jazz to request delisting of the REMS Patent from FDA's Orange Book within 14 days of the Federal Circuit's decision. On 28 February 2023, Jazz complied with the order

of the Federal Circuit and provided a written submission to the FDA requesting delisting of the REMS Patent from FDA's Orange Book. On 1 March 2023, we submitted an amendment to our NDA for LUMRYZ requesting final FDA approval for LUMRYZ. Our receipt of tentative approval and filing of our amendment requesting final approval does not mean we will receive final FDA approval for the LUMRYZ NDA in a timely manner or at all. In addition, a drug product that is granted tentative approval, like LUMRYZ, may be subject to additional review before final approval. The FDA's tentative approval of LUMRYZ was based on information available to the FDA at the time of the tentative approval letter (i.e., information in the application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to the FDA's attention. We cannot legally market LUMRYZ in the U.S. until we obtain final approval from the FDA. Any delay or setback in obtaining final approval or the commercialization of our lead product candidate will adversely affect our business.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that we cannot rely on the Section 505(b)(2) regulatory pathway or other pathways we have selected, as applicable, for our product candidate;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of our product candidate for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the U.S., including any findings that the clinical and other benefits of our product candidate outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for our product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously approved drugs with the same conditions of approval as our product candidate, as applicable;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidate;
- may audit some or all of our clinical research study sites to determine the integrity of our data and may reject any or all of such data;
- may approve our product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may not determine that our product candidate is clinically superior to any previously approved same drug;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidate.

Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials and/or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for the approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions.

We have submitted an NDA for LUMRYZ in the U.S. and will evaluate filing potentially elsewhere. We have determined, following FDA consultation, that the 505(b)(2) approval pathway, which permits an NDA applicant to rely on the FDA's previous findings of safety or effectiveness and data from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, is the appropriate pathway for a LUMRYZ NDA. There can be no assurances, however, that the 505(b)(2) approval pathway in the U.S., or similar approval pathways outside of the U.S., will be available for our product candidate or that the FDA or other regulatory authorities will approve our product candidate through an application based on such pathways.

Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the U.S. or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in

regulatory policy during the period of product development and the emergence of new information regarding our product candidate.

Our business is significantly dependent on the successful development, regulatory approval and commercialization of LUMRYZ, our only product candidate.

We have invested substantially all of our efforts and financial resources in the development of LUMRYZ, which has not yet been approved for sale or commercial use. Currently, LUMRYZ is our only product candidate and we have not licensed, acquired, or invented any other product candidates for preclinical or clinical evaluation. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and that therefore may be able to better sustain a failure of a lead candidate. The success of our business, including our ability to finance our company and generate any revenue in the future, will, at this point, depend entirely on the regulatory approval and commercialization of LUMRYZ, which may never occur. Any failure to obtain regulatory approval of LUMRYZ would have a material and adverse impact on our business. Even if we successfully obtain regulatory approvals to market LUMRYZ, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of LUMRYZ, even if approved.

The commercial success of LUMRYZ will depend on a number of factors, including the following:

- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- our ability to raise any additional required capital to support the commercialization on acceptable terms, or at all;
- our ability to consistently manufacture LUMRYZ on a timely basis;
- our ability to secure and maintain from the U.S. DEA our annual quota for LUMRYZ API;
- our ability to successfully to develop and implement a REMS for the safe use of LUMRYZ;
- the prevalence, duration and severity of potential side effects or other safety issues that patients may experience with LUMRYZ;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to LUMRYZ;
- the differentiation of LUMRYZ from other available approved, or investigational, drugs and treatments of cataplexy or EDS in adults with narcolepsy, and the willingness of physicians, operators of hospitals and clinics and patients to adopt and utilize LUMRYZ's once-at-bedtime formulation;
- our ability to successfully develop a commercial strategy and thereafter commercialize LUMRYZ in the U.S. and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid and similar foreign authorities) and other third-party payors for LUMRYZ;
- patients' ability and willingness to pay out-of-pocket for LUMRYZ, if granted final approval by the FDA, in the absence of coverage and/or adequate reimbursement from third-party payor;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of LUMRYZ, if granted final approval by the FDA;
- patient demand for LUMRYZ, if granted final approval by the FDA;
- our ability to establish and enforce intellectual property rights in and to LUMRYZ; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize LUMRYZ. Even if regulatory approvals are obtained, we may never be able to successfully commercialize LUMRYZ. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of LUMRYZ to continue our business or achieve profitability.

Our lead product candidate and future product candidates may not reach the commercial market for a number of reasons.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Successful research and development of pharmaceutical products is difficult, expensive and time consuming. Many product candidates fail to reach the market. Our success will depend on the development and the successful commercialization of new drugs and products that utilize our drug delivery technologies.

Even if our product candidates and current drug delivery technologies appear promising during development, there may not be successful commercial applications developed for them for a number of reasons, including:

- the FDA, the European Medicines Agency ("EMA"), the competent authority of a European Union ("EU") Member State or an IRB, or an Ethics Committee (EU equivalent to IRB), or our partners may delay or halt applicable clinical trials;
- we or our partners may face slower than expected rate of patient recruitment and enrollment in clinical trials, or may devote insufficient funding to the clinical trials;
- our drug delivery technologies and drug products may be found to be ineffective or to cause harmful side effects, or may fail during any stage of pre-clinical testing or clinical trials;
- we or our partners may find that certain products cannot be manufactured on a commercial scale and, therefore, may not be economical or feasible to produce;
- we or our partners may face delays in completing our clinical trials due to circumstances outside of our control, including natural disasters, labor or civil unrest, global health concerns or pandemics or acts of war or terrorism; or
- our lead product candidate and future product candidates could fail to obtain regulatory approval or, if approved, could fail to achieve market acceptance, could fail to be included within the pricing and reimbursement schemes of the U.S. or EU Member States, or could be precluded from commercialization by proprietary rights of third parties.

If we are not able to use the 505(b)(2) regulatory approval pathway for the regulatory approval of LUMRYZ or if the FDA requires additional clinical or nonclinical data to support an NDA under Section 505(b)(2) than we previously anticipated, it will likely take significantly longer, cost significantly more and be significantly more complicated to gain FDA approval for LUMRYZ, and in any case may not be successful.

We submitted an NDA to the FDA for LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy in December 2020 through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the FDCA. In general, Section 505(b)(2) allows an applicant to rely on the FDA's prior findings of safety or effectiveness for a listed drug only to the extent that the proposed product in the 505(b)(2) application shares common characteristics with the listed drug, or on published literature that the applicant believes supports the safety or efficacy of its proposed product but for which it does not have a right of reference for the underlying data. The 505(b)(2) application must include sufficient data to support differences between the listed drug and the proposed drug in the 505(b)(2) application. If the FDA does not agree that the 505(b)(2) regulatory pathway is appropriate or scientifically justified for LUMRYZ, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. Specifically, the FDA may not agree that we have provided a scientific bridge, through, for example, comparative bioavailability data, to demonstrate that reliance on the prior findings of safety or efficacy for a listed drug is justified. Although the active ingredient in LUMRYZ, sodium oxybate, is approved for the treatment of cataplexy or EDS in patients 7 years of age and older with narcolepsy, it has not previously been approved or demonstrated to be safe for once-at-bedtime administration in these indications. If we are unable to establish a bridge between LUMRYZ and the listed drug upon which we rely to demonstrate that such reliance is justified, we may be required to show safety and efficacy through one or more additional clinical trials. In addition, if we are unable to utilize the 505(b)(2) pathway, the time and financial resources required to obtain FDA approval for LUMRYZ would likely increase substantially. Moreover, the inability to utilize the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than LUMRYZ, which could materially adversely impact its competitive position and prospects.

Even if we are successful in pursuing the 505(b)(2) regulatory pathway for LUMRYZ, we cannot assure you that we will receive the requisite or timely approval for commercialization of LUMRYZ. Although the Section 505(b)(2) pathway allows us to rely in part on the FDA's prior findings of safety or efficacy for approved listed drugs or on published literature for which we do not have a right of reference, the FDA may determine that prior findings by the FDA or the published literature that we believe supports the safety or efficacy of LUMRYZ is insufficient or not applicable to our application or that additional studies will need to be conducted. To the extent that we are relying on the 505(b)(2) regulatory pathway based on the approval of a listed drug for a similar indication, the FDA may require that we include in the labeling of LUMRYZ, if granted final approval

by the FDA, some or all of the safety information that is included in the labeling of the approved listed drug. For example, the labels of current FDA-approved sodium oxybate products include a black box warning regarding risks of central nervous system depression and abuse and misuse. Moreover, even if LUMRYZ is granted final approval by the FDA via the 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, such as a REMS, which is a risk mitigation plan which could include medication guides, physician communication plans, or elements to assure safe use ("ETASU"), such as restricted distribution methods, patient registries and other risk minimization tools.

Our business depends heavily on our ability to successfully commercialize LUMRYZ in the U.S. and in other jurisdictions where we may obtain marketing approval. There is no assurance that our commercialization efforts with respect to LUMRYZ, if granted final approval by the FDA, will be successful or that we will be able to generate revenues at the levels or on the timing we expect, or at levels or on the timing necessary to support our goals.

Our business currently depends heavily on our ability to successfully commercialize LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy in the U.S. and in other jurisdictions where we may obtain marketing approval. Even if we obtain marketing approval for LUMRYZ, we may never be able to successfully commercialize our product or meet our expectations with respect to revenues. There is no guarantee that the infrastructure, systems, processes, policies, relationships, and materials we are building for the commercialization of LUMRYZ in the U.S., or that we may build for other jurisdictions where we may obtain marketing approval, will be sufficient for us to achieve success at the levels we expect. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected. We may encounter issues, delays or other challenges in launching or commercializing LUMRYZ, if granted final approval by the FDA. For example, our results may be negatively impacted if we have not adequately sized our field teams or if our targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes.

We may encounter issues and challenges in commercializing LUMRYZ, if granted final approval by the FDA, and generating sufficient revenues to result in a profit. We may also encounter challenges related to reimbursement of LUMRYZ, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering LUMRYZ. Similarly, healthcare settings or patients may determine that the financial burdens of treatment are not acceptable. We may face other limitations or issues related to the price of LUMRYZ. Our results may also be negatively impacted if we have not adequately sized our field teams or our physician segmentation and targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes. Other factors that may hinder our ability to successfully commercialize LUMRYZ, if granted final approval by the FDA, and generate sufficient revenues to result in a profit, include:

- the acceptance of LUMRYZ by patients and the medical community;
- the ability of our third-party manufacturer(s) to manufacture commercial supplies of LUMRYZ in sufficient quantities at acceptable costs, to remain in good standing with regulatory agencies, maintain applicable registrations and licenses, and to maintain commercially viable manufacturing processes that are, to the extent required, compliant with cGMP regulations;
- our ability to remain compliant with laws and regulations that apply to us and our commercial activities;
- FDA- or other foreign regulatory agency-mandated package insert requirements and successful completion of any related FDA or other foreign regulatory agency post-marketing requirements, including a REMS;
- the actual market size for LUMRYZ, which may be different than expected;
- the length of time that patients who are prescribed our drug remain on treatment;
- the sufficiency of our drug supply to meet commercial demand which could be negatively impacted if our projections regarding the potential number of patients are inaccurate, we are subject to unanticipated regulatory requirements, or our current drug supply is destroyed, or negatively impacted at our manufacturing sites, storage sites, or in transit;
- our ability to effectively complete with other therapies; and
- our ability to maintain, enforce, and defend third party challenges to our intellectual property rights in and to LUMRYZ.

Any of these issues could impair our ability to successfully commercialize our product, if approved, or to generate sufficient revenues to result in a profit or to meet our expectations with respect to the amount or timing of revenues or profits. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition, and prospects. Even if granted final approval, there is no guarantee that we will be successful in our commercialization efforts with respect to LUMRYZ. We may also experience significant fluctuations in sales of LUMRYZ

from period to period and, ultimately, we may never generate sufficient revenues from LUMRYZ to reach or maintain profitability or sustain our anticipated levels of operations. Any inability on our part to successfully commercialize LUMRYZ in the U.S. and any other international markets where it may be approved or any significant delay, could have a material adverse impact on our ability to execute upon our business strategy.

Clinical development of drugs is costly and time-consuming, and the outcomes are uncertain. A failure to prove that LUMRYZ is safe and effective in clinical trials could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Clinical trials are expensive and can take many years to complete, and the outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical testing. For example, we are currently conducting the RESTORE study to examine the long-term safety and maintenance of efficacy of LUMRYZ in patients with narcolepsy who participated in our REST-ON trial, as well as dosing and preference data for patients switching from twice-nightly sodium oxybate to once-at-bedtime LUMRYZ regardless if they participated in REST-ON or not. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study. If any participants in the RESTORE study report any serious adverse events that are deemed to be related to LUMRYZ or if LUMRYZ is not observed to have long-term efficacy, our business, financial condition, results of operations and growth prospects could be material and adversely affected.

In addition to issues relating to the results generated in clinical trials, clinical trials can be delayed or halted for a variety of reasons, including delay or failure in:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board or ethics committee approval at each site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial;
- adding new sites; or
- obtaining clinical materials or manufacturing sufficient quantities of LUMRYZ for use in clinical trials.

We have limited experience as a commercial drug company targeting an orphan drug disease and the marketing and sale of LUMRYZ, if granted final approval by the FDA, may be unsuccessful or less successful than anticipated.

We have limited experience as a commercial drug company targeting an orphan disease and there is limited information about our ability to successfully overcome many of the risks and uncertainties encountered by companies commercializing drugs in the biopharmaceutical industry. To execute our business plan, in addition to successfully obtaining marketing approval and marketing and selling LUMRYZ, we will need to successfully:

- establish and maintain our relationships with healthcare providers who will be treating the patients who may receive our drug;
- obtain adequate pricing and reimbursement for LUMRYZ;
- develop and maintain successful strategic alliances; and
- manage our spending as costs and expenses increase due to marketing approvals and commercialization in multiple jurisdictions, if granted final approval by the FDA.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully commercialize LUMRYZ, raise capital, expand our business or continue our operations.

Our relationships with healthcare providers, physicians, prescribers, purchasers, third-party payors, charitable organizations and patients will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of biotechnology and biopharmaceutical products. Arrangements with third-party payors and customers can expose biotechnology and biopharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute ("AKS"), and the federal False Claims Act ("FCA"), which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biotechnology and biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

The distribution of biopharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biopharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party depend upon a number of factors.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate

reimbursement will be obtained. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the group placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, changes to our manufacturing arrangements; additions or modifications to product labeling; the recall or discontinuation of our products; or additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. If we are slow or unable to adapt to changes in existing requirements or the

adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

LUMRYZ, if successfully developed and approved, may cause undesirable side effects that limit the commercial profile or result in other significant negative consequences for approved products; or delay or prevent further development or regulatory approval with respect to product candidates or new indications, or cause regulatory authorities to require labeling statements, such as boxed warnings.

Undesirable side effects caused by LUMRYZ, if successfully developed and approved, could limit the commercial profile of LUMRYZ or result in significant negative consequences such as a more restrictive label or other limitations or restrictions. Undesirable side effects caused by LUMRYZ could cause us or regulatory authorities to interrupt, delay or halt non-clinical studies and clinical trials or could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities.

Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, certain side effects of LUMRYZ may only be uncovered with a significantly larger number of patients exposed to the drug, and those side effects could be serious or life-threatening. If we or others identify undesirable side effects caused by LUMRYZ (or any other similar drugs), a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their marketing approval of such drugs;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or additions to an existing boxed warning, or a contraindication, including as a result of inclusion in a class of drugs for a particular disease;
- regulatory authorities may refuse to approve label expansions for additional indications for any approved drugs;
- we may be required to change the way such drugs are distributed or administered, conduct additional clinical trials or change the labeling of the drugs;
- regulatory authorities may require a modification of an existing REMS to mitigate risks;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove LUMRYZ from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking LUMRYZ; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of LUMRYZ, if granted final approval by the FDA, and could substantially increase the costs of commercializing LUMRYZ and significantly impact our ability to successfully commercialize LUMRYZ and generate revenues.

We may incur significant liability if governmental authorities allege or determine that we are engaging in commercial activities or promoting LUMRYZ in a way that violates applicable regulations.

Physicians have the discretion to prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies regulate a manufacturer's communications regarding off-label use and prohibit off-label promotion, as well as the dissemination of false or misleading labeling or promotional materials. Manufacturers may not promote drugs for off-label uses. Accordingly, if LUMRYZ is granted final approval by the FDA, we may not promote LUMRYZ in the U.S. for any indications other than its FDA-approved indication. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses, including promoting unapproved dosing regimens, may be subject to significant liability, which may include civil and administrative remedies as well as criminal sanctions.

Notwithstanding regulations related to product promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We currently, and intend to increasingly, engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws and regulatory guidance.

Obtaining and maintaining regulatory approval of LUMRYZ in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of LUMRYZ in other jurisdictions.

Obtaining and maintaining regulatory approval of LUMRYZ in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of LUMRYZ, comparable regulatory authorities in foreign jurisdictions must also approve LUMRYZ in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of LUMRYZ in certain countries. If we fail to comply with the regulatory requirements in international markets or receive applicable marketing approvals, our market will be reduced and our ability to realize the full market potential of LUMRYZ will be harmed.

Laws and regulations governing international operations we have and may expand in the future may preclude us from developing, manufacturing, and selling certain product candidates and products outside of the U.S. and require us to develop and implement costly compliance programs.

As we seek to expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment, or offering anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of such third party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the group to maintain books and records that accurately and fairly reflect all transactions of the group, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials

and have led to FCPA enforcement actions. Similar laws in other countries, such as the U.K. Bribery Act 2010, may apply to our operations.

Various laws, regulations, and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we expand our presence outside of the U.S. in key European markets, we must dedicate additional resources to comply with these laws, and such laws may preclude us from developing, manufacturing, or selling certain product candidates and products outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Governments outside of the U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing authorization for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If we seek approval for our lead product candidate or future product candidates outside of the U.S. and reimbursement of our lead product candidate or future product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Failure to comply with domestic and international privacy and security laws could result in the imposition of significant civil and criminal penalties.

The costs of compliance with privacy and security laws, including protecting electronically stored information from cyber-attacks, and potential liability associated with any compliance failures could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to HIPAA and the General Data Protection Regulation ("GDPR") (Regulation EU 2016/679). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many U.S. states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. GDPR requires us to ensure personal data collected by us is gathered legally and under strict conditions and to protect such personal data from misuse and exploitation. If we fail to comply with HIPAA, GDPR or other similar laws, we will face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

Risks Related to Our Financial Position and Capital Requirements

We incurred a net loss in 2022 and we will likely incur a net loss in 2023, and if we are not able to achieve profitability in the future, the value of our shares may fall.

We incurred a net loss of $137,464 for the year ended 31 December 2022. We do not expect to become profitable in the near future and may never achieve profitability. The amount of our future net losses or net profitability will depend, in part, on the rate of our future expenditures and our ability to recognize revenues from the commercialization of LUMRYZ, if granted final approval by the FDA. We have devoted significant financial resources to research and development, including our clinical development activities, and the pursuit of regulatory approval for LUMRYZ. If we obtain marketing approval, our future revenues will depend upon the size of any markets in which LUMRYZ and any future products have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our product and any future products in those markets. In addition, we are in the process of building a sales organization and supporting commercial infrastructure and, accordingly, we will incur significant expenses in advance of generating any commercial product sales. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

- the timely receipt of approval from the FDA for the commercialization of LUMRYZ;

- our ability to obtain, build and expand manufacturing capacity, including capacity at third-party manufacturers;
- the effectiveness of our sales and marketing strategy;
- the demand and market size for LUMRYZ;
- the level of product and price competition for LUMRYZ;
- our ability to develop new partnerships and additional commercial applications for LUMRYZ and any future product candidates;
- our ability to control our costs;
- the initiation of additional research, preclinical, clinical or other programs as we seek to identify and validate additional product candidates;
- our ability to acquire or in-license other product candidates and technologies;
- our ability to maintain, protect and expand our intellectual property portfolio;
- general economic conditions.

Even if the FDA grants final approval of our NDA for LUMRYZ, we may never recognize revenue in amounts sufficient to achieve and maintain profitability. The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We may require additional financing to develop and commercialize our product candidate and implement our operating plans, which may not be available on favorable terms or at all, and which may result in dilution of the equity interest of the holders of ADSs.

We may require additional financing to fund the development and commercialization of LUMRYZ and possible acquisition of new products and businesses. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize LUMRYZ, if granted final approval by the FDA. If we cannot obtain financing when needed, or obtain it on favorable terms, we may be required to curtail our plans to continue to develop drug delivery technologies, develop new products, or acquire additional products and businesses. Other factors that will affect future capital requirements and may require us to seek additional financing include:

- the development and acquisition of new products and drug delivery technologies;
- the progress of our research and product development programs; and
- the timing of, and amounts received from, future product sales, product development fees and licensing revenue and royalties.

If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in loss of sales, increased costs and reduced revenues. Alternatively, to obtain needed funds for acquisitions or operations, we may seek to issue additional ADSs representing our ordinary shares, or issue equity-linked debt, or we may choose to issue preferred shares, in either case through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of such equity or equity-linked financings, may result in dilution to the holders of ADSs. We could also be required to seek funds through arrangements with collaborative partners and we may be required to relinquish rights to some of our product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

We may be required to or choose to obtain further funding through public equity or equity linked offerings, debt financings, royalty-based financing arrangements, collaborations and licensing arrangements or other sources. To the extent that we raise additional capital through the sale of equity, convertible debt securities or other equity-based derivative securities, investors will be diluted and new investors could gain rights, preferences and privileges senior to the holders of our ADSs. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ADSs to decline and existing shareholders may not agree with our financing plans or the terms of such financings. If we raise additional funds through collaborations or marketing, distribution or licensing, or royalty-based financing arrangements with third parties, we may have to relinquish valuable rights to future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

Our ability to obtain additional financing may be limited by the terms of our financing arrangements and the provisions of Irish law.

Restrictions in our existing and future financing arrangements and mandatory provisions of Irish law may adversely affect our ability to obtain additional financing. For example, the indenture for our October 2023 Notes contains covenants that limit our

ability to engage in specified transactions, including prohibiting us from incurring additional secured or unsecured debt, paying dividends or redeeming equity securities. Future debt agreements or other financing arrangements may include similar or more restrictive terms that limit our ability to raise additional financing when needed. In addition, Irish law requires that our directors must have specific authority from shareholders to allot and issue new shares generally, or to issue new shares for cash to new shareholders without offering such shares to existing shareholders pro-rata to their existing holdings (including, in each case, rights to subscribe for or otherwise acquire any shares), even where such shares form part of our authorized but unissued share capital. At our 2021 annual general meeting of shareholders, our shareholders renewed such authorizations, subject to certain parameters, for a period expiring December 20, 2026. Irish law also provides that, in the event of an actual or potential takeover offer being made for us, various actions, including issuing shares, options or convertible securities, material acquisitions or disposals, entering into contracts other than in the ordinary course of business or any action, other than seeking alternative offers, may be prohibited unless approved by our shareholders or the Irish Takeover Panel. These restrictions may prevent or delay us from taking actions that we believe are in our best interest or from obtaining financing on favorable terms, in adequate amounts or at all, which may adversely impact our results of operations and financial condition.

Our net loss and use of cash in operating activities may limit our ability to fully pursue our business strategy.

We reported net loss of $137,464 in 2022. We reported cash used in operating activities of $70,304. Cash and marketable securities as of 31 December 2022 totaled $96,499. Our business strategy is to primarily focus on the development and potential final FDA approval of LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy. The successful pursuit of all components of our strategy will require substantial financial resources, and there can be no assurance that our existing cash and marketable securities assets and the cash generated by our operations will be adequate for these purposes. We will likely incur a net loss in 2023 and, if we use existing cash and marketable securities, there is no guarantee that we would be able to generate additional cash through our operations or through financing. Failure to implement any component of our strategy may prevent us from achieving profitability in the future or may otherwise have a material adverse effect on our financial condition and results of operation.

Uncertainties relating to our ability to procure additional debt, equity or other financing prior to the maturity of our outstanding exchangeable senior notes raises substantial doubt about our ability to continue as a going concern.

As of 31 December 2022, we had an accumulated shareholders' deficit of approximately $21,145 and approximately $73,981 of cash and cash equivalents and $22,518 of marketable securities available for use to fund our operations and capital requirements. Within twelve months of the date of this Annual Report, our interest and principal payments of $21,187 aggregate principal amount of our October 2023 Notes that was not exchanged and maintains a maturity date of October 2, 2023 will fall due.

The Group has a recent history of generating losses and negative cash flows from operations. Our ability to generate revenue is expected to start following the launch of LUMRYZ, which is dependent, in part, on final approval of LUMRYZ by the FDA. On 29 March 2023, the Group announced a public offering, which was completed on 3 April 2023. The Group received net proceeds from the equity financing of $135,125, of which $40,000 was received on 31 March 2023 and $95,125 was received on 3 April 2023.

As a result of the public offering, the Group has concluded that cash on hand provides sufficient capital to meet the Group's operating, debt service and capital requirements for the next twelve months following the date of this annual report.

Risks Related to Regulation

The distribution and sale of LUMRYZ, if granted final approval by the FDA, will be subject to significant regulatory restrictions, including the requirements of a REMS and safety reporting requirements, and these regulatory requirements will subject us to risks and uncertainties, any of which could negatively impact sales of LUMRYZ.

The API of LUMRYZ is a form of gamma-hydroxybutyric acid, ("GHB"), a central nervous system depressant known to be associated with facilitated sexual assault as well as with respiratory depression and other serious side effects. As a result, the FDA requires that sponsors of sodium oxybate products, such as LUMRYZ, if granted final approval by the FDA, maintain a REMS to help ensure that the benefits of the drug outweigh the serious risks of the drug. If granted final approval by the FDA, the agency will require a REMS for LUMRYZ, which, among other requirements, will impose controls and restrictions on the distribution of the product. Any failure to demonstrate our substantial compliance with such REMS obligations, including as a result of business or other interruptions resulting from the evolving effects of the COVID-19 pandemic, or a determination by the FDA that the REMS is not meeting its goals, could result in enforcement action by the FDA, lead to changes in our REMS obligations, negatively affect sales of LUMRYZ, result in additional costs and expenses for us or require us to invest a

significant amount of resources, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

We cannot predict whether the FDA will request, seek to require or ultimately require modifications to, or impose additional requirements on, the REMS for LUMRYZ, if granted final approval by the FDA. Any modifications approved, required or rejected by the FDA could change the safety profile of LUMRYZ, and have a significant negative impact in terms of product liability, public acceptance of LUMRYZ for treatment of cataplexy or EDS in adults with narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, LUMRYZ, any of which could have a material adverse effect on our business. Modifications approved, required or rejected by the FDA could also make it more difficult or expensive for us to distribute LUMRYZ, make distribution easier for sodium oxybate competitors, disrupt continuity of care for LUMRYZ patients or negatively affect sales of LUMRYZ.

Pharmaceutical companies, including their agents and employees, are required to monitor adverse events occurring during the use of their products and report them to the FDA. As required by the FDA, and similarly for other regulatory agencies, the adverse event information that we collect for LUMRYZ, if granted final approval by the FDA, must be regularly reported to the FDA and could result in the FDA requiring changes to LUMRYZ's labeling, including additional warnings or boxed warnings, or requiring us to take other actions that could have an adverse effect on patient and prescriber acceptance of LUMRYZ.

Any failure to demonstrate our substantial compliance with a REMS required for LUMRYZ, if granted final approval by the FDA, or any other applicable regulatory requirements to the satisfaction of the FDA or another regulatory authority could result in such regulatory authorities taking actions in the future which could have a material adverse effect on sodium oxybate product sales and therefore on our business, financial condition, results of operations and growth prospects.

Disruptions at the FDA, the DEA and other government agencies caused by funding shortages or global health concerns 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 on which the operation of our business may rely, 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, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, DEA and other agencies may also increase the time necessary for new product candidates to be reviewed or approved by necessary government agencies, which would 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 to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. We cannot guarantee that the FDA, DEA and other agencies, as applicable, will be able to complete any required inspections or take other necessary actions in respect to our product candidate or future product candidates.

LUMRYZ, if granted final approval by the FDA, may not obtain desired regulatory exclusivities, including orphan drug exclusivity.

Under the Orphan Drug Act, as amended, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals in the U.S., or a patient

population of 200,000 or more where there is no reasonable expectation that the cost of developing the drug for the rare disease or condition will be recovered from sales of the drug in the U.S. Generally, if a drug with orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease or condition for seven years, except in limited circumstances, such as if the FDA concludes that a subsequent same drug is clinically superior through greater safety, greater effectiveness, or a major contribution to patient care.

Although LUMRYZ obtained orphan drug designation for the treatment of narcolepsy from the FDA in January 2018, there is no guarantee that we will obtain approval or orphan drug exclusivity for LUMRYZ. Orphan drug designation does not give a product candidate any advantage in, or shorten the timeline for, the FDA regulatory review and approval process. In addition, because LUMRYZ would not be the first sodium oxybate product to be approved for the treatment of narcolepsy, we must demonstrate that LUMRYZ is clinically superior to any previously approved same drug in order to obtain orphan drug exclusivity for LUMRYZ, and we may be required to demonstrate clinical superiority for the approval and exclusivity of other product candidates in the future. However, such a demonstration may be difficult to establish, and there can be no assurance that we will be successful in these efforts. Even if we obtain orphan drug exclusivity for LUMRYZ, that exclusivity may not effectively protect LUMRYZ from competition because different drugs can be approved for the same condition. In addition, the FDA could determine that unexpired orphan drug exclusivity for an approved product that is determined to be the same drug could delay the approval of LUMRYZ unless we are able to demonstrate that LUMRYZ is clinically superior to such approved product. For example, final FDA approval of LUMRYZ could be delayed until expiration of the Xywav orphan drug exclusivity. Moreover, any orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantity of LUMRYZ to meet the needs of patients with the particular rare disease or condition. The FDA may reevaluate its regulations and policies under the Orphan Drug Act. We do not know if, when or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

The API in LUMRYZ, sodium oxybate, is a controlled substance subject to U.S. federal and state controlled substance laws and regulations and applicable controlled substance legislation in other countries, and our failure, or the failure of third-parties on whom we rely, to comply with these laws and regulations, or the cost of compliance with these laws and regulations, could materially and adversely affect our business, results of operations, financial condition and growth prospects.

