Avadel Pharmaceuticals plc

Annual Report
for the Year Ended 31 December 2023

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period _____ to _____

Commission file number: 001-37977

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland	**98-1341933**
State or other jurisdiction of incorporation or organization	**(I.R.S. Employer Identification No.)**
10 Earlsfort Terrace Dublin 2, Ireland D02 T380	**Not Applicable**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: +353-1-901-5201

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

Title of each class	Trading Symbol (s)	Name of exchange on which registered
American Depositary Shares*	AVDL	The Nasdaq Global Market
Ordinary Shares, nominal value $0.01 per share**	AVDL	The Nasdaq Global Market

* American Depositary Shares may be evidenced by American Depository Receipts. Each American Depositary Share represents one (1) Ordinary Share.

** Not for trading, but only in connection with the listing of American Depositary Shares. on The Nasdaq Global Market.

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

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

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

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

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

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

Large accelerated filer ☒ Accelerated filer ☐
Non-accelerated filer ☐ Smaller reporting company ☐
Emerging growth company ☐

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of voting stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was $1,459,121,731 based on the closing sale price of the registrant's American Depositary Shares as reported by the Nasdaq Global Market on June 30, 2023. Such market value excludes 781,680 ordinary shares, $0.01 per share nominal value, which may be represented by the registrant's American Depositary Shares, held by each officer and director and by shareholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

The number of the registrant's ordinary shares, $0.01 per share nominal value, outstanding as of February 26, 2024 was 90,576,998.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of either (a) a definitive proxy statement involving the election of directors or (b) an amendment to this Form 10-K, either of which will be filed within 120 days after December 31, 2023, are incorporated by reference into Part III of this Form 10-K.

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SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous material and other risks and uncertainties, including those described in Part I, Item 1A "Risk Factors" in this Annual Report on Form 10-K. The principal risks and uncertainties affecting our business include the following:

- Our business depends heavily on our ability to successfully commercialize LUMRYZ, our lead product, in the United States ("U.S.") and in other jurisdictions where we may obtain marketing approval. There is no assurance that our commercialization efforts with respect to LUMRYZ 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.
- Coverage and reimbursement may be limited or unavailable in certain market segments for LUMRYZ or any future products, if approved, which could make it difficult for us to sell LUMRYZ or any future products profitably.
- LUMRYZ may not maintain regulatory exclusivities, including orphan drug exclusivity, or the benefits of such exclusivities, which may adversely affect the sales of the product.
- LUMRYZ is 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 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.
- We incurred a net loss in 2023 and may incur a net loss in 2024; if we are not able to achieve profitability in the future, the value of our shares may fall.
- We may require additional financing, 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 ordinary shares and American Depositary Shares ("ADSs").
- The distribution and sales of LUMRYZ are subject to significant regulatory restrictions, including the requirements of a Risk Evaluation and Mitigation Strategy ("REMS") and safety reporting requirements, and these regulatory requirements subject us to risks and uncertainties, any of which could negatively impact sales of LUMRYZ.
- Disruptions at the U.S. Food and Drug Administration ("FDA"), the U.S. Drug Enforcement Administration 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.
- We rely, and intend to continue to rely, on a limited number of providers for the manufacture and supply of LUMRYZ, and if we experience problems with those 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.
- If we cannot adequately protect our intellectual property and proprietary information, we may be unable to effectively compete.
- If we are unable to maintain effective sales, marketing and distribution capabilities, or maintain agreements with third parties to market, sell and distribute LUMRYZ, our business, results of operations, financial condition and prospects will be materially and adversely affected.
- We cannot be certain that any product candidates will receive marketing approval. Without marketing approval, we will not be able to commercialize any product candidates.
- We may become involved in lawsuits to protect our products and/or enforce our patents or other intellectual property, which could be expensive, time consuming and/or unsuccessful.
- The price of ADSs representing our ordinary shares has been volatile and may continue to be volatile.

Cautionary Disclosure Regarding Forward-Looking Statements

This Annual Report on Form 10-K includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as "may," "will," "could," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," "continue," and similar expressions, or the negative of these terms, or similar expressions. Accordingly, these statements involve estimates, assumptions, risks and uncertainties which could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus, and in particular those factors referenced in the section "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

This Annual Report on Form 10-K contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. These statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- Our ability to successfully commercialize LUMRYZ (sodium oxybate) in the U.S. for the treatment of cataplexy or excessive daytime sleepiness ("EDS") in adults with narcolepsy;
- Our plans with respect to our commercial infrastructure and marketing, market access and commercial activities;
- Our ability to maintain and receive additional regulatory approvals for LUMRYZ in any other jurisdictions outside the U.S., and any related restrictions, limitations, and/or warnings in the label of LUMRYZ;
- Our expectations regarding the rate and degree of market acceptance for LUMRYZ;
- Our ability to enter into strategic partnerships for the commercialization, manufacturing and distribution of LUMRYZ in the U.S.;
- Our reliance on a single product, LUMRYZ;
- Our dependence on a limited number of suppliers for the manufacturing of LUMRYZ and certain raw materials used in LUMRYZ and any failure of such suppliers to deliver sufficient quantities of these raw materials, which could have a material adverse effect on our business, including commercialization of LUMRYZ in the U.S.;