LUMRYZ contains a controlled substance as defined in the CSA. Controlled substances are subject to a number of requirements and restrictions under the CSA and implementing regulations, including certain registration, security, recordkeeping, reporting, manufacturing and procurement quotas, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V. Schedule I substances by definition have a high potential for abuse, no currently "accepted medical use" in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. which contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, heightened security requirements and additional criteria for importation. The API of LUMRYZ, oxybate salts, are regulated by the DEA as Schedule I controlled substances, and FDA-approved products containing oxybate salts, including sodium oxybate, are currently Schedule III.

Individual states have also established controlled substance laws and regulations. Although state-controlled substances laws often mirror federal law, they may separately schedule our product candidates. We or our partners may also be required to obtain separate state registrations, permits or licenses in order to be able to manufacture, research, distribute, import, export, administer or prescribe controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

U.S. facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing of controlled substances must be registered (licensed) to perform these activities and must comply with the security, control, recordkeeping and reporting obligations under the CSA, DEA regulations and corresponding state requirements. DEA and state regulatory bodies conduct periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations, obtaining and maintaining quotas and complying with the regulatory obligations may result in delay of the importation, export, manufacturing, distribution or research of our lead product candidate and our commercial product, if

approved, and any future products candidates or products. Furthermore, failure to maintain compliance with the CSA and DEA and state regulations by us or any of our contractors, distributors or pharmacies can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. In addition, if we change any third-party upon whom we rely to conduct our research, manufacturing, distributing, importing, exporting, or dispensing activities, doing so will result in additional costs and expenses and may take a significant amount of time, and we may be unsuccessful in identifying a new, satisfactory third-party, any of which could materially and adversely affect our business, financial condition, and results of operations. DEA and state regulatory bodies may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal penalties.

Because LUMRYZ contains sodium oxybate, to conduct clinical trials with LUMRYZ in the U.S. prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that allows those sites to handle and dispense LUMRYZ and to obtain the product candidate. If the DEA delays or denies the grant of a researcher registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. In the event the product candidate would be made outside the U.S., the importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import.

We and our manufacturing partners in the U.S. are subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, even though LUMRYZ, if granted final approval by the FDA, is anticipated to be classified as Schedule III based on current applicable regulations, the active ingredient in the final dosage form, sodium oxybate, is a Schedule I controlled substance and will continue be subject to such quotas as long as it remains classified as Schedule I. The annual quota allocated to us or our U.S. manufacturing partners for sodium oxybate may not be sufficient to complete clinical trials or meet commercial demand of LUMRYZ, if granted final approval by the FDA. Consequently, any delay or refusal by the DEA in establishing our, or U.S. manufacturing partner's, procurement and/or production quota for controlled substances could delay or stop our clinical trials or commercial activities, if approved, which could have a material adverse effect on our business, financial position and results of operations.

If granted final approval by the FDA, LUMRYZ is anticipated to be classified as a Schedule III substance based on current applicable regulations, which would allow an importer to import it for commercial purposes if it obtains the appropriate registrations and licenses from the DEA, including an importer registration and files an application for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. To the extent an importer is utilized for commercial purposes, failure by any current importer or future importer that we identify as an importer, if any are available, to obtain and maintain the necessary import authority from the DEA and other applicable regulatory authorities, including specific quantities, could affect the availability of LUMRYZ and have a material adverse effect on our business, results of operations and financial condition.

Governments outside of the U.S. have similar controlled substance laws, regulations and requirements in their respective jurisdictions, and our failure, or the failure of third parties upon whom we rely, to comply with applicable controlled substance laws, regulations and requirements or secure necessary authorizations would result in similar risks to those described above.

We will need to obtain regulatory approval of any proposed product names for our product candidates, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA or other regulatory authorities in jurisdictions where we may seek approval regardless of whether we have secured a trademark registration from the USPTO or similar protection in other jurisdictions. The FDA and other regulatory authorities each typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA or other regulatory authorities in jurisdictions where we may seek approval may object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA or other regulatory authorities in jurisdictions where we may seek approval objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. There is no guarantee that we will be able to use the same proprietary name for our product candidates in each jurisdiction where we market our products, if approved. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA or other regulatory authorities. The FDA has tentatively accepted our proprietary name for our lead product candidate, LUMRYZ. Final acceptance of a proposed proprietary name occurs as part of the final approval of the drug product. We may be unable to build a successful brand identity for a new proprietary name or trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Related to our Reliance on Third Parties

We rely, and intend to continue to rely on single source providers for the development, manufacture and supply of LUMRYZ, and if we experience problems with these suppliers, or they fail to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, our business would be materially and adversely affected.

Currently, we use single source providers for the development, supply of clinical materials and supply of commercial batches for our lead product candidate, LUMRYZ. We do not own or operate manufacturing facilities for clinical or commercial manufacture of LUMRYZ. We have limited personnel with experience in drug manufacturing and we lack the capabilities to manufacture LUMRYZ clinical or commercial scale. There can be no assurance that our clinical development or commercial product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable quantities or prices to meet commercial demand, if LUMRYZ is granted final approval by the FDA. If the supplies of these products or materials were interrupted for any reason, including but not limited to, natural disasters, labor or civil unrest, global health concerns or pandemics or acts of war or terrorism, delays at the manufacturer, delays related to quality control, delays related to the supply chain and the manufacturing and supply of certain products could be delayed. If the supplies of these products or materials were interrupted for any reason, our manufacturing, clinical development or commercial activities, if approved, of LUMRYZ could be delayed. These delays could be extensive and expensive, especially in situations where a substitution was not readily available or required variations of existing regulatory approvals and certifications or additional regulatory approval For example, an alternative supplier may be required to pass an inspection by the FDA, EMA or the competent authorities of EU Member States for compliance with current cGMP requirements before supplying us with product or before we may incorporate that supplier's ingredients into the manufacturing of LUMRYZ by our contract development and manufacturing organizations ("CDMOs").

Additionally, our third-party suppliers may not be required to, or may be unable to, provide us with any guaranteed minimum production levels or have sufficient dedicated capacity for our drug. Failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

We contract with third parties for the manufacture of LUMRYZ for clinical testing and expect to continue to do so throughout commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidate or product or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of LUMRYZ for clinical testing, as well as for the commercial manufacture of our product if LUMRYZ receives marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidate or product or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by CDMOs generally must be inspected by the FDA pursuant to pre-approval inspections conducted as a part of the FDA's review of an NDA. We do not control the manufacturing process of, and will be completely dependent on, our CDMOs for compliance with cGMPs in connection with the manufacture of our product candidate. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for their manufacturing facilities. In addition, we have no control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidate or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidate, if granted final approval by the FDA.

CDMOs upon whom we rely are also required to comply with the CSA, DEA regulations and other applicable controlled substance laws, regulations and requirements in other countries, where applicable, including and those relating to licensing and registration requirements. The inability of our CDMOs to maintain compliance with applicable controlled substance laws, regulations and requirements and obtain and maintain the necessary licenses and registrations could have a material adverse effect on our business, including our clinical trials, commercial activities, if approved, financial position and results of operations.

If any CDMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In such scenario, our clinical trials or commercial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidate or product, if approved, may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations, including those relating to controlled substances. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate or product according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop LUMRYZ or commercialize our product, if granted final approval by the FDA, in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidate or product that such CDMO owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another CDMO manufacture our product candidate or product. In addition, in the case of CDMOs that supply our product candidate, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Further, our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and approved products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If our current CDMOs cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We outsource important activities to consultants, advisors and outside contractors.

We outsource many key functions of our business and therefore rely on a substantial number of consultants, advisors and outside contractors. If we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by such third parties is compromised for any reason, our development activities may be extended, delayed or terminated which would have an adverse effect on our development program and our business.

We depend on key personnel to execute our business plan. If we cannot attract and retain key personnel, we may not be able to successfully implement our business plan.

We are highly dependent on the expertise of Gregory Divis, our Chief Executive Officer, Thomas S. McHugh, our Chief Financial Officer, and Richard Kim, our Chief Commercial Officer, as well as the other key members of our management, legal, scientific, clinical and commercial team. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any

of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to obtain final FDA approval for LUMRYZ may make it more challenging to recruit and retain qualified personnel.

The commercialization of LUMRYZ, if granted final approval by the FDA, will require us to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

We currently employ approximately 41 full-time employees. If LUMRYZ is granted final approval by the FDA, we expect to expand our full-time employee base to advance the commercialization of LUMRYZ in the U.S. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to recognize and/or grow revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize LUMRYZ, if granted final approval by the FDA, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

We rely on third parties to conduct our clinical trials, and if they do not properly and successfully perform their contractual, legal and regulatory duties, we may not be able to obtain regulatory approvals for or commercialize LUMRYZ and future product candidates.

We rely on CROs and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as a high priority, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as the FDA's and foreign regulatory agencies' requirements, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA and foreign. regulatory agencies enforce good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, CROs or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or foreign regulatory agencies will determine that any of our clinical trials comply with good clinical practices.

If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols, including dosing requirements, or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidate and future product candidates or succeed in our efforts to create approved line extensions for certain of our existing products or generate additional useful clinical data in support of these products.

If we or our partners fail to comply with these laws and regulations, the FDA, or other foreign regulatory agencies, may take actions that could significantly restrict or prohibit commercial distribution of LUMRYZ. If the FDA or other foreign regulatory authorities determine that we are not in compliance with these laws and regulations, they could, among other things:

- issue warning letters;
- impose fines;
- seize products or request or order recalls;
- issue injunctions to stop future sales of products;
- refuse to permit products to be imported into, or exported out of a particular country;
- suspend or limit our production;
- withdraw or vary approval of marketing applications;
- withdraw approval of marketing applications; and
- initiate criminal prosecutions.

We may rely on collaborations with third parties to commercialize LUMRYZ and certain of our future product candidates outside of the U.S., if granted the necessary approvals or authorizations. Such strategy involves risks that could impair our prospects for realizing profits from such products.

We expect that the commercialization of LUMRYZ and our future product candidates outside of the U.S., if granted the necessary approvals or authorizations, may require collaboration with third-party partners involving strategic alliances, licenses, product divestitures or other arrangements. We may not be successful in entering into such collaborations on favorable terms, if at all, or our collaboration partners may not adequately perform under such arrangements, and as a result our ability to commercialize these products will be negatively affected and our prospects will be impaired.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's own evaluation of a potential collaboration. Such factors a potential collaborator will use to evaluate a collaboration may include the design or results of clinical trials, the likelihood of final approval by the FDA or comparable foreign regulatory authorities, the potential market for LUMRYZ or future product candidates, the potential of competing products, the existence of uncertainty with respect to our ownership of our intellectual property, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for LUMRYZ or our future product candidates. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of our product candidates for which we are seeking to collaborate, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop LUMRYZ and our future product candidates outside of the U.S., if granted the necessary approvals or authorizations, or bring these products to market and generate product revenue.

In addition, any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Risks Related to Our Intellectual Property

If we cannot adequately protect our intellectual property and proprietary information, we may be unable to effectively compete.

Our success depends, in part, on our ability to obtain and enforce patents and other intellectual property rights for our product candidate and future product candidates and technology, including our drug delivery technologies, and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our technologies and deprive us of the ability to realize revenues and profits from our product candidate and future product candidates and technologies.

To the extent any of our product candidate and future product candidates may benefit from protections afforded by patents, we face the risk that patent law relating to the scope of claims in the pharmaceutical and biotechnology fields is continually evolving and can be the subject of uncertainty and may change in a way that would limit protection. If challenged, a court or other body may determine that our patents may not be exclusive, valid or enforceable. For example, our patents may not protect us against challenges by companies that submit drug marketing applications to the FDA, or the competent authorities of EU Member States or other jurisdictions in which we may attempt to compete, in particular where such applications rely, at least in part, on safety and efficacy data from our product candidate and future product candidates. In addition, competitors may obtain patents that may have an adverse effect on our ability to conduct business, or they may discover ways to circumvent our patents. The scope of any patent protection may not be sufficiently broad to cover our product candidate and future product candidates or to exclude competing products. Any patent applications we have made or may make relating to our potential products or technologies may not result in patents being issued. Even after issuance, our patents may be challenged in the courts or patent offices in the U.S. and elsewhere. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates, or limit the duration of the patent protection of our product candidate and future product candidates. Further, patent protection once obtained is limited in time, after which competitors may use the covered product or technology without obtaining a license from us. Because of the time required to obtain regulatory marketing approval, the remaining period of effective patent protection for a marketed product is frequently substantially shorter than the full duration of the patent. While a patent term extension can be requested under certain circumstances, the grant of such a request is not guaranteed.

Our partnerships with third parties expose us to risks that they will claim intellectual property rights on our inventions or fail to keep our unpatented products or technology confidential.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

We also rely on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen our competitive position.

To protect our product candidate, trade secrets and proprietary technologies, we rely, in part, on confidentiality agreements with our employees, suppliers, consultants, advisors and partners. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information. If these agreements are breached, we cannot be certain we will have adequate remedies. Further, we cannot guarantee that third parties will not know, discover or independently develop equivalent proprietary information or technologies, or that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee we can maintain and protect unpatented proprietary information and trade secrets. Misappropriation or other loss of our intellectual property would adversely affect our competitive position and may cause us to incur substantial litigation or other costs.

If we and our partners do not adequately protect the trademarks and trade names for our products, then we and our partners may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our competitors or other third parties may challenge, infringe or circumvent the trademarks or trade names for our products. We and our partners may not be able to protect these trademarks and trade names. In addition, if the trademarks or trade names for one of our products infringe the rights of others, we or our partners may be forced to stop using the trademarks or trade names, which we need for name recognition in our markets of interest. If we cannot establish name recognition based on our trademarks and trade names, we and our partners may not be able to compete effectively and our business may be adversely affected.

Changes in U.S. or ex-U.S. patent laws could diminish the value of patents in general, thereby impairing our ability to protect our product candidate and future product candidates.

Changes in either the patent laws or interpretation thereof in the U.S. or in ex-U.S. jurisdictions could increase uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, the Leahy-Smith America Invents Act of 2011 ("AIA"), changed the previous U.S. "first-to-invent" system to the current system that awards a patent to the "first-inventor-to-file" for an application for a patentable invention. This change alters the pool of available materials that can be used to challenge patents in the U.S. and limits the ability to rely on prior research to lay claim to patent rights. Under the current system, disputes are resolved through new derivation proceedings, and the AIA includes mechanisms to allow challenges to issued patents in reexamination, *inter partes* review and post grant proceedings. The AIA also includes bases and procedures that may make it easier for competitors to challenge our patents, which could result in increased competition and have a material adverse effect on our business and results of operations. The AIA may also make it harder to challenge third-party patents and place greater importance on being the first inventor to file a patent application on an invention. The AIA amendments to patent filing and litigation procedures in the U.S. may result in litigation being more complex and expensive and divert the efforts of our technical and management personnel.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals may be particularly uncertain. Depending on future actions by the U.S. Congress, the U.S. federal courts, and the USPTO, or by similarly legislative, judicial, and regulatory authorities in other jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Third parties may claim that our product candidate or future product candidates infringe their rights, and we may incur significant costs resolving these claims. Additionally, legal proceedings related to such claims could materially delay or otherwise adversely affect commercialization plans related to our product candidate, if granted final approval by the FDA.

Third parties may claim infringement of their patents and other intellectual property rights by the manufacture, use, import, offer for sale or sale of our drug delivery technologies or our other products. For example, in connection with us seeking regulatory approval for a product candidate, a third party may allege that our product candidate infringes its patents or other intellectual property rights and file suit to delay/prevent regulatory approval and/or commercialization of such product. In response to any claim of infringement, we may choose or be forced to seek licenses, defend infringement actions or challenge the validity or enforceability of those patent rights in court or administrative proceedings. If we cannot obtain required licenses on commercially reasonably terms, or at all, are found liable for infringement or are not able to have such patent rights declared invalid or unenforceable, our business could be materially harmed. We may be subject to claims (and even held liable) for significant monetary damages (including enhanced damages and/or attorneys' fees), encounter significant delays in bringing products to market or be precluded from the manufacture, use, import, offer for sale or sale of products or methods of drug delivery covered by the patents of others. Even if a license is available, it may not be available on commercially reasonable terms or may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. We may not have identified, or be able to identify in the future, U.S. or non-U.S. patents that pose a risk of potential infringement claims.

In addition to the possibility of intellectual property infringement claims, a third party could submit a citizen's petition to the FDA requesting relief that, if granted, could materially adversely affect the NDA and/or underlying product candidate. For example, such a third-party petition could, if granted, materially adversely affect the likelihood and/or timing of NDA approval, content of final product labeling, and/or resulting regulatory exclusivity (if any) for such product.

Parties making claims against us may be able to sustain the costs of patent litigation more effectively than we can because they have substantially greater resources. In addition, any claims, with or without merit, that our product candidate, future product candidates or drug delivery technologies infringe proprietary rights of third parties could be time-consuming, result in costly litigation or divert the efforts of our technical and management personnel, any of which could disrupt our relationships with our partners and could significantly harm our financial positions and operating results.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidates.

The LUMRYZ NDA was submitted under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) NDA enables

the applicant to reference published literature for which the applicant does not have a right of reference and the FDA's previous findings of safety and effectiveness for a previously approved drug.

For 505(b)(2) NDAs, the patent certification and related provisions of the Hatch-Waxman Amendments apply. Accordingly, if the applicant relies for approval on the safety or effectiveness information for a previously approved drug, referred to as a listed drug, the applicant is required to include patent certifications in its 505(b)(2) NDA regarding any applicable patents covering the listed drug. If there are applicable patents listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, and the applicant seeks to obtain approval prior to the expiration of one or more of those patents, the applicant is required to submit a Paragraph IV certification indicating their belief that the relevant patents are invalid or unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Otherwise, the 505(b)(2) NDA cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug. On 24 May 2022, we were notified by the FDA that the LUMRYZ NDA patent statement pertaining to the REMS Patent was deemed inappropriate. On 29 June 2022, we announced that we had submitted a Paragraph IV certification pertaining to the REMS Patent to LUMRYZ's NDA. On 18 July 2022, we received tentative approval from the FDA for LUMRYZ for the treatment of cataplexy or EDS in adults suffering from narcolepsy. Jazz requested delisting of the REMS Patent from FDA's Orange Book on 28 February 2023, pursuant to the United States Court of Appeals for the Federal Court decision of 24 February 2023, affirming the previous ruling from the Delaware Court, ordering such delisting. On 1 March 2023, we submitted an amendment to our NDA for LUMRYZ requesting final approval. There can be no assurance that we will not be required to submit a Paragraph IV certification in respect of any future product candidates for which we seek approval under Section 505(b)(2).

Following any Paragraph IV certification that may be required, an applicant will be required to provide notice of that certification to the NDA holder and patent owner. Under the Hatch-Waxman Amendments, the patent owner may file a patent infringement lawsuit after receiving such notice. If a patent infringement lawsuit is filed within 45 days of the patent owner's or NDA holder's receipt of notice (whichever is later), a one-time, automatic stay of the FDA's ability to approve the 505(b)(2) NDA is triggered, which typically extends for 30 months unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) NDA will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the listed drug, or for any other drug with the same protected conditions of approval as our product, has expired. The FDA also may require us to perform one or more additional clinical trials or measurements to support the change from the listed drug, which could be time consuming and could substantially delay our achievement of regulatory approval. The FDA also may reject any future 505(b)(2) NDAs and require us to submit traditional NDAs under Section 505(b)(1), which would require extensive data to establish safety and effectiveness of the product for the proposed use and could cause delay and additional costs. In addition, the FDA could reject any future 505(b)(2) application and require us to submit a Section 505(b)(1) NDA or a Section 505(j) ANDA if, before the submission of our 505(b)(2) application, the FDA approves an application for a product that is pharmaceutically equivalent to ours and determines that our product is inappropriate for review through the 505(b)(2) pathway. These factors, among others, may limit our ability to commercialize our product candidates successfully.

If we or our partners are required to obtain licenses from third parties, our revenues and royalties on any future commercialized products could be reduced.

The development of certain products based on our drug delivery technologies may require the use of raw materials (*e.g.,* proprietary excipient), active ingredients, drugs (*e.g.,* proprietary proteins) or technologies developed by third parties. The extent to which efforts by other researchers have resulted or will result in patents and the extent to which we or our partners are forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If we or our partners must obtain licenses from third parties, fees may be required for such licenses, which could reduce the net revenues and royalties we receive on any future commercialized products that incorporate our drug delivery technologies.

Patent terms may be inadequate to protect our competitive position on our product candidate or future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidate and future product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical

to ours.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and/or applications. We rely on our outside counsel to coordinate payment of these fees due to patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidate and future product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our product candidate and future product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in non-U.S. jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in non-U.S. jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

Risks Related to Acceptance, Sales, Marketing and Competition

If we are unable to establish effective sales, marketing and distribution capabilities for LUMRYZ, if granted final approval by the FDA, or enter into agreements with third parties to market, sell and distribute our product candidate, if granted final approval by the FDA, or if we are unable to achieve market acceptance for LUMRYZ, our business, results of operations, financial condition and prospects will be materially adversely affected.

We are continuing to build the systems, processes, policies, relationships and materials necessary for the launch of LUMRYZ in the U.S. for the treatment of cataplexy or EDS in adults with narcolepsy. If we receive regulatory approval to market or sell LUMRYZ, but are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected. We may encounter issues, delays or other challenges in launching or commercializing LUMRYZ.

We have limited experience in building and managing a commercial team, conducting a comprehensive market analysis, obtaining state licenses and reimbursement, or managing distributors and a sales force for our medicines. For example, our results may be negatively impacted if we have not adequately sized our field teams or if our targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. As a result, our ability to successfully commercialize LUMRYZ may involve more inherent risk, take longer, and cost more than it would if we were a company with

substantial experience in launching medicines.

We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing, and commercial distribution capabilities for LUMRYZ in any country or region, we will likely pursue collaborative arrangements regarding the sales and marketing of LUMRYZ. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized LUMRYZ ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our medicines.

Any of these issues could impair our ability to successfully commercialize LUMRYZ or to generate substantial revenues or profits or to meet our expectations with respect to the amount or timing of revenues or profits. There is no guarantee that we will be successful in our launch or commercialization efforts with respect to LUMRYZ, if granted final approval by the FDA, or with respect to any other product candidate that may be approved in the future.

If the market opportunities for LUMRYZ are smaller than we believe they are, and if we are not able to successfully identify patients and achieve significant market share, our revenues may be adversely affected and our business may suffer.

LUMRYZ is an investigational formulation of sodium oxybate designed to be taken once at bedtime for the treatment of cataplexy or EDS in adults with narcolepsy. Our estimates of the market opportunities for LUMRYZ are based on the estimated market size for the twice-nightly administration of sodium oxybate, which is the current standard of care for cataplexy or EDS in patients with narcolepsy, and our expectations with regard to LUMRYZ's potential to take a significant share of this market. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The potential target population for LUMRYZ may turn out to be lower or more difficult to identify than expected. Even if we obtain significant market share for LUMRYZ in this indication, because the potential target population for LUMRYZ is small, we may never achieve profitability without obtaining marketing approval for additional indications.

Any of these factors may negatively affect our ability to recognize revenues from sales of LUMRYZ, if granted final approval by the FDA, and our ability to achieve and maintain profitability and, as a consequence, our business may suffer.

LUMRYZ, if granted final approval by the FDA, may not gain market acceptance.

LUMRYZ, if granted final approval by the FDA, may not gain market acceptance among physicians, patients, healthcare payor and medical communities. The degree of market acceptance of LUMRYZ, if granted final approval by the FDA, will depend on a number of factors, including, but not limited to:

- the clinical indications for which LUMRYZ is approved and any restrictions placed upon the product in connection with its approval, such as a REMS or equivalent obligation by other regulatory authorities, patient registry requirements or labeling restrictions;
- the prevalence of the disease or condition for which LUMRYZ is approved and its diagnosis;
- scheduling classification of sodium oxybate as a controlled substance regulated by the DEA;
- demonstration of the clinical safety and efficacy of the product or technology;
- the absence of evidence of undesirable side effects of the product or technology that delay or extend trials;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- availability of sufficient product inventory to meet demand;
- physicians' decisions relating to treatment practices based on availability;
- physician and patient assessment of the burdens associated with obtaining or maintaining the certifications required under the LUMRYZ REMS, if approved;
- the lack of regulatory delays or other regulatory actions;
- its cost-effectiveness and related access to payor coverage;
- its potential advantage over alternative treatment methods;
- the availability of third-party reimbursement or other assistance for patients who are uninsured or underinsured; and
- the marketing and distribution support it receives.

If LUMRYZ, if granted final approval by the FDA, fails to achieve market acceptance, our ability to generate revenue will be limited, which would have a material adverse effect on our business.

LUMRYZ, if granted final approval by the FDA, will be subject to ongoing enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of LUMRYZ from the market, if we fail to comply with all regulatory requirements. In addition, the terms of the marketing approval of LUMRYZ, if granted final approval by the FDA, and ongoing regulation of our product, may limit how we manufacture and market LUMRYZ and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

If granted final approval by the FDA, LUMRYZ, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for LUMRYZ, will be subject to continual requirements of and review by the FDA and other applicable regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

In the U.S., the FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Violations of such requirements may lead to investigations alleging violations of the FDCA and other statutes, including the FDA and other federal and state healthcare fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers, or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- voluntary recall of products;
- fines, restitution, or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties. Similarly, failure to comply with applicable regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

In addition, we and our CDMOs will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, quality control and distribution. Under the DSCSA, for certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen, and intentionally adulterated products or other products that are otherwise unfit for distribution in the U.S. In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the PDMA, which regulations the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Prescription drug products must also meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. We, our CDMOs and other third parties upon whom we rely will be subject to applicable controlled substances laws, regulations and requirements. Additionally, under the Food and Drug Omnibus Reform Act of 2022 (“FDORA”), sponsors of approved drugs must provide 6 months’ notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product’s ability

to be marketed. If LUMRYZ is granted final approval by the FDA and we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for LUMRYZ withdrawn by regulatory authorities and our ability to market LUMRYZ could be limited, which could adversely affect our ability to achieve or sustain profitability and we could be subject to substantial penalties. As a result, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

If our competitors develop and market technologies or products that are safer, more effective or less costly than ours, or obtain regulatory approval and market such products before we do, our commercial opportunity may be diminished or eliminated.

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with other pharmaceutical and biotechnology companies.

The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, LUMRYZ, if granted final approval, would adversely affect sales of our product candidate. For example, in the future, we expect LUMRYZ to face competition from manufacturers of generic twice-nightly sodium oxybate formulations who have reached settlement agreements with the current brand product marketer. On 3 January 2023, Hikma Pharmaceuticals plc, announced that they launched an authorized generic version of Jazz's Xyrem (sodium oxybate). Hikma will have 180 days of marketing exclusivity for its authorized generic product in the U.S. and will distribute through the same specialty pharmacy that Jazz uses to dispense Xyrem. There are other potential future competitive products that could impact the marketplace. For example, there are some potential competitors who have reached settlement agreements with the current brand product marketer, which allows for entry of other authorized generics in 2023 and other generic products in 2026, or earlier for both under certain circumstances. Beyond generics, there are other potential future competitive products that could impact the narcolepsy treatment marketplace.

If the FDA approves a competitor's application for a product candidate before our application for a similar product candidate, and grants such competitor a period of exclusivity, the FDA may take the position that it cannot approve our 505(b)(2) application for a similar product candidate until the exclusivity period expires. Additionally, even if our 505(b)(2) application for a product candidate is approved first, and we receive a period of statutory marketing exclusivity, we may still be subject to competition from other companies with approved products or approved 505(b)(2) NDAs for different conditions of use that would not be restricted by a grant of exclusivity to us.

Many of our competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do. Furthermore, acquisitions of competing companies by large pharmaceutical companies could enhance our competitors' resources. Accordingly, our competitors may be able to develop, obtain regulatory approval and gain market share for their products more rapidly than us.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the sales of our product candidates, if approved, could be adversely affected.

Once an NDA, including a 505(b)(2) NDA, is approved, the product covered becomes a "listed drug" which can be cited by potential competitors in support of approval of an ANDA or subsequent 505(b)(2) application. FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified versions of a drug to facilitate the approval of an ANDA or other application for similar substitutes. If these manufacturers demonstrate that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our products or product candidates, they might only be required to conduct a relatively inexpensive study to show that their generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our products or product candidates. In some cases, even this limited bioequivalence testing can be waived by the FDA. Laws have also been enacted to facilitate the development of generic drugs based off recently approved NDAs. The Creating and Restoring Equal Access to Equivalent Samples Act ("CREATES Act") was enacted in 2019 requiring sponsors of approved NDAs to provide sufficient quantities of product samples on commercially reasonable, market-based terms to entities developing generic drugs. The law establishes a private right of action allowing developers to sue listed drug holders that refuse to sell them product samples needed to support their applications. If we are required to provide product samples or allocate additional resources to responding to such requests or any legal challenges under this law, our business could be adversely impacted. Competition from generic equivalents to our products or product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products or product candidates.

If we cannot keep pace with the rapid technological change in our industry, we may lose business, and our product candidates, if granted final approval by the FDA, and technologies could become obsolete or noncompetitive.

Our success also depends, in part, on maintaining a competitive position in the development of products and technologies in a rapidly evolving field. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries. If we cannot maintain competitive products and technologies, our competitors may succeed in developing competing technologies or obtaining regulatory approval for products before us, and the products of our competitors may gain market acceptance more rapidly than our product candidate and future product candidates. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our product candidate and future product candidates or technologies obsolete or noncompetitive.

Risks Related to Our Business and Industry

COVID-19 may materially and adversely affect our business and our financial results.

The COVID-19 pandemic has spread globally. The continued spread of COVID-19 could adversely impact our operations, including our ability to fully enroll and complete RESTORE, our OLE/switch study of LUMRYZ, initiate and complete any future clinical trials, manufacture sufficient supply of LUMRYZ at sufficient scale for commercialization, if granted final approval by the FDA.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. We have taken precautionary measures intended to help minimize the risk of the virus to our employees, including allowing employees to work remotely. These measures could negatively affect our business. For instance, temporarily allowing employees to work remotely may induce absenteeism, disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19, the identification of new variations of the virus or the effectiveness of actions to contain and treat COVID-19, particularly in the geographies where we or our third party suppliers and CDMOs, or CROs operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial condition.

Our cost structure optimization efforts, including a reduction in workforce, announced in June 2022, may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In June 2022, we announced a reduction in workforce of nearly 50 percent in connection with cost structure optimization efforts. We may not realize, in full or in part, the anticipated benefits and cost savings from our cost structure optimization efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. We also cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our cost structure optimization efforts may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale.

If we need to take further restructuring actions, necessary third-party consents may not be granted.

In June 2022, we announced our cost structure optimization efforts to reduce our quarterly cash operating expenses through a reduction in workforce of nearly 50 percent. Our management may determine we need to take further restructuring actions to achieve additional cost savings, to generate additional capital needed for our business strategy, or for other purposes. Certain restructuring scenarios that management consider could require obtaining the consent of third parties, such as holders of our 2023 Notes. For example, the voluntary bankruptcy filing by Avadel Specialty Pharmaceuticals LLC ("Specialty Pharma") in February 2019 required the consent of holders of a majority in principal amount of our February 2023 Notes in order to avoid a default under the Indenture governing such February 2023 Notes. While we were successful in obtaining that consent, there can be no assurance we will be successful in obtaining additional consents in the future from such holders or from other third parties whose consents may be required. Failure to obtain these third-party consents would prevent us from taking additional

restructuring actions, which could have a material adverse effect on our cash flow, financial resources and ability to successfully pursue our business strategy.

Risks Related to Litigation and Legal Matters

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidate or future product candidates, the defendant could counterclaim that the patent is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. There is risk that a court could rule in favor of the defendant with respect to such a counterclaim of patent invalidity and/or unenforceability.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidate and future product candidates to market.

Because of the substantial amount of discovery that can occur in connection with intellectual property-related litigation and/or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation/proceeding. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our shares.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ or may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we endeavor to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying any awarded monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and/or be a distraction to management and other employees.

We and companies to which we have licensed, or will license our future products or drug delivery technologies and subcontractors we engage or may engage for services related to the development and manufacturing of our lead product candidate or future product candidates are subject to extensive regulation by the FDA and other regulatory authorities. Our and their failure to meet strict regulatory requirements could adversely affect our business.

We, and companies to which we will license our future products or drug delivery technologies, as well as companies acting as subcontractors for our product developments, including but not limited to non-clinical, pre-clinical and clinical studies, and manufacturing, are subject to extensive regulation by the FDA, other U.S. authorities and equivalent non-U.S. regulatory authorities, particularly the European Commission and the competent authorities of EU Member States. Those regulatory authorities may conduct periodic audits or inspections of the applicable facilities to monitor compliance with regulatory standards and we remain responsible for the compliance of our subcontractors. If the FDA or another regulatory authority finds failure to comply with applicable regulations, the authority may institute a wide variety of enforcement actions, including:

- warning letters or untitled letters;
- fines and civil penalties;
- delays in clearing or approving, or refusal to clear or approve, products;
- withdrawal, suspension or variation of approval of products; product recall or seizure;
- orders to the competent authorities of EU Member States to withdraw or vary national authorization;
- orders for physician notification or device repair, replacement or refund;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

Any adverse action by a competent regulatory agency could lead to unanticipated expenditures to address or defend such action and may impair our ability to produce and market applicable products, which could significantly impact our revenues and royalties that we would be eligible to receive from our potential customers.

We may face product liability claims related to clinical trials for our product candidate or future product candidates or their misuse.

The testing, including through clinical trials, manufacturing and marketing, and the use of our product candidate and future product candidates may expose us to potential product liability and other claims. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from CROs or pharmaceutical and biotechnology companies or hospitals conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Insurance coverage is expensive and difficult to obtain, and we may be unable to obtain coverage in the future on acceptable terms, if at all. We currently maintain general liability insurance and product liability insurance. We cannot be certain that the coverage limits of our insurance policies or those of our strategic partners will be adequate. If we are unable to obtain sufficient insurance at an acceptable cost, a product liability claim or recall could adversely affect our financial condition.

Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical and biotechnology companies with whom we are developing, or will develop, our future products may not protect us from product liability claims from the consumers of those products or from the costs of related litigation.

If we use hazardous biological and/or chemical materials in a manner that causes injury, we may be liable for significant damages.

Our research and development activities involve the controlled use of potentially harmful biological and/or chemical materials, and are subject to U.S., state, EU, national and local laws and regulations governing the use, storage, handling and disposal of those materials and specified waste products. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials, including fires and/or explosions, storage tank leaks and ruptures and discharges or releases of toxic or hazardous substances. These operating risks can cause personal injury, property damage and environmental contamination, and may result in the shutdown of affected facilities and the imposition of civil or criminal penalties. The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results.

We currently maintain property, business interruption and casualty insurance with limits that we believe to be commercially reasonable but may be inadequate to cover any actual liability or damages.

Risks Related to Ownership of Our Securities

The price of ADSs representing our ordinary shares has been volatile and may continue to be volatile.

The trading price of ADSs has been, and is likely to continue to be, highly volatile. The market value of an investment in ADSs may fall sharply at any time due to this volatility. During the year ended 31 December 2022, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged from $1.07 to $10.00. During the year ended 31 December 2021, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged from $6.49 to $11.18. The market prices for securities of drug delivery, specialty pharma, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our share price include, among others:

- fluctuations in our operating results;
- announcements of technological partnerships, innovations or new products by us or our competitors;
- actions with respect to the acquisition of new or complementary businesses;
- governmental regulations;
- developments in patent or other proprietary rights owned by us or others;
- public concern as to the safety of drug delivery technologies developed by us or drugs developed by others using our platform;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- adverse events related to our product candidate or future product candidates;
- lack of efficacy of our product candidate or future product candidates;
- litigation;
- decisions by our pharmaceutical and biotechnology company partners relating to the products that may incorporate our technologies;
- the perception by the market of specialty pharma, biotechnology, and high technology companies generally;
- general market conditions, including the impact of the current financial environment; and
- the dilutive impact of any new equity or convertible debt securities we may issue or have issued.

If we pay dividends, the dividends may be subject to Irish dividend withholding tax.

In certain circumstances, as an Irish tax resident company, we may be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to its shareholders. Shareholders who are resident in the U.S., EU countries (other than Ireland) or other countries with which Ireland has signed a tax treaty (whether the treaty has been ratified or not) generally should not be subject to Irish withholding tax so long as the shareholder (a) where the shareholder is a body corporate, is not under the control of persons resident in Ireland and (b) has provided its broker, for onward transmission to our qualifying intermediary or other designated agent (in the case of shares held beneficially), or us or our transfer agent (in the case of shares held directly), with all the necessary documentation by the appropriate due date prior to payment of the dividend. However, some shareholders may be subject to dividend withholding tax, which could adversely affect the price of ordinary shares and ADSs and the value of their Notes.

Risks Related to the Notes

Servicing our Notes may require a significant amount of cash, and we may not have sufficient cash or the ability to raise the funds necessary to settle exchanges of the Notes in cash, repay the Notes at maturity, or repurchase the Notes as required following a fundamental change.

In February 2018, we issued $143,750 aggregate principal amount of our February 2023 Notes. On 16 March 2022, we executed an agreement to exchange $117,375 of the February 2023 Notes for a new series of Exchangeable Senior Notes due 2 October 2023 (the "October 2023 Notes"). On 4 November 2022, we repurchased $8,875 of our February 2023 Notes and on their maturity date of 1 February 2023, we repaid the remaining $17,500 aggregate principal amount of our February 2023 Notes. On 29 March 2023, we executed an agreement to exchange $96,188 of our $117,375 October 2023 Notes for a new series of Exchangeable Senior Notes due April 2027 (the "April 2027 Notes", together with the October 2023 Notes, the "Notes"). The remaining $21,187 aggregate principal amount of the October 2023 Notes will maintain a maturity date of 2 October 2023.

If holders of the Notes elect to exchange their Notes, unless we elect to deliver solely our ADSs to settle such exchanges, we will be required to make cash payments in respect of the Notes being exchanged. Holders of the Notes also have the right to require us to repurchase all or a portion of their Notes upon the occurrence of a fundamental change (as defined in the applicable indenture governing the Notes) at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest. If the Notes have not previously been exchanged or repurchased, we will be required to repay the Notes in cash at maturity. Our ability to make cash payments in connection with exchanges of the Notes, repurchase the Notes in the event of a fundamental change, or to repay or refinance the Notes at maturity will depend on market conditions and our future performance, which is subject to economic, financial, competitive, and other factors many of which are beyond our control. We incurred a net loss in 2021 and 2022. As a result, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase or repay the Notes or in the event we elect to pay cash with respect to Notes being exchanged.

The exchange feature of the October 2023 Notes, if triggered prior to May 1, 2023 and in any case after May 1, 2023, and in any case may adversely affect our financial condition and operating results.

In the event the conditional exchange feature of the October 2023 Notes is triggered and in any case after 1 May 2023, holders of October 2023 Notes will be entitled to exchange the October 2023 Notes at any time during specified periods at their option. If one or more holders elect to exchange their October 2023 Notes, unless we elect to satisfy our exchange obligation by causing to be delivered solely ADSs (other than paying cash in lieu of any fractional ADSs), we would be required to settle a portion or all of our exchange obligation through the payment of cash, which could adversely affect our liquidity. If we are unable to make the required payments, or if we fail to comply with the various requirements and covenants of the indenture, we will be in default, which would require immediate repayment of the outstanding principal and interest on the October 2023 Notes. In addition, even if holders do not elect to exchange their October 2023 Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the October 2023 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible and exchangeable debt securities that may be settled in cash, such as the Notes, could have a material effect on our reported financial results.

In accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 470, Debt, an entity must separately account for the liability and equity components of convertible debt instruments (such as the October 2023 Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. ASC 470-20 requires the value of the conversion option of the October 2023 Notes, representing the equity component, to be recorded as additional paid-in capital within stockholders' equity in our consolidated balance sheets and as a discount to the October 2023 Notes, which reduces their initial carrying value. In addition, under the treasury stock method, if the conversion value of the October 2023 Notes exceeds their principal amount for a reporting period, then we will calculate our diluted earnings per share assuming that all the October 2023 Notes were converted and that we issued our ADSs to settle the excess. However, if reflecting the October 2023 Notes in diluted earnings per share in this manner is anti-dilutive, or if the conversion value of the October 2023 Notes does not exceed their principal amount for a reporting period, then the shares underlying the October 2023 Notes will not be reflected in our diluted earnings per share.

In August 2020, the FASB issued Accounting Standards Update ("ASU") 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. This would reduce non-cash interest expense, and thereby decrease net loss (or increase net income). Additionally, the treasury stock method for calculating earnings per share will no longer be allowed for convertible debt instruments whose principal amount may be settled using shares and the if-converted method will be required.

We elected to early adopt ASU 2020-06 beginning with our fiscal year ending December 31, 2021, including any interim periods within that fiscal year. Under ASU 2020-06, the 2023 Notes will be subject to the "if-converted" method for calculating diluted earnings per share. Accordingly, under the "if-converted" method, diluted earnings per share will be calculated assuming that all of the Convertible Notes were converted solely into ordinary shares at the beginning of the reporting period, unless the result would be anti-dilutive. This new method of calculating earnings per share may adversely affect our reported financial condition and results.

Exchanges of the Notes will dilute the ownership interest of our existing shareholders and holders of the ADSs, including holders who may exchange their Notes and receive ADSs upon exchange, to the extent our exchange obligation includes ADSs.

The exchange of some or all of the Notes will dilute the ownership interests of our existing shareholders and holders of the ADSs to the extent our exchange obligation includes ADSs. Any sales in the public market of the ADSs issuable upon such exchange of the Notes could adversely affect prevailing market prices of the ADSs and, in turn, the price of the Notes. In addition, the existence of the Notes may encourage short selling by market participants because the exchange of the Notes could depress the price of the ADSs.

The fundamental change repurchase feature of the Notes may delay or prevent an otherwise beneficial takeover attempt of Avadel.

The indenture governing the Notes will require us to repurchase the Notes for cash upon the occurrence of a fundamental change and, in certain circumstances, to increase the exchange rate for a holder that exchanges its Notes in connection with a

make-whole fundamental change. A takeover of Avadel may trigger the requirement that we repurchase the Notes and/or increase the exchange rate, which could make it more costly for a potential acquirer to engage in a combinatory transaction with us. Such additional costs may have the effect of delaying or preventing a takeover of Avadel that would otherwise be beneficial to investors.

General Risk Factors

Provisions of our articles of association could delay or prevent a third-party's effort to acquire us.

Our articles of association could delay, defer or prevent a third-party from acquiring us, even where such a transaction would be beneficial to the holders of ADSs, or could otherwise adversely affect the price of ADSs. For example, certain provisions of our articles of association:

- permit our board of directors to issue preferred shares with such rights and preferences as they may designate, subject to applicable law;
- impose advance notice requirements for shareholder proposals and director nominations to be considered at annual shareholder meetings; and
- require the approval of a supermajority of the voting power of our shares entitled to vote at a general meeting of shareholders to amend or repeal any provisions of our articles of association.

We believe these provisions, if implemented in compliance with applicable law, may provide some protection to holders of ADSs from coercive or otherwise unfair takeover tactics. These provisions are not intended to make us immune from takeovers. They will, however, apply even if some holders of ADSs consider an offer to be beneficial and could delay or prevent an acquisition that our Board of Directors determines is in the best interest of the holders of ADSs. Certain of these provisions may also prevent or discourage attempts to remove and replace incumbent directors.

In addition, mandatory provisions of Irish law could prevent or delay an acquisition of the Group by a third party. For example, Irish law does not permit shareholders of an Irish public limited company to take action by written consent with less than unanimous consent. In addition, an effort to acquire us may be subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in ADSs in certain circumstances.

These provisions may discourage potential takeover attempts or bids for our ordinary shares at a premium over the market price or they may adversely affect the market price of, and the voting and other rights of the holders of, ADSs. These provisions could also discourage proxy contests and make it more difficult for holders of ADSs to elect directors other than the candidates nominated by our board of directors and could depress affect the market price of ADSs.

Irish law differs from the laws in effect in the U.S. and might afford less protection to the holders of ADSs and any actual or potential takeover offer for the group will be subject to Irish Takeover Rules.

Holders of ADSs could have more difficulty protecting their interests than would the shareholders of a corporation incorporated in a jurisdiction of the U.S. As an Irish-incorporated company, we are governed by Irish law, including the Irish Companies Act 2014 and the Irish Takeover Rules, which differs in some significant, and possibly material, respects from provisions set forth in various U.S. state laws applicable to U.S. corporations and their shareholders, including provisions relating to interested directors, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. The duties of directors and officers of an Irish company are generally owed to the group only. Therefore, under Irish law shareholders of Irish companies do not generally have a right to commence a legal action against directors or officers and may only do so in limited circumstances. Directors of an Irish company must act with due care and skill, honestly and in good faith with a view to the best interests of the group. Directors must not put themselves in a position in which their duties to the group and their personal interests conflict and must disclose any personal interest in any contract or arrangement with the group or any of our subsidiaries. A director or officer can be held personally liable to the group in respect of a breach of duty to the group.

It may not be possible to enforce court judgments obtained in the U.S. against us in Ireland based on the civil liability provisions of U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised that the U.S. currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal

or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

In addition, any actual or potential takeover offer for our company will be subject to the Irish Takeover Rules. Under the Irish Takeover Rules, during the course of an offer or at any earlier time during which our Board has reason to believe that an offer for our company may be imminent, the Board will not be permitted to take any action, other than seeking alternative offers, which might frustrate the making of an offer for our ordinary shares unless we obtain approval from our shareholders or from the Irish Takeover Panel for such action. Potentially frustrating actions that are prohibited during the course of an offer, or at any earlier time during which our Board has reason to believe an offer is or may be imminent, include (i) the issuance of shares, options or convertible securities or the redemption or purchase of own shares, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer. Accordingly, if these restrictions become applicable to us, we may be unable to take, or may be delayed in taking, certain actions, in connection with a financing, commercial or strategic transaction or otherwise, that we believe are in the best interest of the Group.

Judgments of U.S. courts, including those predicated on the civil liability provisions of the federal securities laws of the U.S., may not be enforceable in Irish courts.

An investor in the U.S. may find it difficult to:

- effect service of process within the U.S. against us and our non-U.S. resident directors and officers;
- enforce U.S. court judgments based upon the civil liability provisions of the U.S. federal securities laws against us and our non-U.S. resident directors and officers in Ireland; or
- bring an original action in an Irish court to enforce liabilities based upon the U.S. federal securities laws against us and our non-U.S. resident directors and officers.

Judgments of U.S. courts, including those predicated on the civil liability provisions of the federal securities laws of the United States, may not be enforceable in Cayman Islands courts.

We have been advised by our Cayman Islands legal counsel, Maples and Calder, that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against us or Avadel judgments of courts of the U.S. predicated upon the civil liability provisions of the securities laws of the U.S. or any State; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against us or Avadel predicated upon the civil liability provisions of the securities laws of the U.S. or any State, so far as the liabilities imposed by those provisions are penal in nature. In those circumstances, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the U.S., the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, and or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands Court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

Holders of ADSs have fewer rights than shareholders and have to act through the Depositary to exercise those rights.

Holders of ADSs do not have the same rights as shareholders and, accordingly, cannot exercise rights of shareholders against us. The Bank of New York Mellon, as depositary (the "Depositary"), is the registered shareholder of the deposited shares underlying the ADSs. Therefore, holders of ADSs will generally have to exercise the rights attached to those shares through the Depositary. We will use reasonable efforts to request that the Depositary notify the holders of ADSs of upcoming votes and ask for voting instructions from them. If a holder fails to return a voting instruction card to the Depositary by the date established by the Depositary for receipt of such voting instructions, or if the Depositary receives an improperly completed or blank voting instruction card, or if the voting instructions included in the voting instruction card are illegible or unclear, then such holder will be deemed to have instructed the Depositary to vote its shares, and the Depositary shall vote such shares in favor of any resolution proposed or approved by our Board of Directors and against any resolution not so proposed or approved.

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

In the ordinary course of our business, we collect and store on our networks various intellectual property including our proprietary business information and that of former customers, suppliers and business partners. The secure maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information systems and infrastructure may be vulnerable to disruptions such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, investigations by regulatory authorities in the U.S. and EU Member States, disruption to our operations and damage to our reputation, any of which could adversely affect our business.

We could suffer financial loss or the loss of valuable confidential information. Although we develop and maintain systems and controls designed to prevent these events from occurring and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber-attacks or security breaches that could adversely affect our business.

We have broad discretion in the use of our cash and may not use it effectively.

Our management has broad discretion in the use of our cash and may not apply our cash in ways that ultimately increases the value of any investment in our securities. We currently intend to use our cash to fund marketing activities for any future commercialized products, to fund certain clinical trials for product candidates, to fund research and development activities for potential new product candidates, and for working capital, capital expenditures and general corporate purposes. As in the past we expect to invest our excess cash in available-for-sale marketable securities, including corporate bonds, U.S. government securities, other fixed income securities and equities; and these investments may not yield a favorable return. If we do not invest or apply our cash effectively, our financial position and the price of ADSs may decline.

We currently do not intend to pay dividends and cannot assure the holders of our ADSs that we will make dividend payments in the future.

We have never declared or paid a cash dividend on any of our ordinary shares or ADSs and do not anticipate declaring cash dividends in the foreseeable future. Declaration of dividends will depend upon, among other things, future earnings, if any, the operating and financial condition of our business, our capital requirements, general business conditions and such other factors as our Board of Directors deems relevant.

Our effective tax rate could be highly volatile and could adversely affect our operating results.

Our future effective tax rate may be adversely affected by a number of factors, many of which are outside of our control, including:

- the jurisdictions in which profits are determined to be earned and taxed;
- changes in the valuation of our deferred tax assets and liabilities;
- changes in share-based compensation expense;
- changes in domestic or international tax laws or the interpretation of such tax laws;
- changes in available tax credits;
- adjustments to estimated taxes upon finalization of various tax returns; and
- the resolution of issues arising from tax audits with various tax authorities.

Any significant increase in our future effective tax rates could impact our results of operations for future periods adversely.

Changes in tax law could adversely affect our business and financial condition.

We are subject to income and other taxes in the U.S. and foreign jurisdictions. Changes to applicable U.S. or foreign tax laws and regulations, or their interpretation and application (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our ordinary shares or ADSs. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in tax laws on an investment in our ordinary shares or ADSs.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of 31 December 2022, we had $124,443 of net operating losses in the U.S. Of the $124,443 of net operating losses in the U.S., $10,365 were acquired due to the acquisition of FSC Therapeutics and FSC Laboratories, Inc., (collectively "FSC") and $114,078 are due to the losses at Avadel US Holdings, Inc. The portion due to the acquisition of FSC will expire in 2034 through 2035. The U.S. net operating losses acquired as part of the acquisition of FSC are subject to an annual limitation under Internal Revenue Code Section 382 and $1,473 of the $10,365 will not be fully utilized before they expire. The remaining $114,078 of net operating losses do not have an expiration date.

Under U.S. federal tax legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act ("Tax Act"), U.S. federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such U.S. federal net operating losses is limited. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986 (the "Code") if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage-point cumulative change (by value) in the equity ownership of certain shareholders over a rolling three-year period), the corporation's ability to use its pre-change net operating losses and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We may also experience ownership changes as a result of this offering or future issuances of our stock or as a result of subsequent shifts in our stock ownership, some of which are outside our control. We have completed an analysis to determine that no events have been triggered in the past. If any ownership changes are determined to be triggered in the future, our ability to use our current net operating losses to offset post-change taxable income or taxes would be subject to limitation. We will be unable to use our net operating losses if we do not attain profitability sufficient to offset our available net operating losses prior to their expiration.

As of 31 December 2022, we had approximately $147,240 of net operating losses in Ireland that do not have an expiration date. While these losses do not have an expiration date, substantial changes in the activities performed in these jurisdictions could have an impact on our ability to utilize these tax attributes in the future.

U.S. Holders of ordinary shares or ADSs may suffer adverse U.S. tax consequences if we are classified as a passive foreign investment company.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties that are received from unrelated parties in connection with the active conduct of a trade or business. Our status as a PFIC depends on the composition of our income and the composition and value of our assets (for which purpose the total value of our assets may be determined in part by the market value of the ordinary shares or ADSs, which are subject to change) from time to time. If we are characterized as a PFIC, U.S. Holders (as defined below under "Material U.S. Federal Income Tax Considerations for U.S. Holders") of ordinary shares or ADSs may suffer materially adverse tax consequences, including having gains realized on the sale of ordinary shares or ADSs treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on ordinary shares or ADSs by individuals who are U.S. Holders, and having interest charges apply to distributions by us and the proceeds of sales of ordinary shares or ADSs.

We believe that we were not a PFIC for the taxable year ending 31 December 2022 and, based on the expected value of our assets, including any goodwill, and the expected nature and composition of our income and assets, we expect that we will not be a PFIC for our current taxable year. However, our status as a PFIC is a fact-intensive determination subject to various uncertainties, and we cannot provide any assurances regarding our PFIC status for the current, prior or future taxable years.

Certain U.S. Holders that own 10 percent or more of the vote or value of ordinary shares or ADSs may suffer adverse U.S. tax consequences because our non-U.S. subsidiaries are expected to be classified as controlled foreign corporations.

Each ''Ten Percent Shareholder'' (as defined below) in a non-U.S. corporation that is classified as a ''controlled foreign corporation,'' or a CFC, for U.S. federal income tax purposes generally is required to include in income for U.S. federal tax purposes such Ten Percent Shareholder's pro rata share of the CFC's ''Subpart F income'' and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. Subpart F income generally includes dividends, interest, rents, royalties, ''global intangible low-taxed income,'' gains from the sale of securities and income from certain transactions

with related parties. In addition, a Ten Percent Shareholder that realizes gain from the sale or exchange of shares in a CFC may be required to classify a portion of such gain as dividend income rather than capital gain. A non-U.S. corporation generally will be classified as a CFC for U.S. federal income tax purposes if Ten Percent Shareholders own, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A ‘‘Ten Percent Shareholder’’ is a U.S. person (as defined by the Code) who owns or is considered to own 10% or more of the total combined voting power of all classes of stock entitled to vote or 10% or more of the total value of all classes of stock of such corporation.

We believe that we were not a CFC in the 2022 taxable year, but that our non-U.S. subsidiaries were CFCs in the 2022 taxable year. We anticipate that our non-U.S. subsidiaries will remain CFCs in the 2022 taxable year, and it is possible that we may become a CFC in the 2023 taxable year or in a subsequent taxable year. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. U.S. Holders should consult their own tax advisors with respect to the potential adverse U.S. tax consequences of becoming a Ten Percent Shareholder in a CFC, including the possibility and consequences of becoming a Ten Percent Shareholder in one or more of our non-U.S. subsidiaries that are anticipated to be treated as CFCs. If we are classified as both a CFC and a PFIC, we generally will not be treated as a PFIC with respect to those U.S. Holders that meet the definition of a Ten Percent Shareholder during the period in which we are a CFC, subject to certain exceptions.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance requirements, including establishing and maintaining internal controls over financial reporting. We had identified a material weakness in our internal control over financial reporting during 2021 that was remediated in 2022. We may be exposed to potential risks if we are unable to comply the requirements to maintain internal controls over financial reporting or if we identify additional material weaknesses.

As a public company in the United States organized, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the listing rules of the Nasdaq Stock Market ("Nasdaq"), and incur significant legal, accounting and other expenses to comply with applicable requirements. These rules impose various requirements on public companies, including requiring certain corporate governance practices. Our management and other personnel devote a substantial amount of time to these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

For example, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Such compliance may require that we incur substantial accounting expenses and expend significant management efforts.

In connection with the Group’s fiscal 2021 financial statement close process, management identified a deficiency in the design of internal control over financial reporting related to its February 2023 Notes indenture, which has been remediated. In the future we may determine that we have additional material weaknesses. Our failure to remediate the material weaknesses or failure to identify and address any other material weaknesses or control deficiencies could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis, which could cause investors to lose confidence in our reported financial information, which may result in volatility in and a decline in the market price of our ADSs.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Sales of a substantial number of ADSs by us or existing security holders in the public market could cause our share price to fall.

Sales of a substantial number of ADSs by us or existing security holders in the public market or the perception that these sales might occur could depress the market price of ADSs and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of ADSs. In addition, the sale of substantial amounts of ADSs could adversely impact its price. As of 4 May 2023, we had outstanding 76,683 ordinary shares, 488 ordinary shares issuable upon conversion of our preferred shares, options to purchase 9,578 ordinary shares or ADSs, with an average exercise price of $6.70, and unsettled restricted shares and performance shares relating to 34 ordinary shares. In addition, ordinary shares are issuable upon exchange of our outstanding Notes. The sale or the availability for sale of a large number of ADSs in the public market could cause the price of ADSs to decline.

Because we expect we will need to raise additional capital to fund our future activities, we may in the future sell substantial amounts of ADSs or securities convertible into or exchangeable for ordinary shares.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not have control over these analysts. There can be no assurance that existing analysts will continue to provide research coverage or that new analysts will begin to provide research coverage. Although we have obtained analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

A transfer of ordinary shares may be subject to Irish stamp duty.

Transfers of ordinary shares (as opposed to ADSs) could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. Although transfers of ADSs are not subject to Irish stamp duty, the potential for stamp duty to arise on transfers of ordinary shares could adversely affect the price of our ordinary shares or ADSs.

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on our product candidate development, commercialization preparations for LUMRYZ, if approved, and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials for our product candidates and the potential commercial launch of LUMRYZ.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Group's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on 10 March 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on 12 March 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. Although we are not a borrower or party to any such instruments with SVB, Signature or any other financial institution currently in receivership, if any of our lenders or counterparties to any such instruments were to be

placed into receivership, we may be unable to access such funds. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Group, the financial institutions with which the Group has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Group has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and/or delays, inability or reductions in the Group's ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require the Group to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- Potential or actual breach of our long-term debt obligations;
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or parties with whom we conduct business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare

bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a party with whom we conduct business could be adversely affected by any of the liquidity or other risks described above as factors that could result in material adverse impacts on the Group, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer or supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to the Group and may have a material adverse impact on our business.

Financial Risk Management

Our operations include activities in the U.S. and countries outside of the U.S. These operations expose us to a variety of market risks, including the effects of changes in interest rates and currency exchange rates. We monitor and manage these financial exposures as an integral part of our overall risk management program. We do not utilize derivative instruments for trading or speculative purposes.

Interest Rate Risk

The Group is subject to interest rate risk as a result of our portfolio of marketable securities. The primary objectives of our investment policy are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and competitive yield. Although our investments are subject to market risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or certain types of investment. Our investment policy allows us to maintain a portfolio of cash equivalents and marketable securities in a variety of instruments, including U.S. federal government and federal agency securities, European Government bonds, corporate bonds or commercial paper issued by U.S. or European corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, tax-exempt obligations of states, agencies, and municipalities in the U.S and Europe, and equities. A hypothetical 50 basis point change in interest rates would not result in a material decrease or increase in the fair value of our securities due to the general short-term nature of our investment portfolio.

Foreign Exchange Risk

We are exposed to foreign currency exchange risk as the functional currency financial statements of a non-U.S. subsidiary is translated to U.S. dollars. The assets and liabilities of this non-U.S. subsidiary having a functional currency other than the U.S. dollar is translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of profit and loss account in shareholders' (deficit) equity. The reported results of this non-U.S. subsidiary will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposure is related to one subsidiary that has functional currencies denominated in euro. A 10% strengthening/ weakening in the rates used to translate the results of our non-U.S. subsidiaries that have functional currencies denominated in euro as of 31 December 2022 would have had an immaterial impact on net loss for the year ended 31 December 2022.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in investment and other (expense) income, net in the consolidated profit and loss account. As of 31 December 2022, our primary exposure is to transaction risk related to euro net monetary assets and liabilities held by subsidiaries with a U.S. dollar functional currency. Realized and unrealized foreign exchange gains resulting from transactional exposure were immaterial for the year ended 31 December 2022.

Inflation Risk

Inflation generally affects us by increasing our costs of labor and supplies and the costs of our third parties we rely on for the development, manufacture and supply of our product candidates. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the year ended 31 December 2022. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future (especially if inflation rates continue to rise) due to an impact on the costs to conduct clinical trials, the costs to prepare for the potential commercialization of LUMRYZ, labor costs we incur to attract and retain qualified personnel, and other operational costs. Inflationary costs could adversely affect our business, financial condition and results of operations.

Risk Management

The adequacy of our cash resources depends on the outcome of certain business conditions including the cost of our LUMRYZ commercial launch plans, our cost structure, and other factors set forth in "Principal Risks and Uncertainties". To complete the LUMRYZ commercial launch plans we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business. Our assumptions concerning the outcome of certain business conditions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash and marketable securities balances which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business. Additionally, we are unable to estimate the near or long term impact of COVID-19, which may have a material adverse impact on our business.

The Group has a recent history of generating losses and negative cash flows from operations, an accumulated shareholders' deficit as of the date of these audited consolidated financial statements and approximately $73,981 of cash and cash equivalents and $22,518 of marketable securities available for use to fund its operations, debt service and capital requirements. The Group's ability to generate revenue is expected to start following the launch of LUMRYZ, which is dependent, in part, on market acceptance of LUMRYZ and the Company's ability to successfully complete its commercialization efforts.

On 29 March 2023, the Group entered into a royalty purchase agreement with RTW Investments, L.P. that could provide the Group up to $75,000 of royalty financing in two tranches. The first tranche of $30,000 is available subject to the Group's first shipment of LUMRYZ. The second tranche is available to use, at the Group's election, upon achieving quarterly net revenue of $25,000. The second tranche will expire on 31 August 2024, if the quarterly net revenue target is not reached and if it is not used by the Group by that time.

At 31 March 2023, the Group had $117,375 aggregate principal amount of its 4.50% exchangeable senior notes due October 2023 (the "October 2023 Notes"). Over the course of 3 April and 4 April 2023, Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of the Group (the "Issuer"), completed an exchange of $96,188 of its $117,375 October 2023 Notes for $106,268 of a new series 6.0% exchangeable notes due April 2027 (the "April 2027 Notes") (the "2023 Exchange Transaction"). The remaining $21,187 aggregate principal amount of the October 2023 Notes will maintain a maturity date of 2 October 2023.

On 29 March 2023, the Group announced a public offering, which was completed on 3 April 2023. The Group received net proceeds from the equity financing of $135,125, of which $40,000 was received on 31 March 2023 and $95,125 was received on 3 April 2023.

As a result of the 2023 Exchange Transaction and public offering, the Group has concluded that cash on hand provides sufficient capital to meet the Group's operating, debt service and capital requirements for the next twelve months following the date of this annual report.

Accounting records

The directors are responsible for ensuring that the Group and Company keep adequate accounting records and appropriate accounting systems. The measures taken by the directors to ensure compliance with the Group's and Company's obligation to keep adequate accounting records include the use of appropriate systems and procedures and the employment of competent persons. The directors have appointed a Chief Financial Officer who makes regular reports to the directors and ensures compliance with the requirements of Sections 281 to 285 of the Companies Act 2014. The Chief Financial Officer makes regular reports to the Audit Committee. The Audit Committee, in turn, briefs the directors on significant financial matters arising from reports of the Chief Financial Officer and the external auditor**.**

The accounting records of Avadel are maintained at 16640 Chesterfield Grove Rd., St. Louis, Missouri 63005, United States. In accordance with Section 283(2) of the Companies Act 2014, sufficient accounting records are also maintained in the Republic of Ireland to disclose, with reasonable accuracy, the assets, liabilities, financial position and profit or loss of the Group. The accounting records are available at 10 Earlsfort Terrace, Dublin 2, Ireland, which enable such information and returns relating to the Company to be disclosed with reasonable accuracy concerning the assets, liabilities, financial position and profit or loss at intervals not exceeding 6 months.

Directors

The remuneration of statutory directors of the Company during the year is set forth in *Note 19: Key Management Compensation* in the Notes to Consolidated Financial Statements. No director or Company secretary of the Company had an interest in shares or debentures required to be disclosed under Section 329 of the Companies Act 2014 either at the beginning of the financial year, or date of appointment if later, or at the end of the financial year. Note that where the aggregate interest in shares of any

director or secretary (and his or her spouse (or civil partner) and children) represents less than 1% in nominal value of the Group's ordinary shares, the only interests of that director or secretary that are required to be disclosed constitute a right to subscribe for shares in the Company or that arise as a result of the exercise of such a right. Performance stock units where the director or secretary is an employee of the Company and does not make any payment to the Company in respect of the shares are not considered to be rights to subscribe for the purposes of this disclosure and no disclosure is required where they form part of an aggregate less than 1% holding. No Directors or Corporate Secretary had holdings of 1% or more as of 31 December 2022.

Set forth below are the names of the individuals serving as statutory directors during fiscal 2022 through the date of this report:

Nominee	Principal Occupation or Experience	Nationality	Committees
Geoffrey M. Glass	President and Chief Executive Officer of Kiniciti, LLC	American	(1)(3)(4)
Dr. Eric J. Ende	President of Ende BioMedical Consulting Group Director at Matinas BioPharma, Inc.	American	(1)(3)
Dr. Mark A. McCamish	President, Chief Executive Officer of IconOVir Bio, Inc.	American	(1)(2)
Linda S. Palczuk	Chief Operating Officer and Director of Envara Health, Inc.	American	(2)(3)
Peter J. Thornton	President and Chief Financial Officer of Envetec Sustainable Technologies Limited	Irish	(1)(2)
Gregory J. Divis	Chief Executive Officer of the Company	American	

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee
(4) Non-Executive Chairman of the Board of Directors

Set forth below is the name of the individual serving as the company secretary during fiscal 2022 through the date of this report:

Nominee	Principal Occupation or Experience	Nationality
Jerad G. Seurer	Company Secretary	American

Political Donations

No political contributions that require disclosure under Irish law were made during the year.

Subsidiary Companies and Branches

Information regarding subsidiary undertakings, including information regarding branches, is provided in *Note 23: Subsidiary Undertakings* in the Notes to Consolidated Financial Statements.

Disclosure of Information to Auditor

Each of the persons who is a director at the date of approval of this report confirms that:

- so far as that director is aware, there is no relevant audit information of which the Group's auditor is unaware, and
- that director has taken all the steps that ought to have been taken as a director in order to be aware of any relevant audit information and to establish that the Group's auditor is aware of that information.

This confirmation is given and should be interpreted in accordance with the provisions of Section 330 of the Companies Act 2014.

Directors' Compliance Statement

As required by section 225 of the Companies Act 2014, the directors acknowledge that they are responsible for securing the Avadel Pharmaceuticals plc's compliance with its "relevant obligations" (as defined in that legislation). The directors further confirm that a compliance policy statement has been drawn up, and that appropriate arrangements and structures have been put in place that are, in the directors' opinion, designed to secure material compliance with the relevant obligations. A review of those arrangements and structures has been conducted in the financial year to which this report relates. In discharging their responsibilities under section 225, the directors relied on the advice of persons who the directors believe have the requisite knowledge and experience to advise Avadel Pharmaceuticals plc on compliance with its relevant obligations.

Audit Committee

The Board has established an Audit committee that in all material respects meets the requirements of Section 167 of the Companies Act 2014.

Events Since the Balance Sheet Date

Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of Avadel Pharmaceuticals plc, repaid, with cash on hand, the remaining $17,500 aggregate principal amount of its February 2023 Notes on the maturity date of 1 February 2023.

On 29 March 2023, the Group entered into a royalty purchase agreement with RTW Investments, L.P. that could provide the Group up to $75,000 of royalty financing in two tranches. The first tranche of $30,000 is available subject to the Group's first shipment of LUMRYZ. The second tranche is available to use, at the Group's election, upon achieving quarterly net revenue of $25,000. The second tranche will expire on 31 August 2024, if the quarterly net revenue target is not reached and if it is not used by the Group by that time.

Over the course of 3 April and 4 April 2023, Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of the Group (the "Issuer"), completed an exchange of $96,188 of its $117,375 October 2023 Notes for $106,268 of a new series 6.0% exchangeable notes due April 2027 (the "April 2027 Notes") (the "2023 Exchange Transaction"). The remaining $21,187 aggregate principal amount of the October 2023 Notes will maintain a maturity date of 2 October 2023.

On 3 April 2023, the Group completed the sale of ordinary shares, nominal value $0.01 per share ("Ordinary Shares") in the form of American Depositary Shares ("ADSs") and its Series B Non-Voting Convertible Preferred Shares ("Series B Preferred Shares") in an underwritten public offering. The Group issued 4,706 Series B Preferred Shares and 12,205 of its ADSs and received net proceeds from the equity financing of $135,125, of which $40,000 was received on 31 March 2023 and $95,125 was received on 3 April 2023.

On 1 May 2023, LUMRYZ was approved by the U.S. Food and Drug Administration ("FDA"). At that time, the FDA granted Orphan Drug Exclusivity ("ODE") to LUMRYZ for a period of seven years until 1 May 2030.

Going Concern

The directors have a reasonable expectation that Avadel Pharmaceuticals plc and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, the directors continue to adopt the going concern basis in preparing the financial statements. Please see *Note 1: Background and Basis of Presentation,* for additional information

Auditor

The auditor, Deloitte Ireland LLP, Chartered Accountants and Statutory Audit Firm, continues in office in accordance with Section 383(2) of the Companies Act 2014.

On behalf of the Directors

/s/ Peter J. Thornton	/s/ Gregory J. Divis
Peter J. Thornton	Gregory J. Divis
Director	Director
4 May 2023	4 May 2023

AVADEL PHARMACEUTICALS PLC

DIRECTORS' RESPONSIBILITIES STATEMENT

The directors are responsible for preparing the directors' report and financial statements in accordance with the Companies Act 2014.

Irish company law requires the directors to prepare financial statements for each financial year. Under the law, the directors have elected to prepare the Irish statutory group consolidated financial statements of Avadel Pharmaceuticals plc in accordance with U.S. GAAP, as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the group financial statements does not contravene any provision of Part 6 of the Companies Act 2014.

The directors have elected to prepare the Avadel Pharmaceuticals plc parent company financial statements in accordance with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* issued by the Financial Reporting Council ("relevant financial reporting framework").

Under company law, the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position of the group and company as at the financial year end date and of the profit or loss of the group for the financial year and otherwise comply with the Companies Act 2014.

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

- select suitable accounting policies for the Group and company financial statements and then apply them consistently;
- make judgments and estimates that are reasonable and prudent;
- state whether the financial statements have been prepared in accordance with the applicable accounting standards, identify those standards, and note the effect and the reasons for any material departure from those standards; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for ensuring that the company keeps or causes to be kept adequate accounting records which correctly explain and record the transactions of the company; enable at any time the assets, liabilities, financial position and profit or loss of the company to be determined with reasonable accuracy; enable them to ensure that the financial statements and directors' report comply with the Companies Act 2014; and enable the financial statements to be audited. They are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

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

Deloitte.

Independent auditor's report to the members of Avadel Pharmaceuticals plc

Report on the audit of the financial statements

Opinion on the financial statements of Avadel Pharmaceuticals plc (the 'Group')

In our opinion the Group financial statements:

- give a true and fair view of the assets, liabilities and financial position of the Group as at 31 December 2022 and of the loss of the Group for the financial year then ended; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The financial statements we have audited comprise:

- the Consolidated Profit and Loss Account;
- the Consolidated Statement of Other Comprehensive Income;
- the Consolidated Balance Sheet;
- the Consolidated Statement of Cash Flows;
- the Consolidated Statement of Changes in Shareholders' Equity; and
- the related notes 1 to 25, including a summary of significant accounting policies as set out in note 2.

The relevant financial reporting framework that has been applied in the preparation of the Group financial statements is the Companies Act 2014 and US Generally Accepted Accounting Principles (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 the financial statements does not contravene Part 6 of the Companies Act ("the relevant financial reporting framework").

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are described below in the "*Auditor's responsibilities for the audit of the financial statements*" section of our report.

We are independent of the Group in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Summary of our audit approach

Key audit matters	The key audit matter that we identified in the current year was: • *Going concern* Within this report, any new key audit matters are identified with ⏫ and any key audit matters which are the same as the prior year identified with ⏩.
Materiality	The materiality that we used in the current year was $2,720,000 which was determined on the basis of operating costs.

Scoping	We focused our Group audit scope primarily with a full scope audit, predominately performed in the United States, on the Group's US operations which represented 66% of the operating costs and 71% of the assets. The Group's remaining Non US international components were subject to specified audit procedures.
Significant changes in our approach	No significant changes to note.

Conclusions relating to going concern

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.

Our evaluation of the directors' assessment of the Group's ability to continue to adopt the going concern basis of accounting is discussed in the Key Audit Matters section of our report.

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 ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

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

Key Audit Matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current financial year and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, 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 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.

Our prior year audit report included management override of control which has not been determined as key audit matter in the current year.

Going Concern	
Key audit matter description	As stated in note 1 to the financial statements, the directors have assessed that the going concern basis of accounting is appropriate in preparing the financial statements. The Group has a recent history of generating losses and negative cash flows from operations, an accumulated shareholders' deficit as of 31 December 2022 of $21,145 and approximately $73,981 of cash and cash equivalents and $22,518 of marketable securities available for use to fund its operations, debt service and capital requirements. The Group's ability to generate revenue is expected to start following the launch of LUMRYZ, which is dependent, in part, on the Group's ability to successfully complete its commercialisation efforts and on market acceptance of LUMRYZ. The director's assessment is based on steps taken subsequent to the year end to ensure liquidity to the Group.

	At 31 March 2023, the Group had $117,375 aggregate principal amount of its 4.50% exchangeable senior notes due October 2023 (the "October 2023 Notes"). Over the course of 3 April and 4 April 2023, Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of the Group (the "Issuer"), completed an exchange of $96,188 of its $117,375 October 2023 Notes for $106,268 of a new series 6.0% exchangeable notes due April 2027 (the "April 2027 Notes") (the "2023 Exchange Transaction"). The remaining $21,187 aggregate principal amount of the October 2023 Notes will maintain a maturity date of 2 October 2023. On 29 March 2023, the Group announced a public offering, which was completed on 3 April 2023. The Group received net proceeds from the equity financing of $135,125, of which $40,000 was received on 31 March 2023 and $95,125 was received on 3 April 2023. We have identified a key audit matter related to going concern as this is a key area of management focus and involved a significant allocation of resources and efforts of the engagement team.
How the scope of our audit responded to the key audit matter 	• We obtained an understanding of the Group's relevant controls over the preparation of cash flow forecasts, approval of projections and assumptions used in the cash flow forecast to support the going concern assumption and tested the operating effectiveness of the key relevant controls. • We inspected the 2023 Exchange Agreement executed after 31 December 2022 and agreed the amounts, key terms and dates to management's forecasts. • We inspected the net proceeds from the public offering completed on 3 and 4 April 2023. • We inspected the royalty financing agreement with RTW Investments, L.P. that may provide $75,000 of royalty financing. • We confirmed that LUMRYZ was approved by the FDA on 1 May 2023. We confirmed that the FDA also granted Orphan Drug Exclusivity to LUMRYZ at that time for a period of seven years until 1 May 2030. • We tested the clerical accuracy of the cash flow forecast models. • We evaluated management's key assumptions including the Group's LUMRYZ launch and commercialisation plans. • We evaluated the completeness of the Group's future obligations and evaluated consistency of evidence obtained in other areas of the audit. • We performed an assessment of the historical accuracy of forecasts prepared by management. • We evaluated the completeness and accuracy of the disclosures made in the financial statements.
Key observations 	We have concluded that the adoption of the going concern basis of accounting and the related disclosures are appropriate. Please refer to our conclusions in the going concern section of our report.

Our audit procedures relating to these matters were designed in the context of our audit of the financial statements as a whole, and not to express an opinion on individual accounts or disclosures. Our opinion on the financial statements is not modified with respect to any of the risks described above, and we do not express an opinion on these individual matters.

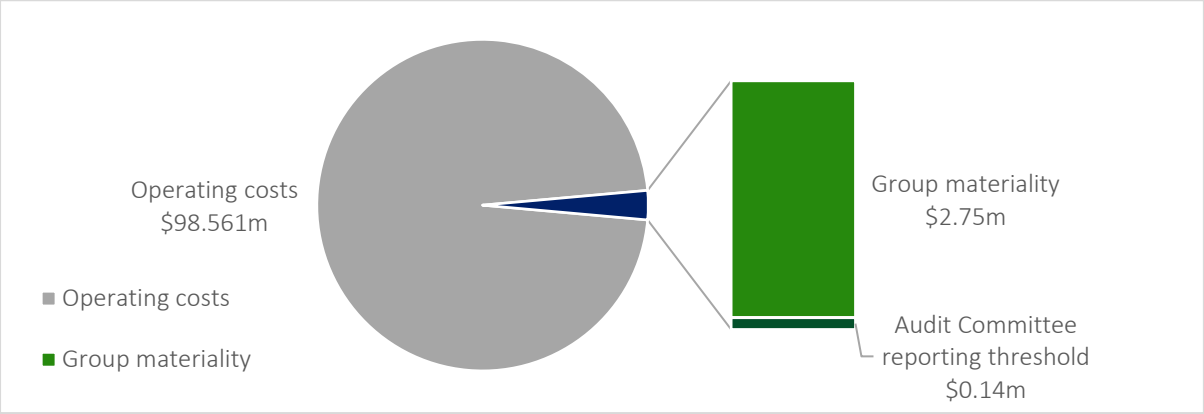
Deloitte.

Our application of materiality

We define materiality as the magnitude of misstatement in the financial statements that makes it probable that the economic decisions of a reasonably knowledgeable person would be changed or influenced. We use materiality both in planning the scope of our audit work and in evaluating the results of our work.

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

Materiality	$2,720,000 (2021: $2,000,000)
Basis for determining materiality	We have determined materiality for the Group based on 2.75% of operating costs.
Rationale for the benchmark applied	We have considered operating costs to be the critical component for determining materiality because it is of the most importance to the principal external users of the financial statements.



We set performance materiality at a level lower than materiality to reduce the probability that, in aggregate, uncorrected and undetected misstatements exceed the materiality for the financial statements as a whole. Performance materiality was set at 77% of materiality for the 2022 audit. In determining performance materiality, we considered the following factors:

a. our understanding of the Group and its environment;
b. the reliability of the Group's internal control over financial reporting;
c. the degree of centralization and common controls/processes;
d. any change to the business that would impact on our ability to forecast potential misstatements;
e. the nature, volume and size of misstatements (corrected and/or uncorrected) in the previous audit, and
f. prior period adjustments.

We agreed with the Audit Committee that we would report to the Committee all audit differences in excess of $136,000 (2021: $100,000), as well as differences below that threshold that, in our view, warranted reporting on qualitative grounds. We also report to the Audit Committee on disclosure matters that we identified when assessing the overall presentation of the financial statements.

An overview of the scope of our audit

Our Group audit was scoped by obtaining an understanding of the Group and its environment, including Group-wide controls, and assessing the risks of material misstatement at the Group level. Based on that assessment, we focused our Group audit scope primarily with a full scope audit, predominately performed in the United States, on the Group's US operations which represented 66% of the operating costs and 71% of the assets. The Group's remaining Non US international components were subject to specified audit procedures, where the extent of our testing was based on our assessment of the risks of material misstatement and of the materiality of the Group's operations in those areas. Overall, 98% of the Group's operating costs and 81% of the Group's assets were subject to direct audit procedures.

These components were selected based on coverage achieved and to provide an appropriate basis for undertaking audit work to address the risks of material misstatements identified above. Our audit work at the Non US International component was executed at levels of materiality applicable to each individual component which were lower than Group materiality at $2,176,000.

Other information

The other information comprises the information included in the Directors' Report and Consolidated Financial Statements, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information contained within the annual report.

Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

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 such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in 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 in this regard.

Responsibilities of directors

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors 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 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 to cease operations, or have no realistic alternative but to do so.

Auditor's 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 auditor's 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.

A further description of our responsibilities for the audit of the financial statements is located on IAASA's website at: https://iaasa.ie/publications/description-of-the-auditors-responsibilities-for-the-audit-of-the-financial-statements/. This description forms part of our auditor's report.

Extent to which the audit was considered capable of detecting irregularities, including fraud

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.

Identifying and assessing potential risks related to irregularities

In identifying and assessing risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, we considered the following:

- the nature of the industry and sector, control environment and business performance including the design of the Group's remuneration policies, key drivers for directors' remuneration, bonus levels and performance targets;
- results of our enquiries of management, internal audit and the audit committee about their own identification and assessment of the risks of irregularities;
- any matters we identified having obtained and reviewed the Group's documentation of their policies and procedures relating to:
    - identifying, evaluating and complying with laws and regulations and whether they were aware of any instances of non-compliance*;*
    - detecting and responding to the risks of fraud and whether they have knowledge of any actual, suspected or alleged fraud *;*
    - the internal controls established to mitigate risks of fraud or non-compliance with laws and regulations;
- the matters discussed among the audit engagement team and relevant internal specialists, including tax, valuations and IT specialists regarding how and where fraud might occur in the financial statements and any potential indicators of fraud.

In common with all audits under ISAs (Ireland), we are also required to perform specific procedures to respond to the risk of management override.

We also obtained an understanding of the legal and regulatory framework that the Group operates in, focusing on provisions of those laws and regulations that had a direct effect on the determination of material amounts and disclosures in the financial statements. The key laws and regulations we considered in this context included the Irish Companies Act and tax legislation.

In addition, we considered provisions of other laws and regulations that do not have a direct effect on the financial statements but compliance with which may be fundamental to the company's ability to operate or to avoid a material penalty. This included the United States Foreign Corrupt Practices Act and regulations relevant to being a NASDAQ listed entity.

Audit response to risks identified

As a result of performing the above, we did not identify any key audit matters related to the potential risk of fraud or non-compliance with laws and regulations.

Our procedures to respond to risks identified included the following:

- reviewing the financial statement disclosures and testing to supporting documentation to assess compliance with provisions of relevant laws and regulations described as having a direct effect on the financial statements;

- enquiring of management, the audit committee and in-house legal counsel concerning actual and potential litigation and claims;
- performing analytical procedures to identify any unusual or unexpected relationships that may indicate risks of material misstatement due to fraud;
- reading minutes of meetings of those charged with governance, reviewing internal audit reports and reviewing correspondence with relevant regulatory authorities; and
- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

We also communicated relevant identified laws and regulations and potential fraud risks to all engagement team members including internal specialists, and remained alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

Report on other legal and regulatory requirements

Opinion on other matters prescribed by the Companies Act 2014

Based solely on the work undertaken in the course of the audit, we report that:

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- The financial statements are in agreement with the accounting records.
- In our opinion the information given in the directors' report is consistent with the financial statements and the directors' report has been prepared in accordance with the Companies Act 2014.

Matters on which we are required to report by exception

Based on the knowledge and understanding of the Group and its environment obtained in the course of the audit, we have not identified material misstatements in the directors' report

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

Use of our report

This report is made solely to the company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

/s/Ann McGonagle
Ann McGonagle
For and on behalf of Deloitte Ireland LLP Chartered Accountants and Statutory Audit Firm
Deloitte & Touche House, Earlsfort Terrace, Dublin 2

4 May 2023

AVADEL PHARMACEUTICALS PLC
CONSOLIDATED PROFIT AND LOSS ACCOUNT
(In thousands, except per share data)

	Note	Years Ended 31 December 2022	2021
Research and development costs		$ (20,700)	$ (17,104)
Distribution and administrative expenses		(74,516)	(68,495)
Restructuring (expense) income	24	(3,345)	53
Operating loss		(98,561)	(85,546)
Investment and other (expense) income, net		(824)	1,706
Interest expense	13	(12,342)	(9,942)
Foreign exchange gain		288	637
Loss on ordinary activities before taxation		(111,439)	(93,145)
Taxation (charge) credit	4	(26,025)	15,816
Loss after taxation		$ (137,464)	$ (77,329)
Loss per share - basic:	5	$ (2.29)	$ (1.32)
Loss per share - diluted:	5	$ (2.29)	$ (1.32)

See accompanying notes to consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE INCOME
(In thousands)

	Years ended 31 December	
	2022	**2021**
Loss after taxation	$ (137,464)	$ (77,329)
Other comprehensive loss, net of taxation:		
Foreign currency translation loss	(597)	(1,228)
Net other comprehensive loss on marketable securities, net of $— and $214, tax, respectively	(1,804)	(1,661)
Total other comprehensive loss, net of taxation	(2,401)	(2,889)
Total comprehensive loss	$ (139,865)	$ (80,218)

See accompanying notes to consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
CONSOLIDATED BALANCE SHEET
(In thousands)

	Note	31 December 2022	31 December 2021
Fixed Assets			
Goodwill and intangible assets	9	$ 16,836	$ 16,836
Tangible assets	8	2,552	2,937
		19,388	19,773
Current Assets			
Debtors	6	16,898	70,271
Investments	7	22,518	106,513
Cash at bank and in hand		73,981	50,708
		113,397	227,492
Creditors (amounts falling due within one year)	10	(55,516)	(20,720)
Net Current Assets		57,881	206,772
Total Assets Less Current Liabilities		77,269	226,545
Creditors (amounts due after more than one year)	11	(92,394)	(144,104)
Provision for Liabilities	12	(6,020)	(4,197)
Net Assets		$ (21,145)	$ 78,244
Capital and Reserves			
Called-up share capital presented as equity	14	$ 659	$ 617
Share premium account	14	305,086	277,127
Other reserves	14	44,114	31,639
Profit and loss account	14	(371,004)	(231,139)
Shareholders' Funds		$ (21,145)	$ 78,244

Approved by the board of directors on 4 May 2023 and signed on its behalf by:

/s/ Peter J. Thornton
Peter J. Thornton
Director

/s/ Gregory J. Divis
Gregory J. Divis
Director

AVADEL PHARMACEUTICALS PLC
CONSOLIDATED STATEMENT OF CASH FLOWS
(In thousands)

	Years ended 31 December	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (137,464)	$ (77,329)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,493	815
Amortization of debt discount and debt issuance costs	6,052	1,248
Changes in deferred tax	26,025	(15,666)
Share-based compensation expense	7,013	8,872
Other adjustments	2,042	1,055
Net changes in assets and liabilities		
Prepaid expenses and other current assets	30,815	(439)
Research and development tax credit receivable	30	2,796
Trade creditors & other current liabilities	(3,108)	4,232
Accrued expenses	227	895
Other assets and liabilities	(3,429)	(3,789)
Net cash used in operating activities	(70,304)	(77,310)
Cash flows from investing activities:		
Purchases of tangible assets	(716)	(26)
Proceeds from disposal of businesses, including cash acquired and other adjustments	—	16,500
Proceeds from turnover of marketable securities	83,828	102,224
Purchases of marketable securities	(3,414)	(61,769)
Net cash provided by (used in) investing activities	79,698	56,929
Cash flows from financing activities:		
Payments for debt issuance costs	(4,804)	
Payments for extinguishment of February 2023 Notes	(8,653)	—
Cash proceeds from issuance of ordinary shares	2,682	263
Proceeds from issuance of shares off the at-the-market offering program	25,318	—
Net cash provided by financing activities	14,543	263
Effect of exchange rate changes on cash and cash equivalents	(664)	(896)
Net change in cash and cash equivalents	23,273	(21,014)
Cash and cash equivalents at 1 January	50,708	71,722
Cash and cash equivalents at 31 December	$ 73,981	$ 50,708
Supplemental disclosures of cash flow information:		
Income taxes (refund) paid, net	$ (29,058)	$ 76
Interest paid	9,660	6,469

See accompanying notes to consolidated financial statements.

AVADEL PHARMACEUTICALS PLC

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' (DEFICIT) EQUITY

(In thousands)

	Called-up Share Capital - Ordinary		Called-up Share Capital - Preferred		Share Premium Account	Other Reserves	Profit and Loss Account	Total
	Number	Amount	Number	Amount				
Balance, 31 December 2020	58,421	$ 609	488	$ 5	$ 276,865	$ 22,769	$ (137,982)	162,266
Impact of accounting standard adoptions	—	—	—	—	—	—	(12,939)	(12,939)
Net loss	—	—	—	—	—	—	(77,329)	(77,329)
Other comprehensive loss	—	—	—	—	—	—	(2,889)	(2,889)
Exercise of stock options	48	1	—	—	168	—	—	169
Vesting of restricted shares	159	2	—	—	—	(2)	—	—
Employee share purchase plan issuance	17	—	—	—	94	—	—	94
Share-based compensation	—	—	—	—	—	8,872	—	8,872
Balance, 31 December 2021	58,645	$ 612	488	$ 5	$ 277,127	$ 31,639	$ (231,139)	$ 78,244
Net loss	—	—	—	—	—	—	(137,464)	(137,464)
Other comprehensive loss	—	—	—	—	—	—	(2,401)	(2,401)
Change in fair value of October 2023 Notes conversion feature	—	—	—	—	—	5,508	—	5,508
Issuance of common stock under at-the-market offering program, net of issuance costs	3,588	36	—	—	25,282	—	—	25,318
Amortization of deferred issuance costs	—	—	—	—	—	(45)	—	(45)
Exercise of stock options	451	4	—	—	2,456	—	—	2,460
Vesting of restricted shares	144	1	—	—	—	(1)	—	—
Employee share purchase plan share issuance	75	1	—	—	221	$ —	—	222
Share-based compensation expense	—	—	—	—	—	7,013	—	7,013
Balance, December 31, 2022	62,903	$ 654	488	5	$ 305,086	$ 44,114	$ (371,004)	$ (21,145)

See accompanying notes to consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(In thousands, except per share data)

NOTE 1: Background and Basis of Presentation

Going Concern Assessment. The Group has a recent history of generating losses and negative cash flows from operations, an accumulated shareholders' deficit as of the date of these audited consolidated financial statements and approximately $73,981 of cash and cash equivalents and $22,518 of marketable securities available for use to fund its operations, debt service and capital requirements. The Group's ability to generate revenue is expected to start following the commercial launch of LUMRYZ in the U.S., which is dependent, in part, on the Company's ability to successfully complete its commercialization efforts and on market acceptance of LUMRYZ in the U.S.

On 29 March 2023, the Group entered into a royalty purchase agreement with RTW Investments, L.P. that could provide the Group up to $75,000 of royalty financing in two tranches. The first tranche of $30,000 is available subject to the Group's first shipment of LUMRYZ. The second tranche is available to use, at the Group's election, upon achieving quarterly net revenue of $25,000. The second tranche will expire on 31 August 2024 if the quarterly net revenue target is not reached and if it is not used by the Group by that time.

At 31 March 2023,, the Group had $117,375 aggregate principal amount of its 4.50% exchangeable senior notes due October 2023 (the "October 2023 Notes"). Over the course of 3 April and 4 April 2023, Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of the Group (the "Issuer"), completed an exchange of $96,188 of its $117,375 October 2023 Notes for $106,268 of a new series 6.0% exchangeable notes due April 2027 (the "April 2027 Notes") (the "2023 Exchange Transaction"). The remaining $21,187 aggregate principal amount of the October 2023 Notes will maintain a maturity date of 2 October 2023.

On 29 March 2023, the Group announced a public offering, which was completed on 3 April 2023. The Group received net proceeds from the equity financing of $135,125, of which $40,000 was received on 31 March 2023 and $95,125 was received on 3 April 2023.

As a result of the 2023 Exchange Transaction and public offering, the Group has concluded that cash on hand provides sufficient capital to meet the Group's operating, debt service and capital requirements for the next twelve months following the date of this annual report.

Background. Avadel Pharmaceuticals plc and its subsidiaries (Nasdaq: AVDL) ("Avadel," the "Group," "we," "our," or "us") is a biopharmaceutical company. The Group's lead product, LUMRYZ, formally known as FT218, is an extended-release formulation of sodium oxybate indicated to be taken once at bedtime for the treatment of cataplexy or excessive daytime sleepiness ("EDS") in adults with narcolepsy. On 1 May, 2023, LUMRYZ was approved by the U.S. Food and Drug Administration ("FDA"). In approving LUMRYZ, the FDA approved a risk evaluation and mitigation strategy ("REMS") for LUMRYZ to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in narcolepsy outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of the drug. Under this REMS, healthcare providers must be specially certified, pharmacies, practitioners, or health care settings that dispense the drug must be specially certified and the drug must be dispensed to patients with documentation of safe use conditions. At that time, the FDA also granted Orphan Drug Exclusivity ("ODE") to LUMRYZ for a period of seven years until 1 May 2030.

Outside of LUMRYZ, the Group continues to evaluate opportunities to expand its product portfolio. As of the date of this report, the Group does not have any other commercialized products in its portfolio.

The Group was incorporated in Ireland on 1 December 2015 as a private limited Company, and re-registered as an Irish public limited Company on 21 November 2016. The address of our registered office is 10 Earlsfort Terrace, Dublin 2, Ireland. Its registered number is 572535.

LUMRYZ

Our lead product LUMRYZ was approved by the United States ("U.S.") Food and Drug Administration ("FDA") in May 2023 for the treatment of cataplexy or EDS in adults with narcolepsy. Additionally, with its approval, the FDA also granted seven years of orphan drug exclusivity to LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy due to a finding of clinical superiority of LUMRYZ relative to currently marketed oxybate treatments. In particular, FDA found that LUMRYZ makes a major contribution to patient care over currently marketed, twice-nightly oxybate treatments by providing a once-nightly dosing regimen that avoids nocturnal arousal to take a second dose. We are advancing our preparations for the commercial launch of LUMRYZ. For example, on 15 March 2023, we were notified by the FDA that we are permitted to

conduct certain pre-launch activities including the importation of foreign manufactured product under the Pre-launch Activities Importation Request ("PLAIR") Program.

With respect to clinical data generated for LUMRYZ, we conducted a Phase 3 clinical trial of LUMRYZ (the "REST-ON trial"), which was a randomized, double-blind, placebo-controlled study that enrolled 212 patients who received at least one dose of LUMRYZ or placebo, and was conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient's last visit was completed at the end of the first quarter of 2020, and positive top line data from the REST-ON trial was announced on 27 April 2020. Patients who received 9 g of once-at-bedtime LUMRYZ, the highest dose administered in the trial, demonstrated statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test ("MWT"), clinical global impression-improvement ("CGI-I"), and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g, also demonstrated statistically significant and clinically meaningful improvement on all three co-primary endpoints compared to placebo. We observed the 9 g dose of once-at-bedtime LUMRYZ to be generally well-tolerated. Adverse reactions commonly associated with sodium oxybate were observed in a small number of patients (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3% and enuresis 9%), and 3.9% of the patients who received 9 g of LUMRYZ discontinued the trial due to adverse reactions.

In January 2018, the FDA granted LUMRYZ orphan drug designation for the treatment of narcolepsy, which made LUMRYZ eligible for certain development and commercial incentives, including potential U.S. market exclusivity for up to seven years. With the approval of LUMRYZ on May 1, 2023, the FDA also granted seven years of orphan drug exclusivity to LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy. That orphan exclusivity will continue until May 1, 2030. Additionally, thirteen LUMRYZ-related U.S. patents have been issued having expiration dates spanning from mid-2037 to early-2042, and there are additional patent applications currently in development and/or pending at the U.S. Patent and Trademark Office ("USPTO"), as well as foreign patent offices.

In July 2020, the Group announced that the first patient was dosed in its open-label extension ("OLE")/switch study of LUMRYZ as a potential treatment for cataplexy or EDS in patients with narcolepsy ("RESTORE"). The RESTORE study is examining the long-term safety and maintenance of efficacy of LUMRYZ in patients with narcolepsy who participated in the REST-ON study, as well as dosing and preference data for patients switching from twice-nightly sodium oxybate to once-at-bedtime LUMRYZ, regardless of whether they participated in REST-ON. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study.

New secondary endpoints from the REST-ON trial were presented at the American Academy of Neurology, beginning 17 April 2021. The first poster described LUMRYZ improvements in disturbed nocturnal sleep ("DNS"), defined in REST-ON as the number of shifts from stages N1, N2, N3, and rapid eye movement ("REM") sleep to wake and from stages N2, N3, and REM sleep to stage N1. LUMRYZ also decreased the number of nocturnal arousals as measured on polysomnography. Improvements in DNS were further supported by post-hoc analyses demonstrating increased time in deep sleep (N3, also known as slow wave sleep), and less time in N1. A second poster described the statistically significant improvements in the Epworth Sleepiness Scale ("ESS"), both the quality of sleep and the refreshing nature of sleep, and a decrease in sleep paralysis. These clinically relevant improvements were observed for all doses, beginning at week 3, for the lowest 6 g dose, compared to placebo. LUMRYZ did not demonstrate significant improvement for hypnagogic hallucinations compared to placebo.

Additional data supportive of the efficacy findings in REST-ON were presented at the 35th Annual Meeting of the Associated Professional Sleep Societies, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, also known as SLEEP 2021, beginning 10 June 2021. New data included post-hoc analyses demonstrating endpoints improvements, regardless of concomitant stimulant use, in both narcolepsy Type 1 ("NT1") or Type 2 ("NT2"). Additionally, a post-hoc analysis showed that LUMRYZ was associated with decreased body mass index compared to placebo, which may be relevant as people with narcolepsy often have co-morbid obesity. In August 2021, the primary results from the REST-ON trial were published by Kushida et al. in the journal SLEEP.

New data was presented at the American College of Chest Physicians annual meeting ("CHEST"), beginning 17 October 2021, including additional post-hoc analyses from the REST-ON trial, demonstrating a greater proportion of patients receiving LUMRYZ experienced reductions in weekly cataplexy attacks and improvement in mean sleep latency compared to placebo, as well as the results of a discrete choice experiment, indicating that the overall driver of patient preference between sodium oxybate treatments is a once-at-bedtime, versus twice-nightly, formulation.

New data was presented at World Sleep 2022 congress in March 2022, in Rome, Italy. A total of eight posters were presented, including five new post-hoc analyses from the REST-ON trial. Most notably, the post-hoc analyses showed that LUMRYZ demonstrated improvement in subjective measures of daytime sleepiness, sleep quality and refreshing nature of sleep as early as week 1 with the 4.5 g starting dose, with even greater improvement at week 2 soon after starting the 6 g dose compared to

placebo. Additional post-hoc analyses, stratified by narcolepsy type, as well as concomitant stimulant use, or without stimulants, demonstrated positive results that are generally consistent with previously reported positive endpoints from REST-ON and add to the existing body of evidence for LUMRYZ.

In addition, the results of a discrete choice experiment ("DCE") were presented, which showed that once-at-bedtime dosing, when compared to twice-nightly dosing, was the most important attribute driving both patient and clinician preference for overall oxybate product choice, as well as patient quality of life and reduction of patient anxiety/stress; dosing frequency (twice-nightly versus once-at-bedtime) was also viewed as a more important attribute as compared to other attributes assessed, including sodium content. Accompanying the DCE was a background survey for both patients and clinicians, which showed that dosing frequency was noted as a significant stressor by both patients and clinicians. The World Sleep 2022 presentations also included the first presentation of an interim safety analysis from the ongoing RESTORE study, which showed that LUMRYZ has generally been well-tolerated, with some patients receiving therapy for more than 18 months.

Additional peer-reviewed publications have included data on improvement on DNS, the first DCE and a Plain Language Summary reviewing sodium oxybate and cardiovascular health, which did not identify a signal of cardiovascular disease in the twenty years that sodium oxybate has been available. At the annual SLEEP Congress in June 2022, nine posters were presented, including five post-hoc analyses from REST-ON which support the following:

- A low number-needed-to-treat to achieve effectiveness across all three evaluated doses, as well as effect sizes, showing a moderate-to-high effect for improving MWT, ESS, and number of cataplexy attacks;
- Confirmation via various statistical methods to handle missing data that LUMRYZ improved cataplexy and EDS symptoms versus placebo;
- Confirmation of benefit for NT1 and NT2 for DNS and ESS;
- Confirmation of benefit for subgroups taking stimulants and those without stimulants for DNS and ESS; and
- Early efficacy (Week 1 and Week 2) for ESS, refreshing nature of sleep and quality of sleep.

In addition, interim data from RESTORE were presented demonstrating that a high proportion of patients switching from twice-nightly sodium oxybate formulations had difficulty in taking the second dose, with a high proportion (92.5%) stating a preference for the once-at-bedtime dosing regimen and that most participants (62%) switching from twice-nightly sodium oxybate formulations had a stable dose equal to their starting dose; participants not currently taking sodium oxybate formulations or oxybate naive reached a stable dose with 2–4 dose titrations within four weeks.

Additional peer-review publications have included a relative bioavailability pharmacokinetics ("PK") study and a Plain Language Summary of the primary REST-ON trial results.

The Group believes that LUMRYZ has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standard of care for cataplexy or EDS in patients with narcolepsy.

Basis of Presentation. The directors have elected to prepare the Irish statutory group consolidated financial statements of Avadel Pharmaceuticals plc in accordance with Section 279 of the Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position, and profit or loss may be given by preparing the financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of Part 6 of the Companies Act 2014. The consolidated financial statements include the accounts of the parent company and all subsidiaries. All inter-group accounts and transactions have been eliminated. The format of the consolidated profit and loss account has been adopted where necessary to better reflect the nature of the business.

Reclassifications. Certain reclassifications are made to prior year amounts whenever necessary to conform with the current year presentation. Certain reclassifications have been made to the Consolidated Profit and Loss Account and the Consolidated Statements of Cash Flows for the fiscal year ended 31 December 2021 to condense line items of the same nature into a single line. This change does not affect previously reported net loss in the Consolidated Profit and Loss Account and or net cash flows used in operating activities in the Consolidated Statements of Cash Flows.

NOTE 2: Accounting Estimates and Related Accounting Policies

Accounting Estimates and the related Accounting Policies

Research and Development ("R&D"). R&D expenses consist primarily of costs related to outside services, personnel expenses, clinical studies and other R&D expenses. Outside services and clinical studies costs relate primarily to services performed by clinical research organizations and related clinical or development manufacturing costs, materials and supplies, filing fees, regulatory support, and other third-party fees. Personnel expenses relate primarily to salaries, benefits and share-based compensation. Other R&D expenses primarily include overhead allocations consisting of various support and facilities-related costs. R&D expenditures are charged to operations as incurred. Raw materials used in the production of pre-clinical and clinical products are expensed as R&D costs.

The Group recognizes refundable R&D tax credits received for spending on innovative R&D as an offset of R&D expenses. The amount offset to expense was $568 and $529 for the financial years ended 31 December 2022 and 2021, respectively.

Share-based Compensation. The Group accounts for share-based compensation based on the estimated grant-date fair value. The fair value of stock options is estimated using Black-Scholes option-pricing valuation models ("Black-Scholes model"). As required by the Black-Scholes model, estimates are made of the underlying volatility of Avadel stock, a risk-free rate and an expected term of the option or warrant. The Group estimates the expected term using a simplified method, as it does not have enough historical exercise data for a majority of such options upon which to estimate an expected term. The Group recognizes compensation cost, net of an estimated forfeiture rate, using the accelerated method over the requisite service period of the award.

Income Taxes. The Group accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Group determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Group recognizes deferred tax assets to the extent that the Group believes that these assets are more likely than not to be realized. In making such a determination, the Group considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Group determines that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, the Group would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. As of 31 December 2022, the Group's cumulative loss position was significant negative evidence in assessing the need for a valuation allowance on its deferred tax assets. Given the weight of objectively verifiable historical losses from operations, the Group recorded a full valuation allowance on its deferred tax assets. The Group will be able to reverse the valuation allowance when it has shown its ability to generate taxable income on a consistent basis in future periods. The valuation allowance does not have an impact on the Group's ability to utilize any net operating losses or other tax attributes to offset cash taxes payable as these items are still eligible to be used.

The Group records uncertain tax positions on the basis of a two-step process in which (1) the Group determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Group recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

The Group recognizes interest and penalties related to unrecognized tax benefits in the taxation credit line in the consolidated profit and loss account. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheets.

Goodwill. Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. The Group has determined that it operates in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. The Group tests goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. The Group determined that no impairment of goodwill existed at 31 December 2022 and 2021.

True and fair override. Irish company law requires goodwill to be amortized. However, the directors do not believe this gives a true and fair view because not all goodwill decline in value. In addition, since goodwill that does decline in value rarely do so on a straight-line basis, straight-line amortization of goodwill over an arbitrary period does not reflect the economic reality. Therefore, in order to present a true and fair view of the economic reality, and consistent with U.S. GAAP, goodwill is not amortized but are tested for impairment at each reporting date. If goodwill was amortized, the impact on the financial

statements would be an additional expense in the Consolidated Profit and Loss Account and Statement of Other Comprehensive Income and a corresponding decrease to the carrying value of the asset.

Summary of Other Accounting Policies

Cash at Bank and in Hand. The Group classifies cash on hand and deposited in banks including commercial paper, money market accounts and other investments it may hold from time to time, with an original maturity to the Group of three months or less, as cash at bank and in hand.

Marketable Securities. The Group's marketable securities are considered to be available for sale and are carried at fair value, with unrealized gains and losses, net of taxes, reported as a component of profit and loss account in shareholders' equity, with the exception of unrealized gains and losses on equity instruments and allowances for expected credit losses, if any, which are reported in earnings in the current period. The cost of securities sold is based upon the specific identification method. See *Note 16: Fair Value Measurements* for a discussion on how fair value is determined.

For available-for-sale debt securities in an unrealized loss position, the Group assesses whether it intends to sell or if it is more likely than not that the Group will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value. If the criteria are not met, the Group evaluates whether the decline in fair value has resulted from a credit loss or other factors. In making this assessment, management considers, among other factors, the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of the cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded for the credit loss, limited by the amount that the fair value is less than the amortized costs basis.

Tangible Assets. Tangible assets are stated at historical cost less accumulated depreciation. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

Office and computer equipment	3 years
Leasehold improvements, furniture, fixtures and fittings	2-10 years

Long-Lived Assets. Long-lived assets include tangible assets. Long-lived assets are reviewed for impairment whenever conditions indicate that the carrying value of the assets may not be fully recoverable. Such impairment tests are based on a comparison of the pretax undiscounted cash flows expected to be generated by the asset to the recorded value of the asset or other market-based value approaches. If impairment is indicated, the asset value is written down to its market value if readily determinable or its estimated fair value based on discounted cash flows. Any significant changes in business or market conditions that vary from current expectations could have an impact on the fair value of these assets and any potential associated impairment. Certain long-lived assets are amortized using the straight-line method over a five year useful life. Total amortization expense of long-lived assets for the year ended 31 December 2022 and 2021 was $391 and $0, respectively.

Advertising Expenses. The Group expenses the costs of advertising as incurred. Branded advertising expenses were immaterial for the years ended 31 December 2022 and 2021, respectively.

Use of Estimates. The preparation of consolidated financial statements in conformity with U.S. GAAP requires the Group to make estimates and assumptions that affect the reported amounts of assets and liabilities, including marketable securities and contingent liabilities at the date of the consolidated financial statements and the reported amounts of sales and expenses during the periods presented. These estimates and assumptions are based on the best information available to the Group at the balance sheet dates and depending on the nature of the estimate can require significant judgments. Changes to these estimates and judgments can have and have had a material impact on our consolidated profit and loss account and balance sheet. Actual results could differ from those estimates under different assumptions or conditions.

Lease Obligations. The Group determines if a contract is a lease at the inception of the arrangement. Right-of-use assets and operating lease liabilities are recognized at commencement date based on the present value of remaining lease payments over the lease term. For this purpose, the Group considers only payments that are fixed and determinable at the time of commencement. The Group reviews all options to extend, terminate, or purchase its right-of-use assets at the inception of the lease and will include these options in the lease term when they are reasonably certain of being exercised. Short term leases with an initial term of 12 months or less are not recorded on the balance sheet and the associated lease payments are recognized in the consolidated profit and loss account on a straight-line basis over the lease term. The Group's lease contracts do not provide a readily determinable implicit rate. The Group's estimated incremental borrowing rate is based on information

available at the inception of the lease. The Group's lease agreements may contain variable costs such as common area maintenance, insurance, real estate taxes or other costs. Variable lease costs are expensed as incurred on the consolidated profit and loss account.

Allowance for Credit Losses. Amounts owed to the Group are presented net of an allowance that includes as assessment of expected credit losses. An allowance for credit losses is established based on expected losses. Expected losses are estimated by reviewing individual accounts, considering aging, financial condition of the debtor, payment history, current and forecast economic conditions and other relevant factors. To the extent that the Group identifies that any individual customer's credit quality has deteriorated, the Group establishes allowances based on the individual risk characteristics of that customer. The Group makes concerted efforts to collect all outstanding balances due from customers; however, amounts are written off against the allowance when the related balances are no longer deemed collectible.

NOTE 3: Effect of New Accounting Standards

Previously Adopted Accounting Guidance

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. The FASB's amendments primarily impact ASC 740, Income Taxes, and may impact both interim and annual reporting periods. ASU 2019-12 is effective for fiscal years beginning after 15 December 2020, and interim periods within those fiscal years and early adoption is permitted. The Group adopted the provisions of ASU 2019-12 on 1 January 2021. Adoption of ASU 2019-12 did not have any impact on the Group's consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging- Contracts in Entity's Own Equity (Subtopic 815-40)*, to reduce the complexity associated with applying U.S. GAAP principles for certain financial instruments with characteristics of liabilities and equity. The amendments in this ASU reduce the number of accounting models for convertible instruments and expand the existing disclosure requirements over earnings per share as it relates to convertible instruments. Convertible debt will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The update also requires the if-converted method to be used for convertible instruments and the effect of potential share settlement be included in the diluted earnings per share calculation when an instrument may be settled in cash or shares. This ASU will be effective for the Group's fiscal year beginning 1 January 2022 and interim periods therein. Early adoption is permitted, but no earlier than fiscal years beginning after 15 December 2020. The amendments may be adopted through either a modified retrospective method, or a fully retrospective method.

The Group elected to early adopt ASU 2020-06 as of 1 January 2021 using a modified retrospective method. The Group's 4.50% exchangeable senior notes due 2023 (the "2023 Notes") are a convertible instrument with a cash-conversion feature that is accounted for within the scope of Subtopic 470-20. The Group calculated the cumulative-effect adjustment as of 1 January 2021 by comparing (i) the historical amortization schedule for the 2023 Notes through 31 December 2020 and (ii) an updated amortization schedule wherein the conversion feature within the 2023 Notes would not be separated as an equity component and subsequently recognized as non-cash interest expense under ASC 835-30. The adoption resulted in a $12,939 decrease in the profit and loss account and a $12,939 increase in long-term debt.

NOTE 4: Taxation Credit

The components of (loss) income before taxation for the years ended 31 December are as follows:

(Loss) Income on Ordinary Activities Before Taxation	2022	2021
Ireland	$ (53,717)	$ (36,631)
U.S.	(57,755)	(56,687)
France	33	173
Loss on ordinary activities before taxation	$ (111,439)	$ (93,145)

The taxation credit for the years ended 31 December are as follows:

Taxation Charge (Credit)	2022	2021
Current:		
U.S. - State	—	60
Total current	—	60
Deferred:		
U.S. - Federal	25,896	(15,876)
U.S. - State	129	0
Total deferred	26,025	(15,876)
Taxation charge (credit)	$ 26,025	$ (15,816)

The items accounting for the difference between the taxation charge computed at the jurisdiction of incorporation statutory rate and the Group's effective tax rate are as follows for the years ended 31 December:

Reconciliation to Effective Income Tax Rate:	2022	2021
Taxation charge (credit) - at statutory tax rate	$ (13,916)	$ (11,642)
Differences in international tax rates	(9,921)	(8,950)
Change in valuation allowances	48,734	4,296
Nondeductible share-based compensation	1,424	645
Unrecognized tax benefit	258	239
State and local taxes (net of federal)	(4,467)	60
Nondeductible interest expense	4,239	2,173
Orphan drug and R&D tax credit	—	(1,524)
Other	(326)	(1,113)
Taxation charge (credit) - at effective income tax rate	$ 26,025	$ (15,816)

In 2022, the income tax charge was $26,025, a change of $41,841 from income tax credit of $15,816. The change in the effective tax rate for the year ended 31 December 2022 is primarily driven by the valuation allowances recorded against our deferred tax assets during the period. The effective tax rate for 2021 was impacted by the geographic mix of earnings.

Unrecognized Tax Benefits

The Group or one of its subsidiaries files income tax returns in Ireland, France, U.S. and various states. The Group is no longer subject to Irish, French, U.S. Federal, and state and local examinations for years before 2018.

The following table summarizes the activity related to the Group's unrecognized tax benefits for the twelve months ended 31 December:

Unrecognized Tax Benefit Activity	2022	2021
Balance at January 1:	$ 3,143	$ 3,143
Settlements	—	—
Balance at December 31:	$ 3,143	$ 3,143

The Group expects that within the next twelve months the unrecognized tax benefits could decrease by an immaterial amount and the interest could increase by an immaterial amount.

At 31 December 2022 and 2021, there are $3,143 and $2,483 of unrecognized tax benefits that if recognized would affect the annual effective tax rate.

The Group recognizes interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the

years ended 31 December 2022 and 2021, the Group recognized approximately $258 and $239 in interest and penalties. The Group had approximately $2,103 and $1,777 for the payment of interest and penalties accrued at 31 December 2022 and 2021 respectively.

Deferred Tax Assets (Liabilities)

Deferred income tax provisions reflect the effect of temporary differences between consolidated financial statement and tax reporting of income and expense items. The net deferred tax assets (liabilities) at 31 December 2022 and 2021 resulted from the following temporary differences:

Net Deferred Tax Assets and Liabilities:	**2022**	**2021**
Deferred tax assets:		
Net operating loss carryforwards	$ 53,393	$ 34,399
Share-based compensation	4,684	4,108
Amortization	3,541	3,429
Orphan drug and R&D tax credit	4,964	4,964
Capitalized research costs	2,108	—
Other	1,521	662
Interest expense carryforward	1,216	1,591
Gross deferred tax assets	71,427	49,153
Deferred tax liabilities:		
Prepaid expenses	(86)	(75)
Other	—	(925)
Total deferred tax liabilities	(86)	(1,000)
Less: valuation allowance	(71,341)	(24,025)
Net deferred tax assets	$ —	$ 24,128

At 31 December 2022, the Group had $147,240 of net operating losses in Ireland that do not have an expiration date and $124,443 of net operating loss and $5,032 163(j) credits in the U.S. Of the $124,443 of net operating losses in the U.S., $10,365 were acquired due to the acquisition of FSC Therapeutics and FSC Laboratories, Inc., (collectively “FSC”) and $114,078 are due to the losses at US Holdings, of which $3,494 are state net operating losses. The portion due to the acquisition of FSC will expire in 2034 through 2035. A valuation allowance is recorded if, based on the weight of available evidence, it is more likely than not that a deferred tax asset will not be realized. This assessment is based on an evaluation of the level of historical taxable income and projections for future taxable income. For the year ended 31 December 2022, the Group recorded additional valuation allowances related to Irish current year net operating losses of $5,547. The U.S. net operating losses are subject to an annual limitation as a result of the FSC acquisition under Internal Revenue Code Section 382 and will not be fully utilized before they expire.

The Group’s cumulative loss position was significant negative evidence in assessing the need for a valuation allowance on its deferred tax assets in the U.S. Given the weight of objectively verifiable historical losses from operations, the Group recorded a full valuation allowance on its deferred tax assets. The Group will be able to reverse the valuation allowance when it has shown its ability to generate taxable income on a consistent basis in future periods. The valuation allowance does not have an impact on the Group's ability to utilize any net operating losses or other tax attributes to offset cash taxes payable as these items are still eligible to be used.

The Group recorded a valuation allowance against all of our net operating losses in Ireland, France and the U.S. as of 31 December 2022 and recorded a valuation allowance against all of its net operating losses in Ireland and France as of 31 December 2021. The Group intends to continue maintaining a full valuation allowance on the Irish and U.S. net operating losses until there is sufficient evidence to support the reversal of all or some portion of these allowances.

At 31 December 2022, the Group has unremitted earnings of $3,967 outside of Ireland as measured on a U.S. GAAP basis. Whereas the measure of earnings for purposes of taxation of a distribution may be different for tax purposes, these earnings,

which are considered to be invested indefinitely, would become subject to income tax if they were remitted as dividends or if the Group were to sell our stock in the subsidiaries, net of any prior income taxes paid. It is not practicable to estimate the amount of deferred tax liability on such earnings, if any.

R&D Tax Credits Receivable

The French and Irish governments provide tax credits to companies for spending on innovative R&D. These credits are recorded as an offset of R&D expenses and are credited against income taxes payable in years after being incurred or, if not so utilized, are recoverable in cash after a specified period of time, which may differ depending on the tax credit regime. As of 31 December 2022, the Group's net research tax credit receivable amounts to $3,480 and represents a French gross research tax credit of $2,912 and an Irish gross research tax credit of $568. As of 31 December 2021, the Group's net research tax credit receivable amounts to $3,668 and represents a French gross research tax credit of $3,139 and an Irish gross research tax credit of $529.

2020 CARES Act

The CARES Act, enacted on March 27, 2020, includes significant business tax provisions. In particular, the CARES Act modified the rules associated with net operating losses. Under the temporary provisions of the CARES Act, net operating loss carryforwards and carrybacks may offset 100% of taxable income for taxable years beginning before 2021. In addition, net operating losses arising in 2018, 2019 and 2020 taxable years may be carried back to each of the preceding five years to generate a refund. The Group filed refund claims for $18,753 associated with the carryback of 2019 tax losses and a $10,273 refund claim associated with the carryback of 2020 tax losses. During the year ended 31 December 2022, the Group collected all of the outstanding receivables due to the Group related to net operating loss carrybacks.

NOTE 5: Loss Per Ordinary Share

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding during each period. Diluted net loss per share is calculated by dividing net loss - diluted by the diluted number of shares outstanding during each period. Except where the result would be anti-dilutive to net loss, diluted net loss per share would be calculated assuming the impact of the conversion of the 2023 Notes, the conversion of the Group's preferred shares, the exercise of outstanding equity compensation awards, and ordinary shares expected to be issued under the Group's Employee Share Purchase Plan ("ESPP").

The Group has a choice to settle the conversion obligation under the 2023 Notes in cash, shares or any combination of the two. The Group utilizes the if-converted method to reflect the impact of the conversion of the 2023 Notes, unless the result is anti-dilutive. This method assumes the conversion of the 2023 Notes into shares of our ordinary shares and reflects the elimination of the interest expense related to the 2023 Notes.

The dilutive effect of the stock options, restricted stock units, preferred shares and ordinary shares expected to be issued under our ESPP has been calculated using the treasury stock method.

A reconciliation of basic and diluted net loss per share, together with the related shares outstanding in thousands for the years ended 31 December 2022 and 2021, is as follows:

Basic and Diluted Loss Per Share:	2022	2021
Loss per share numerator:		
Loss from ordinary operations attributable to common shareholders before allocation of earnings to participating securities	$ (137,464)	$ (77,329)
Less: earnings allocated to participating securities	—	—
Loss attributable to common shareholders, after allocation of earnings to participating securities	$ (137,464)	$ (77,329)
Loss per share denominator:		
Weighted-average shares outstanding - basic	60,094	58,535
Impact of dilutive securities	—	—
Weighted-average shares outstanding - dilute	60,094	58,535
Basic loss per share attributable to common shareholders:	$ (2.29)	$ (1.32)
Diluted loss per share attributable to common shareholders:	$ (2.29)	$ (1.32)

Potential common shares of 17,941 and 15,327 were excluded from the calculation of weighted average shares for the years ended 31 December 2022, and 2021, respectively, because either their effect was considered to be anti-dilutive or they were related to shares from performance share units awards ("PSUs") for which the contingent vesting condition had not been achieved. For the years ended 31 December 2022 and 2021, the effects of dilutive securities were entirely excluded from the calculation of net loss per share as a net loss was reported in these periods.

NOTE 6: Debtors

At the end of fiscal 2022 and 2021, debtors were comprised of:

	2022	2021
Debtors (amounts receivable within one year):		
Research and development tax credit receivable	$ 2,248	$ 2,443
Prepaid and other expenses	1,523	3,179
Guarantee from Armistice (see *Note 15: Contingent Liabilities and Commitments*)	276	279
Value-added tax recoverable	115	111
Other	113	160
Income tax receivable	69	29,097
Total	$ 4,344	$ 35,269
Debtors (amounts receivable after one year):		
Right of use assets at contract manufacturing organizations	$ 10,686	$ 8,549
Research and development tax credit receivable	1,232	1,225
Guarantee from Armistice (see *Note 15: Contingent Liabilities and Commitments*)	495	771
Other	141	329
Deferred tax assets (*see Note 4: Taxation Credit)*	—	24,128
Total	$ 12,554	$ 35,002
Total	$ 16,898	$ 70,271

NOTE 7: Investments

The Group had investments in available-for-sale debt securities that are recorded at fair market value. The change in the fair value of available-for-sale debt investments is recorded in the Profit and Loss Account in shareholders' (deficit) equity, net of income tax effects. As of 31 December 2022, the Group considered any decreases in fair value on our marketable securities to be driven by factors other than credit risk, including market risk.

The following tables show the Group's available-for-sale securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category as of 31 December 2022 and 2021, respectively:

	2022			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Money market and mutual funds	$ 24,407	$ —	$ (1,889)	$ 22,518
Total	$ 24,407	$ —	$ (1,889)	$ 22,518

	2021			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Money market and mutual funds	$ 78,331	$ 813	$ (1,046)	$ 78,098
Corporate bonds	16,478	94	(93)	16,479
Government securities - U.S.	9,530	39	(98)	9,471
Other fixed-income securities	2,473	2	(10)	2,465
Total	$ 106,812	$ 948	$ (1,247)	$ 106,513

The Group determines realized gains or losses on the sale of marketable securities on a specific identification method. The Group reflects these gains and losses as a component of interest income in the accompanying consolidated profit and loss account.

The Group recognized gross realized gains of $584 and $174 for the twelve months ended 31 December 2022 and 2021, respectively. These realized gains were offset by realized losses of $2,338 and $275 for the twelve-months ended 31 December 2022 and 2021, respectively.

The Group has classified its investment in available-for-sale marketable securities as current assets in the consolidated balance sheets at 31 December 2022 and 2021, respectively, as the securities need to be available for use, if required, to fund current operations. There are no restrictions on the sale of any securities in the Group's investment portfolio.

Total gross unrealized losses of our marketable securities at 31 December 2022 have been driven by factors other than credit risk. The Group does not intend to sell the investments and it is not more likely than not that it will be required to sell the investments before recovery of their amortized cost bases.

NOTE 8: Tangible Assets

Tangible asset activity for fiscal year 2022 and 2021 was as follows:

	Office and Computer Equipment	Furniture, Fixtures, and Fittings	Operating lease right-of-use assets	Total Tangible Assets
Cost:				
At 31 December 2020	$ 1,443	$ 300	$ 4,117	$ 5,860
Additions	24	2	763	789
Disposals	(980)	—	—	(980)
Currency translation and other	(39)	—	—	(39)
At 31 December 2021	$ 448	$ 302	$ 4,880	$ 5,630
Additions	384	332	—	716
Disposals	—	—	—	—
Currency translation and other	—	—	—	—
At 31 December 2022	$ 832	$ 634	$ 4,880	$ 6,346
Depreciation:				
At 31 December 2020	$ (1,211)	$ (173)	$ (1,513)	$ (2,897)
Depreciation expense	(65)	(32)	(715)	(812)
Disposal of tangible assets	980	—	—	980
Currency translation and other	36	—	—	36
At 31 December 2021	$ (260)	$ (205)	$ (2,228)	$ (2,693)
Depreciation expense	(109)	(54)	(938)	(1,101)
Disposal of tangible assets	—	—	—	—
Currency translation and other	—	—	—	—
At 31 December 2022	$ (369)	$ (259)	$ (3,166)	$ (3,794)
Net Book Value				
At 31 December 2021	$ 188	$ 97	$ 2,652	$ 2,937
At 31 December 2022	$ 463	$ 375	$ 1,714	$ 2,552

Gain or loss on disposal of tangible assets was immaterial in both fiscal 2022 and 2021.

NOTE 9: Goodwill and Intangible Assets

The Group's goodwill is $16,836 at 31 December 2022 and 2021.

No impairment loss related to goodwill was recognized during the years ended 31 December 2022 or 2021.

NOTE 10: Creditors (amounts falling due within one year)

At the end of fiscal 2022 and 2021, creditors (amounts falling due within one year) were comprised of:

Creditors (amounts falling due within one year):	**2022**	**2021**
Debt (*Note 13: Long-Term Debt*)	$ 37,668	$ —
Trade creditors	7,890	7,679
Other	5,704	7,668
Accrued compensation	1,613	3,167
Accrued outsourced contract manufacturing costs	1,208	1,048
Current portion of operating lease liability	960	900
Accrued restructuring *(see Note 24)*	473	41
Customer allowances	—	217
Total	$ 55,516	$ 20,720

NOTE 11: Creditors (amounts falling due after more than a year)

At the end of fiscal 2022 and 2021, creditors (amounts falling due after more than a year) were comprised of:

Creditors (amounts falling after more than a year):	2022	2021
Debt (*Note 13: Long-Term Debt*)	91,614	142,397
Long-term operating lease liability	$ 780	$ 1,707
Total	$ 92,394	$ 144,104

NOTE 12: Provisions for Liabilities

	Unrecognized Tax Benefits (Note 4)	Guarantee to Deerfield (Note 15)	Provision for Liabilities
At 31 December 2020	$ 3,143	$ 1,372	$ 4,515
Additions during the year	—	—	—
Amounts charged against the provision	—	(318)	(318)
Changes in the fair value	—	—	—
At 31 December 2021	$ 3,143	$ 1,054	$ 4,197
Additions during the year	$ —	$ —	—
Amounts charged against the provision	2,103	(280)	1,823
Changes in the fair value	—	—	—
At 31 December 2022	$ 5,246	$ 774	$ 6,020

NOTE 13: Long-Term Debt

Long-term debt is summarized as follows:

	31 December	
	2022	2021
Principal amount of 4.50% exchangeable senior notes due February 2023	$ 17,500	$ 143,750
Principal amount of 4.50% exchangeable senior notes due October 2023	117,375	—
Less: unamortized debt discount and issuance costs, net	(5,593)	(1,353)
Net carrying amount of liability component	129,282	142,397
Less: current maturities	37,668	—
Long-term debt	$ 91,614	$ 142,397

For the years ended 31 December 2022 and 2021, the total interest expense was $12,342, and $9,942, respectively, with coupon interest expense of $6,405 and $6,469 for each period, respectively, and the amortization of debt issuance costs and debt discount of $6,052 and $1,248 for each period, respectively.

On 4 November 2022, the Group repurchased $8,875 of its February 2023 Notes for $8,653 of cash consideration through an open market purchase. The Group recorded a $203 net gain on the early extinguishment that is included as a reduction to current period interest expense.

For the years ended 31 December 2022 and 2021, interest expense also included $88 and $2,225, respectively, of additional interest expense owed as a result of not removing a restrictive legend from the 2023 Notes 365 days following original issuance of the 2023 Notes on 16 February 2018. The additional interest was paid to the trustee on 10 March 2022. Additionally, on 14 March 2022, the restrictive legend on the 2023 Notes was removed and the Group is not subject to any additional interest after that date. This interest will not be applicable to future periods.

On 16 February 2018, Avadel Finance Cayman Limited, a Cayman Islands exempted company (the “Issuer”) and an indirect wholly-owned subsidiary of the Company, issued $125,000 aggregate principal amount of its February 2023 Notes in a private placement (the “Offering”) to qualified institutional buyers pursuant to Rule 144A under the Securities Act. In connection with

the Offering, the Issuer granted the initial purchasers of the February 2023 Notes a 30-day option to purchase up to an additional $18,750 aggregate principal amount of the February 2023 Notes, which was fully exercised on 16 February 2018. Net proceeds received by the Group, after issuance costs and discounts, were approximately $137,560. The February 2023 Notes are the Group's senior unsecured obligations and rank equally in right of payment with all of the Group's existing and future senior unsecured indebtedness and effectively junior to any of the Group's existing and future secured indebtedness, to the extent of the value of the assets securing such indebtedness.

On 5 April 2022, the Issuer completed the exchange of $117,375 of its February 2023 Notes for a new series of its October 2023 Notes (the "Exchange Transaction"). The remaining $26,375 aggregate principal amount of the February 2023 Notes were not exchanged and maintained a maturity date of 1 February 2023. On 4 November 2022, the Company repurchased $8,875 of its February 2023 Notes and on the maturity date of 1 February 2023, the Group repaid, with cash on hand, the remaining $17,500 aggregate principal amount of its February 2023 Notes.

The Group accounted for the October 2023 Notes as a modification to the February 2023 Notes. The Group paid $4,804 in fees to note holders of the October 2023 Notes that are amortized over the remaining term of the October 2023 Notes. The Group paid approximately $5,450 in fees to third parties that were expensed as part of the completed Exchange Transaction. Additionally, the fair value of the unseparated, embedded conversion feature increased by $5,508, which reduced the carrying amount of the convertible debt instrument as an unamortized debt discount, with a corresponding increase in additional paid-in capital. The $5,508 are amortized over the remaining term of the October 2023 Notes as a component of interest expense.

On 29 March 2023, the Group executed an agreement to exchange $96,188 of its $117,375 October 2023 Notes for a new series of 6.0% exchangeable notes due April 2027 (the "April 2027 Notes") (the "2023 Exchange Transaction"). The remaining $21,187 aggregate principal amount of the October 2023 Notes will maintain a maturity date of 2 October 2023. Due to the 2023 Exchange Transaction, the $96,188 principal amount of the October 2023 Notes is classified as long-term debt, net of unamortized debt discount and issuance costs, as of 31 December 2022.

The 2023 Notes are exchangeable at the option of the holders at an initial exchange rate of 92.6956 ADSs per $1 principal amount of 2023 Notes, which is equivalent to an initial exchange price of approximately $10.79 per ADS. Such initial exchange price represents a premium of approximately 20% to the $8.99 per ADS closing price on The Nasdaq Global Market on 13 February 2018. Upon the exchange of any 2023 Notes, the Issuer will pay or cause to be delivered, as the case may be, cash, ADSs or a combination of cash and ADSs, at the Issuer's election.

October 2023 Notes

Holders of the October 2023 Notes may convert their October 2023 Notes, at their option, only under the following circumstances prior to the close of business on the business day immediately preceding 1 May 2023, under the circumstances and during the periods set forth below and regardless of the conditions described below, on or after 1 May 2023 and prior to the close of business on the business day immediately preceding the maturity date:

- Prior to the close of business on the business day immediately preceding 1 May 2023, a holder of the October 2023 Notes may surrender all or any portion of its October 2023 Notes for exchange at any time during the five business day period immediately after any five consecutive trading day period (the "Measurement Period") in which the trading price per $1 principal amount of October 2023 Notes, as determined following a request by a holder of the October 2023 Notes, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the ADSs and the exchange rate on each such trading day.

- If a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs prior to the close of business on the business day immediately preceding 1 May 2023, regardless of whether a holder of the October 2023 Notes has the right to require the Group to repurchase the October 2023 Notes, or if Avadel is a party to a merger event that occurs prior to the close of business on the business day immediately preceding 1 May 2023, all or any portion of the holder's October 2023 Notes may be surrendered for exchange at any time from or after the date that is 95 scheduled trading days prior to the anticipated effective date of the transaction (or, if later, the earlier of (x) the business day after the Group gives notice of such transaction and (y) the actual effective date of such transaction) until 35 trading days after the actual effective date of such transaction or, if such transaction also constitutes a fundamental change, until the related fundamental change repurchase date.

- Prior to the close of business on the business day immediately preceding 1 May 2023, a holder of the October 2023 Notes may surrender all or any portion of its October 2023 Notes for exchange at any time during any calendar quarter commencing after the calendar quarter ending on 31 March 2022 (and only during such calendar quarter), if the last

reported sale price of the ADSs for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the exchange price on each applicable trading day.

- If the Group calls the October 2023 Notes for redemption pursuant to Article 16 to the Indenture prior to the close of business on the business day immediately preceding 1 May 2023, then a holder of the October 2023 Notes may surrender all or any portion of its October 2023 Notes for exchange at any time prior to the close of business on the second business day prior to the redemption date, even if the October 2023 Notes are not otherwise exchangeable at such time. After that time, the right to exchange shall expire, unless the Group defaults in the payment of the redemption price, in which case a holder of the October 2023 Notes may exchange its October 2023 Notes until the redemption price has been paid or duly provided for.

The Group, at its option, may redeem for cash all of the October 2023 Notes if the last reported sale price (as defined by the indenture) of the ADSs has been at least 130% of the Exchange Price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending on, and including, the trading day immediately preceding the date on which the Company provides notice to redeem the October 2023 Notes.

The Group considered the guidance in ASC 815-15, *Embedded Derivatives*, to determine if this instrument contains an embedded feature that should be separately accounted for as a derivative. ASC 815 provides for an exception to this rule when convertible notes, as host instruments, are deemed to be conventional, as defined by ASC 815-40. The Group determined that this exception applies due, in part, to our ability to settle the 2023 Notes in cash, ADSs or a combination of cash and ADSs, at our option. The Group has therefore applied the guidance provided by ASC 470-20, *Debt with Conversion and Other Options,* as amended by ASU 2020-06.

NOTE 14: Called-up Share Capital and Reserves

Called-up Share Capital

Upon exercise of stock options, or upon the issuance of free share awards, the Group issues new shares.

(In thousands, except per share data)	2022	2021
Authorised:		
25 deferred ordinary shares of €1.00 each at 31 December 2022 and 2021	$ 26	$ 26
500,000 ordinary shares of $0.01 each at 31 December 2022 and 2021	5,000	5,000
50,000 preferred shares of $0.01 each at 31 December 2022 and 2021	500	500
Allotted, Called Up and Fully Paid:		
25 deferred ordinary shares of €1.00 each at 31 December 2022 and 2021	$ 26	$ 26
62,878 and 58,620 ordinary shares of $0.01 each at 31 December 2022 and 2021, respectively	628	586
488 preferred shares of $0.01 at 31 December 2022 and 2021	5	5
Called up share capital presented as equity	$ 659	$ 617

The Board of Directors is authorized to issue preferred stock in series, and with respect to each series, to fix its designation, relative rights (including voting, dividend, conversion, sinking fund, and redemption rights), preferences (including dividends and liquidation) and limitations. We have 50,000 shares of authorized preferred shares, $0.01 nominal value, of which 488 are currently issued and outstanding as of 31 December 2022.

Shelf Registration Statement on Form S-3

In February 2020, the Company filed with the SEC a new shelf registration statement on Form S-3 (the "2020 Shelf Registration Statement") (File No. 333-236258) that allows issuance and sale by the Company, from time to time, of:

a. up to $250,000 in aggregate of ordinary shares, nominal value US$0.01 per share (the "Ordinary Shares"), each of which may be represented by American Depositary Shares ("ADSs"), preferred shares, nominal value US$0.01 per share (the "Preferred Shares"), debt securities (the "Debt Securities"), warrants to purchase Ordinary Shares, ADSs,

Preferred Shares and/or Debt Securities (the "Warrants"), and/or units consisting of Ordinary Shares, ADSs, Preferred Shares, one or more Debt Securities or Warrants in one or more series, in any combination, pursuant to the terms of the 2020 Shelf Registration Statement, the base prospectus contained in the 2020 Shelf Registration Statement (the "2020 Base Prospectus"), and any amendments or supplements thereto; including

b. up to $50,000 of ADSs that may be issued and sold from time to time pursuant to the terms of an Open Market Sale Agreement[SM], entered into with Jefferies LLC ("Jefferies") on 4 February 2020 (the "Sales Agreement"), the 2020 Shelf Registration Statement, the 2020 Base Prospectus and the terms of the sales agreement prospectus contained in the 2020 Shelf Registration Statement. The Company agreed to pay Jefferies a commission up to 3.0% of the aggregate gross sales proceeds of such ADSs.

As of 31 December 2022, the Company had issued and sold 3,588 ADSs, resulting in net proceeds to the Company of approximately $25,318, pursuant to the Sales Agreement.

The transaction costs associated with the 2020 Shelf Registration Statement totaled $428, of which $169 remain recorded within prepaid expenses and other current assets at 31 December 2022.

In August 2022, the Company filed with the SEC a new shelf registration statement on Form S-3 (the "2022 Shelf Registration Statement") (File No. 333-267198) that allows issuance and sale by the Company, from time to time, of:

a. up to $500,000 in aggregate of Ordinary Shares, each of which may be represented by ADSs, Preferred Shares, Debt Securities, Warrants, and/or units consisting of Ordinary Shares, ADSs, Preferred Shares, one or more Debt Securities or Warrants in one or more series, in any combination, pursuant to the terms of the 2022 Shelf Registration Statement, the base prospectus contained in the 2022 Shelf Registration Statement (the "2022 Base Prospectus"), and any amendments or supplements thereto; including

b. up to $100,000 of ADSs that may be issued and sold from time to time pursuant to the Sales Agreement, the 2022 Shelf Registration Statement, the 2022 Base Prospectus and the terms of the sales agreement prospectus contained in the 2022 Shelf Registration Statement.

At 31 December 2022, the Company had up to $123,899 of ADSs available for sale under the ATM Program pursuant to the Sales Agreement.

The transactions costs associated with the 2022 Shelf Registration Statement totaled $192, which are recorded within prepaid expenses and other current assets at 31 December 2022.

February 2020 Private Placement

On 21 February 2020, the Group announced that we entered into a definitive agreement for the sale of its ADSs and Series A Non-Voting Convertible Preferred Shares ("Series A Preferred") in a private placement to a group of institutional accredited investors. The private placement resulted in gross proceeds of approximately $65,000 before deducting placement agent and other offering expenses, which resulted in net proceeds of $60,570.

Pursuant to the terms of the private placement, the Group issued 8,680 ADSs and 488 shares of Series A Preferred at a price of $7.09 per share, priced at-the-market under Nasdaq rules. Each share of non-voting Series A Preferred is convertible into one ADS, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.99% of the total number of Avadel ADSs outstanding. The closing of the private placement occurred on 25 February 2020.

Issuance costs of $4,430 have been recorded as a reduction of Other Reserves.

May 2020 Public Offering

In connection with the shelf registration statement described above, on 28 April 2020, the Group announced the pricing of an underwritten public offering of 11,630 Ordinary Shares, in the form of ADSs at a price to the public of $10.75 per ADS. Each ADS represents the right to receive one Ordinary Share. All of the ADSs were offered by the Group and the gross proceeds to the Group from the offering were approximately $125,000, before deducting underwriting discounts and commissions and offering expenses, which resulted in net proceeds of $116,924. The offering closed on 1 May 2020.

Issuance costs of $8,098 have been recorded as a reduction of Other Reserves.

Called-up Share Capital - Ordinary

In fiscal 2022, the change in ordinary shares of $42 is the result of the issuance of $36 from the sale of shares through the at-the-market offering program, exercise of stock options of $4, vesting of restricted shares of $1, and issuance of shares through the employee share purchase plan of $1. In fiscal 2021, the change in ordinary shares of $3 is a result of the vesting of restricted shares of $2 and the exercise of stock options of $1.

Share Premium Account

In fiscal 2022, the share premium account increased due to common stock under at-the-market offering program issuance of $25,282, the exercise of stock options of $2,456 and employee share purchase plan issuance of $221.

Other Reserves

In fiscal 2022, other reserves increased, driven by the issuance of $7,013 of share-based compensation and $5,508 change in fair value of the October 2023 Notes conversion feature, partially offset by amortization of deferred issuance costs of $45 and the vesting of restricted shares of $1.

Profit and Loss Account

In fiscal 2022, the profit and loss account activity was driven by the 2022 net loss of $137,464 and the change in other comprehensive loss of $2,401.

NOTE 14.1: Equity Instruments and Stock Based Compensation

Compensation expense included in the consolidated profit and loss account for all share-based compensation arrangements was as follows for the periods ended 31 December:

Share-based Compensation Expense:	2022	2021
Research and development	$ 169	$ 758
Distribution and administrative	6,844	8,114
Total share-based compensation expense	$ 7,013	$ 8,872

As of 31 December 2022, the Group expects $9,040 of unrecognized expense related to granted, but non-vested share-based compensation arrangements to be incurred in future periods. This expense is expected to be recognized over a weighted average period of 2.54 years.

In 2022, the Group granted options with performance conditions to employees of which 50% vest upon the achievement of certain commercial milestones related to LUMRYZ and the other 50% vest one year following achievement of those milestones (“2022 Performance Options”). At 31 December 2022, achievement of these milestones was not considered probable and the Group has not yet recognized any share-based compensation on the 2022 Performance Options. In the event the performance conditions are met, $8,027 of share-based compensation expense is expected to be recognized.

The excess tax benefit related to share-based compensation recorded by the Group was immaterial for the years ended 31 December 2022 and 2021.

Upon exercise of stock options, or upon the issuance of restricted share awards or performance share unit awards, the Group issues new shares.

At 31 December 2022, there were 752 shares authorized for stock option grants, restricted share award grants, and performance share unit award grants in subsequent periods.

Inducement Plan

In November 2021, the Board of Directors approved the Avadel Pharmaceuticals plc 2021 Inducement Plan (the “Inducement Plan”), which allows the Group to grant equity awards to induce highly-qualified prospective officers and employees who are not currently employed by the Group to accept employment and provide them with a proprietary interest in the Group. The

maximum number of shares reserved and available for issuance under the Plan is 1,500 shares. As of December 31, 2022, the Company had 1,278 shares available for issuance under this Inducement Plan in subsequent periods.

Determining the Fair Value of Stock Options and Warrants

The Group measures the total fair value of stock options on the grant date using the Black-Scholes option-pricing model and recognizes each grant's fair value as compensation expense over the period that the option vests. Other than the 2022 Performance Options described above, options are granted to employees of the Group and become exercisable ratably over four years following the grant date and expire ten years after the grant date. Prior to 2021, the Group issued stock options to its Board of Directors as compensation for services rendered that are exercisable ratably over three years following the grant date, and expire ten years after the grant date. Beginning in 2021, the Group issued stock options to its Board of Directors as compensation for services rendered and are exercisable one year following the grant date and expire ten years after the grant date.

The weighted-average assumptions under the Black-Scholes option-pricing model for stock option grants as of 31 December 2022 and 2021, are as follows:

Stock Option Assumptions:	**2022**	**2021**
Stock option grants:		
Expected term (years)	6.09	6.20
Expected volatility	93.41 %	73.91 %
Risk-free interest rate	2.73 %	1.10 %
Expected dividend yield	—	—

Expected term: The expected term of the options represents the period of time between the grant date and the time the options are either exercised or forfeited, including an estimate of future forfeitures for outstanding options. Given the limited historical data, the simplified method has been used to calculate the expected life.

Expected volatility: The expected volatility is calculated based on an average of the historical volatility of the Group's stock price for a period approximating the expected term.

Risk-free interest rate: The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant and a maturity that approximates the expected term.

Expected dividend yield: The Group has not distributed any dividends since our inception, and has no plan to distribute dividends in the foreseeable future.

Stock Options

A summary of the combined stock option activity and other data for the Group's stock option plans for the year ended 31 December 2022 is as follows:

Stock Option Activity and Other Data:	**Number of Stock Options**	**Weighted Average Exercise Price per Share**	**Weighted Average Remaining Contractual Life**	**Aggregate Intrinsic Value**
Stock options outstanding, 1 January 2022	8,403	$ 7.39		
Granted	3,268	5.29		
Exercised	(450)	5.46		
Forfeited	(1,496)	7.24		
Expired	(421)	9.65		
Stock options outstanding, 31 December 2022	9,304	$ 6.67	7.78 years	$ 8,710
Stock options exercisable, 31 December 2022	4,059	$ 7.40	6.33 years	$ 6,859

A summary of the combined stock option activity and other data for the Group's stock option plans for the year ended 31 December 2021 is as follows:

Stock Option Activity and Other Data:	Number of Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Stock options outstanding, 1 January 2021	5,898	$ 7.02		$ —
Granted	2,857	8.20		
Exercised	(48)	3.54		
Forfeited	(234)	7.13		
Expired	(70)	12.62		
Stock options outstanding, 31 December 2021	8,403	$ 7.39	7.83 years	$ 12,204
Stock options exercisable, 31 December 2021	3,256	$ 7.88	5.88 years	$ 6,291

The aggregate intrinsic value of options exercised during the years ended 31 December 2022 and 2021 was $877 and $249, respectively.

The weighted average grant date fair value of options granted during the years ended 31 December 2022 and 2021 was $4.02 and $5.36 per share, respectively.

Restricted Share Awards

Restricted share awards represent Group shares issued free of charge to employees of the Group as compensation for services rendered. The Group measures the total fair value of restricted share awards on the grant date using the Group's stock price at the time of the grant. Restricted share awards granted from 2017-2020 vest over a three-year period; two-thirds (2/3) vesting on the second anniversary of the grant date and the remaining one-third (1/3) vesting on the third anniversary of the grant date. In 2021, restricted share awards granted to employees vest over a four-year period; one-fourth (1/4) on each anniversary of the grant date. In 2018, the Group issued restricted share awards to our Board of Directors vesting over a three-year period; one-third (1/3) vesting on each of the three anniversaries of the grant date. Compensation expense for such awards granted during and after 2017 is recognized over the applicable vesting period.

A summary of the Group's restricted share awards as of 31 December 2022, and changes during the year then ended, is reflected in the table below.

Restricted Share Activity and Other Data:	Number of Restricted Share Awards	Weighted Average Grant Date Fair Value
Non-vested restricted share awards outstanding, 1 January 2022	274	$ 7.14
Granted	—	—
Vested	(144)	6.37
Forfeited	(74)	8.04
Non-vested restricted shares awards outstanding, 31 December 2022	56	$ 7.95

A summary of the Group's restricted share awards as of 31 December 2021, and changes during the year then ended, is reflected in the table below.

Restricted Share Activity and Other Data:	Number of Restricted Share Awards	Weighted Average Grant Date Fair Value
Non-vested restricted share awards outstanding, 1 January 2021	347	$ 5.87
Granted	99	8.22
Vested	(160)	5.05
Forfeited	(12)	7.08
Non-vested restricted shares awards outstanding, 31 December 2021	274	$ 7.14

No restricted share awards were granted during the year ended 31 December 2022. The weighted average grant date fair value of restricted share awards granted during the year ended 31 December 2021 was $8.22 per share.

Performance Share Units Awards

PSUs represent Group shares issued free of charge to employees of the Group as compensation for achieving various results. The Group measures the total fair value of performance share unit awards on the grant date using the Group's stock price at the time of the grant. In 2020, the Group granted performance share awards, of which 50% vest upon the achievement of certain regulatory milestones related to LUMRYZ and the other 50% vest one year following achievement of those milestones ("2020 PSU awards"). The regulatory milestones were not met and the 2020 PSU awards were forfeited in 2022. The Company did not recognize any share-based compensation expense related to the 2020 PSU awards as of 31 December 2022.

In 2021, the Group granted performance share awards of which 50% vest upon achievement of certain corporate objectives and the second 50% vests one year following achievement of those objectives ("2021 PSU awards"). The objectives of the 2021 PSU awards were not met and the 2021 PSU awards were forfeited in 2022. The Company did not recognize any share-based compensation expense related to the 2021 PSU awards as of 31 December 2022.

A summary of the Group's performance share units awards as of 31 December 2022, and changes during the year then ended, is reflected in the table below.

Performance Unit Share Activity and Other Data:	Number of Performance Unit Share Awards	Weighted Average Grant Date Fair Value
Non-vested performance share awards outstanding, 1 January 2022	535	$ 7.71
Granted	—	—
Vested	—	—
Forfeited	(535)	7.71
Non-vested performance shares awards outstanding, 31 December 2022	—	$ —

A summary of the Group's performance share units awards as of 31 December 2021, and changes during the year then ended, is reflected in the table below.

Performance Unit Share Activity and Other Data:	Number of Performance Unit Share Awards	Weighted Average Grant Date Fair Value
Non-vested performance share awards outstanding, 1 January 2021	257	$ 7.09
Granted	285	8.20
Vested	—	—
Forfeited	(7)	5.36
Non-vested performance shares awards outstanding, 31 December 2021	535	$ 7.71

There were no performance share awards granted during the year ended 31 December 2022. The weighted average grant date fair value of performance share awards granted during the years ended 31 December 2021 was $8.20 per share.

Employee Share Purchase Plan

In 2017, the Board of Directors approved the Avadel Pharmaceuticals plc 2017 Avadel Employee Share Purchase Plan ("ESPP"). The total number of Company ordinary shares, nominal value $0.01 per share, or ADSs representing such ordinary shares (collectively, "Shares") which may be issued under the ESPP is 1,000. The purchase price at which a share will be issued or sold for a given offering period will be established by the Compensation Committee of the Board ("Committee") (and may differ among participants, as determined by the Committee in its sole discretion) but will in no event be less than 85% of the lesser of: (a) the fair market value of a Share on the offering date; or (b) the fair market value of a Share on the purchase date. During the years ended 31 December 2022 and 2021, the Group issued 75 and 17 ordinary shares to employees, respectively. Expense related to the ESPP for the years ended 31 December 2022 and 2021 was immaterial.

NOTE 15: Contingent Liabilities and Commitments

Litigation

The Group is subject to potential liabilities generally incidental to our business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Group accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At 31 December 2022 and 31 December 2021, there were no contingent liabilities with respect to any litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Group's consolidated financial position, results of operations, cash flows or liquidity.

First Jazz Complaint

On 12 May 2021, Jazz Pharmaceuticals, Inc. ("Jazz") filed a formal complaint (the "First Complaint") initiating a lawsuit in the United States District Court for the District of Delaware (the "Court") against Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Management Corporation, Avadel Legacy Pharmaceuticals, LLC, Avadel Specialty Pharmaceuticals, LLC, and Avadel CNS Pharmaceuticals, LLC (collectively, the "Avadel Parties"). In the First Complaint, Jazz alleges the sodium oxybate product ("Proposed Product") described in the NDA owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 8731963, 10758488, 10813885, 10959956 and/or 10966931 (collectively, the "patents-in-suit"). The First Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses.

On 3 June 2021, the Avadel Parties timely filed their Answer and Counterclaims (the "Avadel Answer") with the Court in response to the First Complaint. The Avadel Answer generally denies the allegations set forth in the First Complaint, includes numerous affirmative defenses (including, but not limited to, non-infringement and invalidity of the patents-in-suit), and asserts a number of counterclaims seeking i) a declaratory judgment of non-infringement of each patent-in-suit, and ii) a declaratory judgment of invalidity of each patent-in-suit.

On 18 June 2021, Jazz filed its Answer ("Jazz Answer") with the Court in response to the Avadel Answer. The Jazz Answer generally denies the allegations set forth in the Avadel Answer and sets forth a single affirmative defense asserting that Avadel has failed to state a claim for which relief can be granted.

On 21 June 2021, the Court issued an oral order requiring the parties to i) confer regarding proposed dates to be included in the Court's scheduling order for the case, and ii) submit a proposed order, including a proposal for the length and timing of trial, to the Court by no later than 21 July 2021.

On 30 July 2021, the Court issued a scheduling order establishing timing for litigation events including i) a claim construction hearing date of 2 August 2022, and ii) a trial date of 30 October 2023.

On 18 October 2021, consistent with the scheduling order, Jazz filed a status update with the Court indicating that Jazz did not intend to file a preliminary injunction with the Court at this time. Jazz further indicated that it would provide the Court with an update regarding whether preliminary injunction proceedings may be necessary after receiving further information regarding the FDA's action on Avadel's NDA.

On 4 January 2022, the Court entered an agreed order dismissing this case with respect to Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, and Avadel Management Corporation. A corresponding order was entered in the two below cases on the same day.

On 25 February 2022, Jazz filed an amended Answer to Avadel's Counterclaims ("the Jazz First Amended Answer"). The Jazz First Amended Answer is substantially similar to the Jazz Answer except insofar as it adds an affirmative defense for judicial estoppel and unclean hands. Corresponding amended Answers were filed in the two below cases on the same day.

On 23 June 2022, Avadel CNS filed a Renewed Motion for Judgment on the Pleadings, with respect to its counterclaim against Jazz seeking to have U.S. Patent No. 8731963 (the "REMS Patent") delisted from the Orange Book and seeking to have the motion resolved concurrent with the parties' *Markman* hearing on 31 August 2022. On 7 July 2022, Jazz filed a response it styled as Objections to Avadel CNS' Motion for Judgment on the Pleadings. On 14 July 2022, Avadel CNS replied to Jazz's response, and on 21 July 2022, Avadel CNS requested oral argument on its delisting motion simultaneous with the *Markman* hearing. On 24 August 2022, the Court ordered Jazz to respond substantively to Avadel CNS' motion, which Jazz did on 26 August 2022. Avadel CNS filed its reply on 28 August 2022.

On 23 August 2022, the *Markman* hearing was postponed. On 7 September 2022, the case was reassigned to a new judge, and the *Markman* hearing was held on 25 October 2022. At the *Markman* hearing, Avadel CNS reiterated its request for an expedited hearing on the Renewed Motion for Judgment on the Pleadings for the delisting of the REMS Patent. On 28 October 2022, the Court granted Avadel CNS' request and scheduled the hearing for 15 November 2022.

The Court held the *Markman* hearing on 15 November 2022 and issued a claim construction ruling on 18 November 2022. Also on 18 November 2022 the Court granted Avadel's Renewed Motion for Judgment on the Pleadings and ordered Jazz to request delisting of the REMS Patent from the Orange Book. On 22 November 2022, Jazz appealed that decision and on 14 December 2022, the Federal Circuit issued a stay of the delisting order until further notice. Oral argument was held 14 February 2023. On 24 February 2023, the United States Court of Appeals for the Federal Court affirmed the previous ruling from the Court, ordering the delisting of the REMS Patent from the Orange Book, which has since occurred. On 7 March 2023, in response to a joint stipulation filed by the parties, the Court issued an order dismissing Jazz's infringement claims against the Avadel Parties relating to the REMS Patent as well as Avadel Parties' noninfringement and invalidity counterclaims relating to the REMS Patent.

Second Jazz Complaint

On 4 August 2021, Jazz filed another formal complaint (the "Second Complaint") initiating a lawsuit in the Court against the Avadel Parties. In the Second Complaint, Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 11077079. The Second Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses.

On 9 September 2021, the Avadel Parties timely filed their Answer and Counterclaims (the "Second Avadel Answer") with the Court in response to the Second Complaint. The Second Avadel Answer generally denies the allegations set forth in the Second Complaint, includes numerous affirmative defenses (including, but not limited to, non-infringement and invalidity of the patent-in-suit), and asserts a number of counterclaims seeking i) a declaratory judgment of non-infringement of the patent-in-suit, and ii) a declaratory judgment of invalidity of the patent-in-suit.

On 22 October 2021, the Court issued an oral order stating that this case should proceed on the same schedule as the case filed on 12 May 2021.

On 7 September 2022, the case was reassigned to a new judge.

Third Jazz Complaint

On 10 November 2021, Jazz filed another formal complaint (the "Third Complaint") initiating a lawsuit in the Court against the Avadel Parties. In the Third Complaint, Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 11147782. The Third Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses. This case will proceed on the same schedule as the cases associated with the First and Second Complaints above.

On 21 December 2021, the Court entered a revised schedule for the First, Second and Third Complaints, setting a new claim construction date of 31 August 2022.

On 7 January 2022, Avadel CNS Pharmaceuticals LLC timely filed its Answer and Counterclaims (the "Third Avadel Answer") with the Court in response to the Third Complaint. The Third Avadel Answer generally denies the allegations set forth in the Third Complaint, includes numerous affirmative defenses (including, but not limited to, non-infringement and invalidity of the patent-in-suit), and asserts a number of counterclaims seeking i) a declaratory judgment of non-infringement of the patent-in-suit, and ii) a declaratory judgment of invalidity/unenforceability of the patent-in-suit.

On 7 September 2022, the case was reassigned to a new judge.

Fourth Jazz Complaint

On 15 July 2022, Jazz filed another formal complaint (the "Fourth Complaint") initiating a lawsuit in the Court against Avadel CNS. In the Fourth Complaint, Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS will infringe at least one claim of the REMS Patent, which was asserted in the First Complaint. The FDA required Avadel CNS to file a Paragraph IV certification against the REMS Patent, which Avadel CNS did under protest, consistent with its Renewed Motion for Judgment on the Pleadings for the delisting of the REMS Patent from the Orange Book, which was later ordered to be delisted in the above First Jazz Complaint action. Avadel CNS provided the required notice of its Paragraph IV certification to Jazz, and Jazz reasserted the REMS Patent in a separate action following receipt of that notice. The Fourth Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses.

On 7 September 2022, the case was reassigned to a new judge.

On 21 September 2022, Jazz served the Fourth Complaint. On 21 October 2022, Avadel CNS timely filed its Answer and Counterclaims (the "Fourth Avadel Answer") with the Court in response to the Fourth Complaint. The Fourth Avadel Answer generally denies the allegations set forth in the Fourth Complaint, includes numerous affirmative defenses (including, but not limited to, non-infringement and invalidity of the patent-in-suit), and asserts a number of counterclaims for i) a declaratory judgment of non-infringement of the patent-in-suit, ii) a declaratory judgment of invalidity/unenforceability of the patent-in-suit, iii) delisting of the patent-in-suit from the Orange Book; iv) monopolization under the Sherman Antitrust Act of 1890 (the "Sherman Act"); and v) attempted monopolization under the Sherman Act.

On 9 December 2022, Jazz filed a Motion to Dismiss Avadel's Antitrust Counterclaims. Avadel filed its opposition brief on 27 December 2022, and Jazz filed its reply brief on 6 January 2022. On 11 January 2023, Avadel filed a request for oral argument on the motion, which is still pending.

On 6 March 6 2023, the parties filed a stipulation of dismissal, dismissing Jazz's claims with respect to the REMS Patent and Avadel's related non-infringement and invalidity counterclaims. The Court entered that stipulation on March 7, 2023.

Avadel Complaint

On 14 April 2022, Avadel CNS and Avadel Pharmaceuticals plc (collectively the "Avadel Plaintiffs") filed a formal complaint (the "Avadel Complaint") initiating a lawsuit in the Court against Jazz and Jazz Pharmaceuticals Ireland Ltd. (collectively, the "Jazz Parties"). In the Avadel Complaint, the Avadel Plaintiffs allege that the Jazz Parties breached certain confidential disclosure agreements and misappropriated certain of the Avadel Plaintiffs' trade secrets. The Avadel Complaint further includes typical relief requests such as injunctive relief, monetary damages and attorneys' fees, costs and expenses, as well as seeking correction of inventorship of certain Jazz patents, for which the Jazz Parties claim ownership, to include former Avadel Plaintiffs' scientists.

On 2 June 2022, Jazz answered the Avadel Complaint. The Answer generally denies the allegations set forth in the Avadel Complaint and includes various affirmative defenses.

On 8 July 2022, Jazz filed a Motion for Judgment on the Pleadings seeking to have all Counts dismissed for failure to state a claim upon which relief can be granted. The Avadel Plaintiffs' response to that Motion was filed with the Court on July 29, 2022. Jazz's reply was filed with the Court on 5 August 2022. On 2 February 2023, the Court held a hearing on Jazz's Motion for Judgment on the Pleadings.

On 7 September 2022, the case was reassigned to a new judge.

On 2 February 2023, the Court held a hearing on Jazz's Motion for Judgment on the Pleadings.

Administrative Procedure Act Complaint

On 21 July 2022, Avadel CNS filed an Administrative Procedure Act suit against the FDA, the U.S. Department of Health and Human Services, the Secretary of Health and Human Services and the Commissioner of Food and Drugs (the "Federal Defendants") in the United States District Court for the District of Columbia (the "DC Court") related to the NDA for LUMRYZ (sodium oxybate). This suit alleges that the FDA's decision requiring Avadel CNS to file a patent certification

concerning the REMS Patent was arbitrary, capricious and contrary to law and asks the DC Court to vacate the FDA's decision and order the FDA to take final action on the LUMRYZ NDA. On 28 July 2022, the DC Court granted Jazz's unopposed motion to intervene in the case to defend the FDA's decision. The DC Court also entered an expedited briefing schedule governing Avadel CNS's motion for preliminary injunction or, in the alternative, summary judgment, and the Federal Defendant's and Jazz's oppositions to that motion and anticipated cross-motions for summary judgment. On 19 August 2022, the Federal Defendants and Jazz filed their combined oppositions to Avadel CNS's motion for preliminary injunction or, in the alternative, summary judgment, and cross-motions for summary judgment. On 2 September 2022, Avadel CNS filed its combined reply in support of its motion for preliminary injunction or, in the alternative, summary judgment, and opposition to the cross-motions for summary judgment. On 14 September 2022, the Federal Defendants and Jazz filed their replies in support of their cross-motions for summary judgment. On 7 October 2022, the DC Court heard oral arguments of Avadel CNS's motion and the Federal Defendants and Jazz's cross-motions. On 3 November 2022, the DC Court issued its opinion determining that Avadel CNS is not entitled to seek relief under the APA because of the availability of adequate alternative relief in the Court, specifically, in the form of its counterclaim to have the REMS Patent delisted from the FDA's Orange Book described above in the section regarding the First Jazz Complaint.

Material Commitments

The Group has a commitment with a contract manufacturer of approximately $2,400 to $3,000 per year. If LUMRYZ is approved by the FDA and the contract manufacturer is subsequently approved, the annual commitment could be up to $4,200 per year.

Guarantees

The fair values of the Group's guarantee to Deerfield Capital L.P. ("Deerfield") and the guarantee received by the Group from Armistice Capital Master Fund, Ltd. largely offset and when combined are not material.

Deerfield Guarantee

In connection with the Group's February 2018 divestiture of our pediatric assets, including four pediatric commercial stage assets – Karbinal™ ER, Cefaclor, Flexichamber™ and AcipHex® Sprinkle™ ("FSC products"), to Cerecor, Inc. ("Cerecor") the Group guaranteed to Deerfield a quarterly royalty payment of 15% on net sales of the FSC products through 6 February 2026 ("FSC Product Royalties"), in an aggregate amount of up to approximately $10,300. Given the Group's explicit guarantee to Deerfield, the Group recorded the guarantee in accordance with ASC 460. The balance of this guarantee liability was $774 at 31 December 2022. This liability is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

Armistice Guarantee

In connection with the Group's February 2018 divestiture of the pediatric assets, Armistice Capital Master Fund, Ltd., the majority shareholder of Cerecor, guaranteed to the Group the FSC Product Royalties. The Group recorded the guarantee in accordance with ASC 460. The balance of this guarantee asset was $771 at 31 December 2022. This asset is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield noted above.

NOTE 16: Fair Value Measurements

The Group is required to measure certain assets and liabilities at fair value, either upon initial recognition or for subsequent accounting or reporting. For example, we use fair value extensively when accounting for and reporting certain financial instruments, when measuring certain contingent consideration liabilities and in the initial recognition of net assets acquired in a business combination. Fair value is estimated by applying the hierarchy described below, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement.

ASC 820, *Fair Value Measurements and Disclosures* defines fair value as a market-based measurement that should be determined based on the assumptions that marketplace participants would use in pricing an asset or liability. When estimating fair value, depending on the nature and complexity of the asset or liability, we may generally use one or each of the following techniques:

- Income approach, which is based on the present value of a future stream of net cash flows.

- Market approach, which is based on market prices and other information from market transactions involving identical or comparable assets or liabilities.

As a basis for considering the assumptions used in these techniques, the standard establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value as follows:

- Level 1 - Quoted prices for identical assets or liabilities in active markets.
- Level 2 - Quoted prices for similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are directly or indirectly observable, or inputs that are derived principally from, or corroborated by, observable market data by correlation or other means.
- Level 3 - Unobservable inputs that reflect estimates and assumptions.

The following table summarizes the financial instruments measured at fair value on a recurring basis classified in the fair value hierarchy (Level 1, 2 or 3) based on the inputs used for valuation in the accompanying consolidated balance sheet:

	As of 31 December 2022			As of 31 December 2021		
Fair Value Measurements:	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Investments (see *Note 7: Investments*)						
Money market and mutual funds	$ 22,518	$ —	$ —	$ 78,098	$ —	$ —
Corporate bonds	—	—	—	—	16,479	—
Government securities - U.S.	—	—	—	—	9,471	—
Other fixed-income securities	—	—	—	—	2,465	—
Total assets	$ 22,518	$ —	$ —	$ 78,098	$ 28,415	$ —

A review of fair value hierarchy classifications is conducted on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification for certain investments or liabilities. During the fiscal year ended 31 December 2022, there were no transfers in and out of Level 1, 2, or 3. During the twelve months ended 31 December 2022 and 2021, we did not recognize any allowances for credit losses.

The following table summarizes changes to the Group's investments, a recurring Level 1 and Level 2 measurement, for the twelve-month period ended 31 December 2022:

Investments	**Balance**
Balance at 31 December 2021	$ 106,513
Purchases	3,414
Issues	(83,828)
Total gains or losses:	
Profit and Loss Account	(1,991)
Other Comprehensive (Loss) Income	(1,590)
Balance at 31 December 2022	$ 22,518

Some of the Group's financial instruments, such as cash and cash equivalents, trade debtors and creditors, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

Debt

The Group estimates the fair value of its $17,500 aggregate principal amount of its February 2023 Notes and its $117,375 aggregate principal amount of its October 2023 Notes based on interest rates that would be currently available to the Group for issuance of similar types of debt instruments with similar terms and remaining maturities or recent trading prices obtained from brokers (a Level 2 input). The estimated fair values of the February 2023 Notes and October 2023 Notes at 31 December 2022 are $16,975 and $112,973, respectively.

See *Note 13: Long-Term Debt* for additional information regarding our debt obligations.

NOTE 17: Group Operations by Product, Customer and Geographic Area

The Group has determined that it operates in one segment, the development and commercialization of pharmaceutical products, including controlled-release therapeutic products based on its proprietary polymer based technology. The Group's Chief Operating Decision Maker is the Chief Executive Officer ("CEO"). The CEO reviews profit and loss information on a consolidated basis to assess performance and make overall operating decisions as well as resource allocations. All products are included in one segment because the Group's products have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods and regulatory environment. The Group had no revenue during the years ended 31 December 2022 and 2021.

Currently, the Group is working with contract manufacturing organizations for the manufacture of LUMRYZ. Additionally, the Company purchases raw materials used in LUMRYZ from a limited number of suppliers, including a single supplier for certain key ingredients.

Non-monetary long-lived assets primarily consist of tangible assets and goodwill. The following table summarizes non-monetary long-lived assets by geographic region as of 31 December 2022 and 2021:

Long-lived Assets by Geographic Region:	2022	2021
United States	$ 19,414	$ 19,605
Ireland	11,296	9,817
Total	$ 30,710	$ 29,422

NOTE 18: Loss Attributable to Avadel Pharmaceuticals plc

In accordance with Section 304(2) of the Companies Act 2014, the Group is availing itself of the exemption from presenting and filing its parent company profit and loss account. Avadel Pharmaceuticals plc loss for the year ended 31 December 2022 as determined in accordance with Irish GAAP (FRS 102) was $15,946 (2021: loss $15,700).

NOTE 19: Key Management Compensation

Key Management Compensation	2022	2021
Aggregate emoluments	$ 4,115	$ 2,338
Aggregate amount of gains on the exercise of share options during the financial year	—	—
Aggregate amount of the money or value of other assets under long term incentive schemes	790	6,374
Total	$ 4,905	$ 8,712

Total key managements' share-based compensation charged to profit and loss in accordance with ASC 718 was $4,277 and $4,137 for the year ended 31 December 2022 and 2021 respectively.

See *Note* 5: *Directors' Remuneration* to the Company Financial Statements for directors' remuneration.

NOTE 20: Auditor's Remuneration

Auditor's remuneration was as follows:

	2022	2021
Audit of group financial statements	$ 159	$ 166
Other assurance services	35	36
Total	$ 194	$ 202

No amounts were incurred for tax advisory services and other non-audit services. The Group incurred additional fees of $861 and $763 during fiscal 2022 and 2021, respectively, payable to affiliates of Deloitte Ireland LLP. These additional amounts reflect fees for all professional services rendered, including audit fees payable to Deloitte & Touche LLP in the United States for the audit of the 10-K.

NOTE 21: Employees

The average number of persons, including executive directors, employed by the Group during the year was as follows:

Average Number of Employees	2022	2021
Research and development	3	3
General, administrative and sales	50	47
Total	53	50

Employee costs consisted of the following:

Employee Costs	2022	2021
Wages and salaries	$ 14,737	$ 13,389
Social security costs and other tax	892	662
Defined contribution cost	521	360
Share-based compensation	7,014	8,871
Total	$ 23,164	$ 23,282

During fiscal 2022 and 2021, the Group received credits of $0 and $956, respectively, related to the Employee Retention Credit under the CARES Act. These amounts are not included in the table above.

There was an immaterial amount of employee costs capitalized during the years ended 31 December 2022 and 2021.

NOTE 22: Post Balance Sheet Events

Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of Avadel Pharmaceuticals plc, repaid, with cash on hand, the remaining $17,500 aggregate principal amount of its February 2023 Notes on the maturity date of 1 February 2023.

On 29 March 2023, the Group entered into a royalty purchase agreement with RTW Investments, L.P. that could provide the Group up to $75,000 of royalty financing in two tranches. The first tranche of $30,000 is available subject to the Group's first shipment of LUMRYZ. The second tranche is available to use, at the Group's election, upon achieving quarterly net revenue of $25,000. The second tranche will expire on 31 August 2024 if the quarterly net revenue target is not reached and if it is not used by the Group by that time.

Over the course of 3 April and 4 April 2023, the Issuer completed an exchange of $96,188 of its $117,375 October 2023 Notes. The $96,188 of notes were exchanged for $106,268 of a new series of 6.0% exchangeable notes due April 2027 (the "April 2027 Notes"). The remaining $21,187 aggregate principal amount of the October 2023 Notes will mature October 2, 2023.

On 3 April 2023, the Group completed the sale of ordinary shares, nominal value $0.01 per share ("Ordinary Shares") in the form of American Depositary Shares ("ADSs") and its Series B Non-Voting Convertible Preferred Shares ("Series B Preferred Shares") in an underwritten public offering. The Group issued 4,706 Series B Preferred Shares and 12,205 of its ADSs and received net proceeds from the equity financing of $135,125, of which $40,000 was received on 31 March 2023 and $95,125 was received on 3 April 2023.

On 1 May 2023, LUMRYZ was approved by the U.S. Food and Drug Administration ("FDA"). At that time, the FDA granted Orphan Drug Exclusivity ("ODE") to LUMRYZ for a period of seven years until 1 May 2030.

NOTE 23: Subsidiary Undertakings

As of 31 December 2022, the Group had 100% interest in the equity of the following subsidiaries:

Name	Jurisdiction	Registered Office
Avadel Pharmaceuticals plc (the Registrant):	Ireland	10 Earlsfort Terrace Dublin 2
1) Avadel US Holdings, Inc. *(f/k/a Flamel US Holdings, Inc.)*	United States (Delaware)	16640 Chesterfield Grove Road Suite 200 Chesterfield, MO 63005
A. Avadel Legacy Pharmaceuticals, LLC *(f/k/a Éclat Pharmaceuticals LLC)*	United States (Delaware)	16640 Chesterfield Grove Road Suite 200 Chesterfield, MO 63005
B. Avadel Management Corporation	United States (Delaware)	16640 Chesterfield Grove Road Suite 200 Chesterfield, MO 63005
C. Avadel CNS Pharmaceuticals, LLC	United States (Delaware)	16640 Chesterfield Grove Road Suite 200 Chesterfield, MO 63005
2) Flamel Ireland Limited *(t/a Avadel Ireland Ltd.)*	Ireland	10 Earlsfort Terrace Dublin 2
3) Avadel Investment Company, Ltd.	Cayman Islands	PO Box 309, Ugland House Grand Cayman Cayman Islands, KY 1-1104
4) Avadel France Holding SAS	France	2 Bis Rue tête d'or 69006 Lyon
A. Avadel Research SAS	France	2 Bis Rue tête d'or 69006 Lyon
5) Avadel Finance Ireland Designated Activity Company	Ireland	10 Earlsfort Terrace Dublin 2
A. Avadel Finance Cayman Ltd.	Cayman Islands	PO Box 309, Ugland House Grand Cayman Cayman Islands, KY 1-1104

The Group does not have any interest in any other subsidiaries, other than the ones mentioned above.

Note 24: Restructuring Costs

2022 Corporate Restructuring Plan

In June 2022, the Group announced a plan to optimize its cost structure to reduce total quarterly cash operating expenses, excluding inventory purchases.

The Group's cost structure optimization efforts included a nearly 50% reduction in its workforce that was completed at the end of August 2022 (the "2022 Corporate Restructuring Plan"). Restructuring expense of $3,345, comprised primarily of severance related costs, was recorded for the year ended 31 December, 2022.

The following table sets forth activities for the Group's 2022 Corporate Restructuring Plan obligations as of 31 December 2022:

2022 Corporate Restructuring Plan Obligation:	2022
Balance of 2022 Corporate Restructuring Plan accrual at 1 January,	$ —
Charges for employee severance, benefits and other costs	3,592
Payments	(2,910)
Other adjustments	(247)
Balance of 2022 Corporate Restructuring Plan accrual at 31 December,	$ 435

The 2022 Corporate Restructuring Plan liabilities of $435 are included in the consolidated balance sheet in creditors at 31 December 2022.

2019 French Restructuring

During the second quarter of 2019, the Group initiated a plan to discontinue all French business activities, which resulted in the redundancy of its entire workforce at its Vénissieux, France site and the cessation of all business activities there ("2019 French Restructuring"). This reduction was part of an effort to align the Group's cost structure with its ongoing and future planned projects. The discontinuation of business activities and elimination of the workforce in France was completed during the year ended 31 December 2020. Restructuring charges associated with this plan recognized during the years ended 31 December 2022 and 2021 were immaterial. The Group does not expect to incur any additional expenses related to the 2019 French Restructuring. The following table sets forth activities for the Group's cost reduction plan obligations for the years ended 31 December 2022 and 2021:

2019 French Restructuring Obligation:	2022	2021
Balance of restructuring accrual at 1 January,	$ 41	$ 248
(Benefit) charges for employee severance, benefits and other costs	—	(122)
Payments	—	(77)
Foreign currency impact	(3)	(8)
Balance of restructuring accrual at 31 December,	$ 38	$ 41

The 2019 French Restructuring liability of $38 is included in the consolidated balance sheet in creditors at 31 December 2022.

NOTE 25: Leases

The Group leases office space and a production suite. All leased facilities are classified as operating leases with remaining lease terms between one and three years. The Group determines if a contract is a lease at the inception of the arrangement. The Group reviews all options to extend, terminate, or purchase its right-of-use assets at the inception of the lease and will include these options in the lease term when they are reasonably certain of being exercised. The Group's lease agreements do not contain any material residual value guarantees or material variable lease payments. For the Group's leased production suite, contract consideration was allocated to lease and non-lease components on the basis of relative standalone price.

The components of lease costs, which are included in selling, general and administrative expenses in the consolidated profit and loss account of years ended 31 December 2022 and 2021 were as follows:

Lease cost:	2022	2021
Operating lease costs [1]	$ 1,028	$ 821
Sublease income [2]	(116)	(110)
Total lease cost	$ 912	$ 711

[1] Variable lease costs were immaterial for the years ended 31 December 2022 and 2021.
[2] Represents sublease income received for office leases.

During the years ended 31 December 2022 and 2021, the Group reduced its operating lease liabilities by $963 and $578 for cash paid.

As of 31 December 2022, the Group's operating leases have a weighted-average remaining lease term of 2.0 years and a weighted-average discount rate of 5.0%. The Group's lease contracts do not provide a readily determinable implicit rate. The Group's estimated incremental borrowing rate is based on information available at the inception of the lease.

Maturities of the Group's operating lease liabilities were as follows:

Maturities:	Operating Leases
2023	$ 1,013
2024	614
2025	206
2026	—
2027	—
Thereafter	—
Total lease payments	1,833
Less: interest	93
Present value of lease liabilities	$ 1,740

AVADEL PHARMACEUTICALS PLC
Company Financial Statements
For the year ended 31 December 2022

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Independent auditor's report to the members of Avadel Pharmaceuticals plc

Report on the audit of the financial statements

Opinion on the financial statements of Avadel Pharmaceuticals plc (the 'company')

In our opinion the parent company financial statements:

- give a true and fair view of the assets, liabilities and financial position of the parent company as at 31 December 2022; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The parent company financial statements we have audited comprise:

- the Company Balance Sheet;
- the Company Statement of Changes in Equity; and
- the related notes 1 to 15, including a summary of significant accounting policies as set out in note [x].

The relevant financial reporting framework that has been applied in their preparation is the Companies Act 2014 and FRS 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" issued by the Financial Reporting Council ("the relevant financial reporting framework").

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are described below in the "*Auditor's responsibilities for the audit of the financial statements*" section of our report.

We are independent of the company in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Summary of our audit approach

Key audit matters	The key audit matters that we identified in the current year were: • *Going concern* • *Carrying value of financial assets* Within this report, any new key audit matters are identified with ⏫ and any key audit matters which are the same as the prior year identified with ⏩.
Materiality	The materiality that we used in the current year was $1,632,000 which was determined on the basis of net assets.
Scoping	We have determined the scope of our audit by obtaining an understanding of the Company and its environment, including assessing the risks of material misstatement at the Company level.

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Significant changes in our approach	No significant changes to note.

Conclusions relating to going concern

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.

Our evaluation of the directors' assessment of the Company's ability to continue to adopt the going concern basis of accounting is discussed in the Key Audit Matters section of our report.

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 Company's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

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

Key Audit Matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current financial year and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, 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 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.

Going Concern

Key audit matter description

As stated in note 1 to the consolidated financial statements, the directors have assessed that the going concern basis of accounting for the Group and Company is appropriate in preparing the financial statements. The Group has a recent history of generating losses and negative cash flows from operations, an accumulated shareholders' deficit as of 31 December 2022 of $21,145 and approximately $73,981 of cash and cash equivalents and $22,518 of marketable securities available for use to fund its operations, debt service and capital requirements. The Group's ability to generate revenue is expected to start following the launch of LUMRYZ, which is dependent, in part, on the Group's ability to successfully complete its commercialisation efforts and on market acceptance of LUMRYZ. The director's assessment is based on steps taken subsequent to the year end to ensure liquidity to the Group.

At 31 March 2023, the Group had $117,375 aggregate principal amount of its 4.50% exchangeable senior notes due October 2023 (the "October 2023 Notes"). Over the course of 3 April and 4 April 2023, Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of the Group (the "Issuer"), completed an exchange of $96,188 of its $117,375 October 2023 Notes for

	$106,268 of a new series 6.0% exchangeable notes due April 2027 (the "April 2027 Notes") (the "2023 Exchange Transaction"). The remaining $21,187 aggregate principal amount of the October 2023 Notes will maintain a maturity date of 2 October 2023. On 29 March 2023, the Group announced a public offering, which was completed on 3 April 2023. The Group received net proceeds from the equity financing of $135,125, of which $40,000 was received on 31 March 2023 and $95,125 was received on 3 April 2023. We have identified a key audit matter related to going concern as this is a key area of management focus and involved a significant allocation of resources and efforts of the engagement team.
How the scope of our audit responded to the key audit matter	• We obtained an understanding of the Group's relevant controls over the preparation of cash flow forecasts, approval of projections and assumptions used in the cash flow forecast to support the going concern assumption and tested the effectiveness of the key relevant controls. • We inspected the 2023 Exchange Agreement executed after 31 December 2022 and agreed the amounts, key terms and dates to management's forecasts. • We inspected the net proceeds from the public offering completed on 3 and 4 April 2023. • We inspected the royalty financing agreement with RTW Investments, L.P. that may provide $75,000 of royalty financing. • We confirmed that LUMRYZ was approved by the FDA on 1 May 2023. We confirmed that the FDA also granted Orphan Drug Exclusivity to LUMRYZ at that time for a period of seven years until 1 May 2030. • We tested the clerical accuracy of the cash flow forecast models. • We evaluated management's key assumptions including the Group's LUMRYZ launch and commercialisation plans. • We evaluated the completeness of the Group's future obligations and evaluated consistency of evidence obtained in other areas of the audit. • We performed an assessment of the historical accuracy of forecasts prepared by management. • We evaluated the completeness and accuracy of the disclosures made in the financial statements.
Key observations	We have concluded that the adoption of the going concern basis of accounting and the related disclosures are appropriate. Please refer to our conclusions in the going concern section of our report.

Carrying Value of Financial Assets

Key audit matter description	There is a risk that an impairment in the company's investments in subsidiary is not appropriately recorded in the financial statements. As of 31 December 2022 the market capitalisation of the Group was lower than the net assets of the parent company. This was considered an indicator of impairment.

	Refer to Note 1 (accounting policy for Investments in Subsidiary) and Note 7 (Financial Fixed Assets).
How the scope of our audit responded to the key audit matter 	• We considered the appropriateness of the directors' approach to impairment review which considers the valuation of the parent company's subsidiaries and net assets against other indicators of value, such as the overall market capitalisation of the Group adjusted for the control premium. • We have assessed the methodology applied by management in determining share prices and control premium, and we reviewed key inputs to supporting evidence. • We have assessed the adequacy of the related disclosure.
Key observations 	We have no observations that impact on our audit in respect of carrying value of financial assets.

Our audit procedures relating to these matters were designed in the context of our audit of the financial statements as a whole, and not to express an opinion on individual accounts or disclosures. Our opinion on the financial statements is not modified with respect to any of the risks described above, and we do not express an opinion on these individual matters.

Our application of materiality

We define materiality as the magnitude of misstatement in the financial statements that makes it probable that the economic decisions of a reasonably knowledgeable person would be changed or influenced. We use materiality both in planning the scope of our audit work and in evaluating the results of our work.

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

Materiality	$1,632,000 (2021: $1,600,000)
Basis for determining materiality	We determined materiality based on 2% of net assets of the Company which is capped at 60% of Group materiality.
Rationale for the benchmark applied	We determined net assets to be of most importance to the principal external users of these financial statements as this is the key balance in this legal entity and holding this investment is the purpose of the entity.

We set performance materiality at a level lower than materiality to reduce the probability that, in aggregate, uncorrected and undetected misstatements exceed the materiality for the financial statements as a whole. Performance materiality was set at 79% of materiality for the 2022 audit. In determining performance materiality, we considered the following factors:

a. Our understanding of the Company and its environment;
b. the reliability of the Company's internal control over financial reporting;
c. the degree of centralization and common controls/processes;
d. any change to the business that would impact on our ability to forecast potential misstatements;
e. the nature, volume and size of misstatements (corrected and/or uncorrected) in the previous audit, and
f. prior period adjustments.

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An overview of the scope of our audit

Our audit is a risk-based approach taking into account the structure of the company, our knowledge of the Company and industry in which the company operates and the accounting processes and controls in place.

Other information

The other information comprises the information included in the Directors' Report and Consolidated Financial Statements, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information contained within the annual report.

Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

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 such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in 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 in this regard.

Responsibilities of directors

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors 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 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 company or to cease operations, or have no realistic alternative but to do so.

Auditor's 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 auditor's 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.

A further description of our responsibilities for the audit of the financial statements is located on IAASA's website at: https://iaasa.ie/publications/description-of-the-auditors-responsibilities-for-the-audit-of-the-financial-statements/. This description forms part of our auditor's report.

Extent to which the audit was considered capable of detecting irregularities, including fraud

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.

Identifying and assessing potential risks related to irregularities

In identifying and assessing risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations, we considered the following:

- the nature of the industry and sector, control environment and business performance including the design of the remuneration policies, key drivers for directors' remuneration, bonus levels and performance targets;
- results of our enquiries of management, internal audit and the audit committee about their own identification and assessment of the risks of irregularities;
- any matters we identified having obtained and reviewed the documentation of their policies and procedures relating to:
    - identifying, evaluating and complying with laws and regulations and whether they were aware of any instances of non-compliance
    - detecting and responding to the risks of fraud and whether they have knowledge of any actual, suspected or alleged fraud;
    - the internal controls established to mitigate risks of fraud or non-compliance with laws and regulations;
- the matters discussed among the audit engagement team and relevant internal specialists, including tax, valuations, and IT specialists regarding how and where fraud might occur in the financial statements and any potential indicators of fraud.

In common with all audits under ISAs (Ireland), we are also required to perform specific procedures to respond to the risk of management override.

We also obtained an understanding of the legal and regulatory framework that the company operates in, focusing on provisions of those laws and regulations that had a direct effect on the determination of material amounts and disclosures in the financial statements. The key laws and regulations we considered in this context included the Irish Companies Act and tax legislation.

In addition, we considered provisions of other laws and regulations that do not have a direct effect on the financial statements but compliance with which may be fundamental to the company's ability to operate or to avoid a material penalty. This included the United States Foreign Corrupt Practices Act and regulations relevant to being a NASDAQ listed entity.

Audit response to risks identified

As a result of performing the above, we did not identify any key audit matters related to the potential risk of fraud or non-compliance with laws and regulations.

Our procedures to respond to risks identified included the following:

- reviewing the financial statement disclosures and testing to supporting documentation to assess compliance with provisions of relevant laws and regulations described as having a direct effect on the financial statements;
- enquiring of management, the audit committee and in-house legal counsel concerning actual and potential litigation and claims;
- performing analytical procedures to identify any unusual or unexpected relationships that may indicate risks of material misstatement due to fraud;
- reading minutes of meetings of those charged with governance, reviewing internal audit reports and reviewing correspondence with relevant regulatory authorities; and

- in addressing the risk of fraud through management override of controls, testing the appropriateness of journal entries and other adjustments; assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

We also communicated relevant identified laws and regulations and potential fraud risks to all engagement team members including internal specialists, and remained alert to any indications of fraud or non-compliance with laws and regulations throughout the audit.

Report on other legal and regulatory requirements

Opinion on other matters prescribed by the Companies Act 2014

Based solely on the work undertaken in the course of the audit, we report that:

- 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 company were sufficient to permit the financial statements to be readily and properly audited.
- The company balance sheet is in agreement with the accounting records.
- In our opinion the information given in the directors' report is consistent with the financial statements and the directors' report has been prepared in accordance with the Companies Act 2014.

Matters on which we are required to report by exception

Based on the knowledge and understanding of the company and its environment obtained in the course of the audit, we have not identified material misstatements in the directors' report

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

Use of our report

This report is made solely to the company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

/s/Ann McGonagle
Ann McGonagle
For and on behalf of Deloitte Ireland LLP Chartered
Accountants and Statutory Audit Firm
Deloitte & Touche House, Earlsfort Terrace, Dublin 2

4 May 2023

AVADEL PHARMACEUTICALS PLC
COMPANY BALANCE SHEET
AT 31 DECEMBER 2022
(*Amounts in $ thousands*)

	Note	2022	2021
FIXED ASSETS			
Intangible assets	*6*	$ 26	$ 55
Financial assets	*7*	436,166	430,474
		436,192	430,529
CURRENT ASSETS			
Debtors			
-Due within one year	*8*	54,646	43,475
-Due after one year	*8*	141	328
Cash at bank and in hand		39,705	37,339
		94,492	81,142
CURRENT LIABILITIES			
Creditors (amounts falling due within one year)	*9*	(939)	(948)
NET CURRENT ASSETS		93,553	80,194
Total assets less current liabilities		529,745	510,723
NET ASSETS		$ 529,745	$ 510,723
CAPITAL AND RESERVES			
Called up share capital presented as equity	*10*	$ 659	$ 617
Share premium	*11*	305,086	277,127
Other reserves	*11*	22,798	15,830
Profit and loss account		201,202	217,149
SHAREHOLDERS' FUNDS		$ 529,745	$ 510,723

In accordance with Section 304(2) of the Irish Companies Act 2014, Avadel Pharmaceuticals plc is availing itself of the exemption from presenting and filing its individual profit and loss account. Avadel Pharmaceuticals plc's net loss as determined in accordance with FRS 102 was $15,946 (2021: loss $15,700).

The financial statements were approved by the board on 4 May 2023 and signed on its behalf by:

/s/ Peter J. Thornton
Peter J. Thornton
Director

/s/ Gregory J. Divis
Gregory J. Divis
Director

AVADEL PHARMACEUTICALS PLC
STATEMENT OF CHANGES IN EQUITY
FOR THE YEAR ENDED 31 DECEMBER 2022
(*Amounts in $ Thousands*)

	Share Capital - Ordinary	Share Capital - Preferred	Share Premium	Other Reserves	Profit and Loss Account	Total Equity
At 31 December 2020	$ 609	$ 5	$ 276,865	$ 6,958	$ 232,851	$ 517,288
Result for the Period	—	—	—	—	(15,700)	(15,700)
Vesting of restricted shares	2	—	—	—	(2)	—
Share-based compensation expense	—	—	—	8,872	—	8,872
Employee share purchase plan issuance	—	—	94	—	—	94
Exercise of stock options	1	—	168	—	—	169
At 31 December 2021	$ 612	$ 5	$ 277,127	$ 15,830	$ 217,149	$ 510,723
Result for the Period	—	—	—	—	(15,946)	(15,946)
Issuance of common stock under at-the-market offering program, net of issuance costs	36	—	25,282	—	—	25,318
Amortization of deferred issuance costs	—	—	—	(45)	—	(45)
Vesting of restricted shares	1	—	—	—	(1)	—
Exercise of stock options	4	—	2,456	—	—	2,460
Share-based compensation expense	—	—	—	7,013	—	7,013
Employee share purchase plan issuance	1	—	221	—	—	222
At 31 December 2022	$ 654	$ 5	$ 305,086	$ 22,798	$ 201,202	$ 529,745

Share premium

In 2021, the share premium account increased due to the employee purchase plan issuance of $94 and the exercise of stock options of $168. In 2022, the share premium account increased due to the issuance of common stock through the Company's at-the-market offering program of $25,282, the exercise of stock options of $2,456 and employee purchase plan issuance of $221.

Other reserves

The increase in the balance as of 31 December 2021 was due to $8,872 of accumulated share-based compensation. The increase in the balance as of 31 December 2022 was due to $7,013 of accumulated share-based compensation, offset by $45 of amortized issuance costs.

AVADEL PHARMACEUTICALS PLC

NOTES TO THE FINANCIAL STATEMENTS FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2021

NOTE 1: Accounting Policies

Basis of preparation and statement of compliance

The company financial statements have been prepared on a going concern basis and comply with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* and have been prepared in accordance with the Companies Act 2014. The financial statements are prepared for the year ended 31 December 2022 with comparatives presented for the year ended 31 December 2021.

The principal accounting policies are summarised below. They have all been applied consistently throughout the financial year.

In accordance with section 304 of the Companies Act 2014, the company is availing of the exemption from presenting the individual statement of comprehensive income.

General information and basis of accounting

Avadel Pharmaceuticals plc was incorporated on 1 December 2015 as an Irish private limited company under the Companies Act 2014, and re-registered as an Irish public limited company, or plc, on 21 November 2016. Its registered office is located at 10 Earlsfort Terrace, Dublin 2, Ireland. Its headquarters are in St. Louis, MO, USA. Its website is www.Avadel.com. The Company registration number is 572535.

The Company is the successor to Flamel Technologies S.A., a French société anonyme ("Flamel"), as the result of the merger of Flamel with and into the company which was completed at 11:59:59 p.m., Central Europe Time, on 31 December 2016 (the "Merger") pursuant to the agreement between Flamel and Avadel entitled Common Draft Terms of Cross-Border Merger dated as of 29 June 2016. Immediately prior to the merger, the Company was a wholly owned subsidiary of Flamel. In accordance with the merger agreement, Flamel ceased to exist as a separate entity and the company continued as the surviving entity and assumed all of the assets and liabilities of Flamel. These assets and liabilities were valued using the book value of the assets and liabilities at the time of the merger.

On 1 January 2017, Avadel Pharmaceuticals plc contributed all the assets and liabilities associated with the research and development services business performed in France to Avadel Research SAS, which is a wholly owned subsidiary of Avadel France Holding SAS, in exchange for stock in Avadel Research SAS.

The functional currency of the Company is considered to be US dollar because that is the currency of the primary economic environment in which the company operates.

Going concern

The directors have a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Thus, they continue to adopt the going concern basis of accounting in preparing the financial statements. See *Note 1: Background and Basis of Presentation* of the Group's Notes to Consolidated Financial Statements for further information.

Intangible assets

Intangible assets are stated at cost or valuation, net of amortisation and any provisions for impairment. Amortisation is provided on amortisable intangible assets at rates calculated to write off the cost or valuation, less estimated residual value, of each asset on a straight-line basis over its expected useful life, as follows:

Asset:	Useful life:
Software	2-10 years

Residual value represents the estimated amount which would currently be obtained from disposal of an asset, after deducting estimated costs of disposal, if the asset were already of the age and in the condition expected at the end of its useful life.

Financial instruments

Financial Assets and Liabilities

For financial instruments, the company has adopted the recognition and measurement criteria of sections 11 and 12 of FRS 102. All financial assets and liabilities are initially measured at transaction price (including transaction costs), except for those financial assets classified as at fair value through profit or loss, which are initially measured at fair value (which is normally the transaction price excluding transaction costs), unless the arrangement constitutes a financing transaction. If an arrangement constitutes a finance transaction, the financial asset or financial liability is measured at the present value of the future payments discounted at a market rate of interest for a similar debt instrument.

Non-current debt instruments which meet the following conditions are subsequently measured at amortised cost using the effective interest method:

a. Returns to the holder are (i) a fixed amount; or (ii) a fixed rate of return over the life of the instrument; or (iii) a variable return that, throughout the life of the instrument, is equal to a single referenced quoted or observable interest rate; or (iv) some combination of such fixed rate and variable rates, providing that both rates are positive.

b. There is no contractual provision that could, by its terms, result in the holder losing the principal amount or any interest attributable to the current period or prior periods.

c. Contractual provisions that permit the issuer to prepay a debt instrument or permit the holder to put it back to the issuer before maturity are not contingent on future events, other than to protect the holder against the credit deterioration of the issuer or a change in control of the issuer, or to protect the holder or issuer against changes in relevant taxation or law.

d. There are no conditional returns or repayment provisions except for the variable rate return described in (a) and prepayment provisions described in (c).

Debt instruments that are classified as payable or receivable within one year and which meet the above conditions are measured at the undiscounted amount of the cash or other consideration expected to be paid or received, net of impairment.

Other debt instruments not meeting these conditions are measured at fair value through profit or loss.

Financial assets are derecognised when and only when:

a. The contractual rights to the cash flows from the financial asset expire or are settled,

b. The Company transfers to another party substantially all of the risks and rewards of ownership of the financial asset, or

c. The Company, despite having retained some significant risks and rewards of ownership, has transferred control of the asset to another party and the other party has the practical ability to sell the asset in its entirety to an unrelated third party and is able to exercise that ability unilaterally and without needing to impose additional restrictions on the transfer.

Impairment of Assets

Assets, other than those measured at fair value, are assessed for indicators of impairment at each balance sheet date. If there is objective evidence of impairment, an impairment loss is recognised in profit or loss as described below.

Financial Fixed Assets (including investments in subsidiaries)

For financial assets carried at amortised cost, the amount of an impairment is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the financial asset's original effective interest rate.

For financial assets carried at cost less impairment, the impairment loss is the difference between the asset's carrying amount and the best estimate of the amount that would be received for the asset if it were to be sold at the reporting date.

The Company's investment in subsidiaries are initially recorded at fair value of consideration given plus any directly attributable costs (at cost). The investments are carried at cost less accumulated impairment if circumstances or indicators suggest that impairment may exist. Where there are indicators of impairment of financial assets, the Company performs impairment tests based on the valuation of the Company's subsidiaries and net assets against other indicators of value, such as

the overall group market capitalisation adjusted for control premium and carrying value of net assets in the consolidated financial statements.

Where indicators exist for a decrease in impairment loss, and the decrease can be related objectively to an event occurring after the impairment was recognised, the prior impairment loss is tested to determine reversal. An impairment loss is reversed on an individual impaired financial asset to the extent that the revised recoverable value does not lead to a revised carrying amount higher than the carrying value had no impairment been recognised.

Taxation

Current tax, including Irish corporation tax and foreign tax, is provided at amounts expected to be paid (or recovered) using the tax rates and laws that have been enacted or substantively enacted by the balance sheet date.

Deferred tax is recognised in respect of all timing differences that have originated but not reversed at the balance sheet date where transactions or events that result in an obligation to pay more tax in the future or a right to pay less tax in the future have occurred at the balance sheet date. Timing differences are differences between the company's taxable profits and its results as stated in the financial statements that arise from the inclusion of gains and losses in tax assessments in periods different from those in which they are recognised in the financial statements.

Unrelieved tax losses and other deferred tax assets are recognised only to the extent that, on the basis of all available evidence, it can be regarded as more likely than not that there will be suitable taxable profits from which the future reversal of the underlying timing differences can be deducted.

When the amount that can be deducted for tax for an asset (other than goodwill) that is recognised in a business combination is less (more) than the value at which it is recognised, a deferred tax liability (asset) is recognised for the additional tax that will be paid (avoided) in respect of that difference. Similarly, a deferred tax asset (liability) is recognised for the additional tax that will be avoided (paid) because of a difference between the value at which a liability is recognised and the amount that will be assessed for tax. The amount attributed to goodwill is adjusted by the amount of deferred tax recognised.

Deferred tax liabilities are recognised for timing differences arising from investments in subsidiaries and associates, except where the company is able to control the reversal of the timing difference and it is probable that it will not reverse in the foreseeable future.

Deferred tax is measured using the tax rates and laws that have been enacted or substantively enacted by the balance sheet date that are expected to apply to the reversal of the timing difference. Deferred tax relating to tangible assets measured using the revaluation model and investment property is measured using the tax rates and allowances that apply to sale of the asset.

The tax expense or income is presented in the same component of comprehensive income or equity as the transaction or other event that resulted in the tax expense or income.

Current tax assets and liabilities are offset only when there is a legally enforceable right to set off the amounts and the company intends either to settle on a net basis or to realise the asset and settle the liability simultaneously.

Deferred tax assets and liabilities are offset only if: a) the company has a legally enforceable right to set off current tax assets against current tax liabilities; and b) the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Financial Guarantees

At the time the Company issues a guarantee, the Company recognizes an initial liability for the fair value of the obligation which the Company assumes under that guarantee.

Foreign currency

Transactions in foreign currencies are recorded at the rate of exchange at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are reported at the rates of exchange prevailing at that date.

Exchange differences arising on translation of the opening net assets are reported in other comprehensive income and accumulated in equity. Other exchange differences are recognised in profit or loss in the period in which they arise except for exchange differences arising on gains or losses on non-monetary items which are recognized in other comprehensive income.

Cash and cash equivalents

Cash and cash equivalents on the Balance Sheet comprise cash at banks and in hand and short term deposits readily convertible to known amounts of cash with an original maturity date of three months or less.

Share-based payment

The Company issues equity-settled share options and equity-settled share appreciation rights to certain employees within the Group. Equity-settled share based payment transactions are measured at fair value of the equity instruments (excluding the effect of non market-based vesting conditions) at the date of grant. The fair value determined at the grant date of the equity-settled share based payments is expensed on a straight-line basis over the vesting period, based on the Group's estimate of shares that will eventually vest and adjusted for the effect of non market-based vesting conditions.

Fair value of the equity-settled share options is measured by use of the Black Scholes pricing model which is considered by management to be the most appropriate method of valuation. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions, and behavioural considerations. Fair value of the equity-settled share appreciation rights is measured on the grant date using the Group's stock price at the time of the grant.

Avadel Pharmaceuticals plc accounts for share-based payments available to members within the Group as a deemed equity contribution and increases the value of the investment in subsidiary undertakings by the value associated with the share-based payment. In the event that there is a net forfeiture this would result in a decrease in the value of the investment in subsidiary undertakings.

Statement of cash flow exemption and other disclosure exemptions under FRS 102

The Company meets the definition of a qualifying entity under FRS 102 and has therefore taken advantage of the disclosure exemptions available to it in respect of its separate financial statements, which are presented alongside the consolidated financial statements. Exemptions have been taken in relation to presentation of a cash flow statement, share-based payments, financial instruments and remuneration of key management personnel. Please refer to the Consolidated Statement of Cash Flows, *Note 14.1: Equity Instruments and Stock Based Compensation*, *Note 16: Fair Value Measurements* and *Note 19: Key Management Compensation* in the Group's Notes to Consolidated Financial Statements.

NOTE 2: Critical Accounting Judgements and Key Sources of Estimation Uncertainty

In the application of the Company's accounting policies, which are described in *Note 1: Accounting Policies*, the directors are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

The following are the critical judgements, apart from those involving estimations (which are dealt with separately below), that the directors have made in the process of applying the company's accounting policies and that have the most significant effect on the amounts recognised in the financial statements.

Impairment of Financial Fixed Assets

Where there are indicators of impairment of financial assets, the Company performs impairment tests based on the valuation of the Company's subsidiaries and net assets against other indicators of value, such as the overall market capitalisation of the Avadel Pharmaceutical Group and carrying value of net assets in the consolidated financial statements. The overall market capitalisation calculation used an average stock price of Avadel Pharmaceutical plc at the year end, increased by a control premium based on available data from similar, observable market transactions. Additional, publicly-available analysis from unrelated parties is also used to verify market capitalisation assumptions for the analysis.

NOTE 3: Turnover

The Company did not have any turnover for the year ended 31 December 2022 (2021: $nil).

NOTE 4: Auditor's Remuneration (Amounts in $ thousands)

The analysis of the auditor's remuneration is as follows:

Auditor's remuneration for work carried out for the Company in respect of the financial period is as follows:	2022	2021
Audit of Company accounts	$ 16	$ 17
Other assurance services	143	149

No amounts were incurred for tax advisory services or other non-audit services. *Note 20: Auditor's Remuneration* to the Group's Notes to Consolidated Financial Statements provides additional details of fees paid by the Group.

NOTE 5: Directors' Remuneration (Amounts in $ thousands)

Directors' Remuneration	2022	2021
Aggregate emoluments in respect to qualifying services	$ 1,146	$ 1,245
Aggregate amount of gains on the exercise of share options during the financial year in respect to qualifying services	—	—
Aggregate amount of the money or value of other assets under long term incentive schemes in respect to qualifying services	790	2,730
Total	$ 1,936	$ 3,975

The Company had no other employees apart from the directors during the financial year and the prior financial year. Total directors' share-based compensation charged to profit and loss was $2,716 and $2,441 for the years ended 31 December 2022 and 2021 respectively. All required disclosure items in section 305 - 306 of Companies Act 2014 are $0 for the years ended 31 December 2022 and 2021, other than those included in the table above.

See *Note 19: Key Management Compensation* to the Group's Notes to Consolidated Financial Statements for key management compensation.

NOTE 6: Intangible Assets (Amounts in $ thousands)

	Software	Total
Cost:		
At 31 December 2021	$ 59	$ 59
Additions	—	$ —
At 31 December 2022	$ 59	$ 59
Depreciation		
At 31 December 2021	$ 4	$ 4
Charge for the year	29	29
At 31 December 2022	33	$ 33
Net Book Value:		
At 31 December 2021	$ 55	$ 55
At 31 December 2022	$ 26	$ 26

NOTE 7: Financial Fixed Assets (Amounts in $ thousands)

Principal Company Investments - Subsidiary Undertakings

	Financial Fixed Assets
At 31 December 2020	**$ 422,836**
Deemed contributions of stock based compensation	7,638
At 31 December 2021	**$ 430,474**
Deemed contributions of stock based compensation	5,692
At 31 December 2022	**$ 436,166**

Avadel Pharmaceuticals plc has investments in the following subsidiary undertakings. All ownership related to subsidiaries is common equity. An impairment review was performed at the 31 December 2022, which considered the valuation of the Company's subsidiaries and net assets against other indicators of value, such as the overall group market capitalisation adjusted for control premium. No impairment charge was recorded during the year.

Direct Subsidiary Undertakings:	Country	Principal Activity	%
Avadel US Holdings Inc	USA	Marketing Services	100
Avadel France Holding SAS	France	Holding Company	100
Flamel Ireland Ltd	Ireland	Research & Development	100
Avadel Investment Company Limited	Cayman Islands	Investment Services	100
Avadel Finance Designated Activity Company	Ireland	Finance Services	100

Refer to *Note 23: Subsidiary Undertakings* of the Group's Notes to Consolidated Financial Statements for the full list of subsidiary undertakings for the Group and respective registered offices.

Avadel Pharmaceuticals plc accounts for share-based payments available to members within the Group as a deemed equity contribution and increases the value of their investment in subsidiary undertakings by the value associated with the share-based payment. In 2022 and 2021, the value associated with share-based payments provided to employees in subsidiary undertakings was $5,692 and $7,638, respectively.

NOTE 8: Debtors (Amounts in $ thousands)

	2022	2021
Amounts Falling Due Within One Year:		
Prepayments and accrued income	$ 685	$ 552
VAT receivable	114	116
Intercompany accounts receivable	53,847	42,807
Total	$ 54,646	$ 43,475
Amounts Falling Due After One Year:		
Prepayments	$ 141	$ 328
Total	$ 141	$ 328

At 31 December 2022, the outstanding intercompany receivable balances were comprised of a $10,087 (2021: $11,297) receivable from Avadel US Holdings and a $43,759 (2021: $31,510) receivable from Flamel Ireland Ltd.

NOTE 9: Creditors (Amounts in $ thousands)

	2022	2021
Amounts Falling Due Within One Year:		
Trade creditors	$ 326	$ 225
Accruals and other creditors	613	723
	$ 939	948

Trade creditors are repayable within 30 to 60 days of the amount owing.

NOTE 10: Called Up Share Capital (Amounts in $ thousands, except per share data)

	2022	2021
Authorised:		
25 deferred ordinary shares of €1.00 each at 31 December 2022 and 2021	$ 26	$ 26
500,000 ordinary shares of $0.01 each at 31 December 2022 and 2021	5,000	5,000
50,000 preferred shares of $0.01 each at 31 December 2022 and 2021	500	500
Allotted, Called Up and Fully Paid:		
25 deferred ordinary shares of €1.00 each at 31 December 2022 and 2021	$ 26	$ 26
62,878 and 58,620 ordinary shares of $0.01 each at 31 December 2022 and 2021, respectively	628	586
488 preferred shares of $0.01 at 31 December 2022 and 2021	5	5
Called up share capital presented as equity	$ 659	$ 617

The Board of Directors is authorized to issue preferred stock in series, and with respect to each series, to fix its designation, relative rights (including voting, dividend, conversion, sinking fund, and redemption rights), preferences (including dividends and liquidation) and limitations. We have 50,000 shares of authorized preferred shares, $0.01 nominal value, of which 488 are currently issued and outstanding as of 31 December 2022.

In 2022, 75 shares were issued as part of the employee share purchase plan for $221. In 2021, 17 shares were issued as part of employee share purchase for $94.

Called-up Share Capital - Ordinary

In fiscal 2022, the change in ordinary shares of $42 is the result of the issuance of $36 from the sale of shares through the at-the-market offering program, exercise of stock options of $4, vesting of restricted shares of $1, and issuance of shares through the employee share purchase plan of $1. In fiscal 2021, the change in ordinary shares of $3 is a result of the vesting of restricted shares of $2 and the exercise of stock options of $1.

NOTE 11: Other Reserves (Amounts in $ thousands)

Share premium

This reserve records the excess of the fair value of the consideration receivable for issued shares above the nominal value of shares issued. On 6 March 2017, following approval from the High Court, $317,254 of the Company's share premium can be treated as distributable reserves. This amount was transferred to the Profit and Loss Account.

In 2021, the share premium account increased due to the employee purchase plan issuance of $94 and the exercise of stock options of $168. In 2022, the share premium account increased due to the issuance of common stock through the Company's at-the-market offering program of $25,282, the exercise of stock options of $2,456 and employee purchase plan issuance of $221.

Other reserves

The increase in the balance as of 31 December 2021 was due to $8,872 of accumulated share-based compensation. The increase in the balance as of 31 December 2022 was due to $7,013 of accumulated share-based compensation, offset by $45 of amortized issuance costs.

NOTE 12: Guarantees (Amounts in $ thousands)

At 31 December 2022, Avadel Pharmaceuticals plc has provided guarantees to several financing and leasing agreements of certain of its subsidiaries. Material guarantees are as follows:

As set out in *Note 13: Long-Term Debt* to the Group's Notes to Consolidated Financial Statements, Avadel Pharmaceuticals plc is a guarantor to $134,875 of convertible loan notes issued by its subsidiary, Avadel Cayman Limited. At the balance sheet date the company assessed the likelihood being called upon to honor the guarantee as unlikely and accordingly no provision was made.

Avadel Pharmaceuticals plc is the guarantor of a lease agreement in the United States where Avadel Ireland Ltd leases office space in Chesterfield, Missouri.

Avadel Pharmaceuticals plc is the guarantor of a lease agreement in the United States where Avadel Ireland Ltd leases a production suite in Winchester, Kentucky.

NOTE 13: Post Balance Sheet Events

Note 22: Post Balance Sheet Events to the Group's Notes to Consolidated Financial Statements provides details of post balance sheet events. Avadel Pharmaceuticals plc was a party (along with other entities in the Group) to the listed post balance sheet event.

NOTE 14: Related Party Disclosures

The company has availed of the exemption provided in FRS 102 Section 33 "Related Party Disclosures" for wholly owned subsidiary undertakings whose voting rights are controlled within the group, from the requirements to give details of transactions with entities that are part of the group or investees of the group qualifying as related parties.

NOTE 15: Approval of the Financial Statements

The financial statements were approved and authorised for issue on 4 May 2023.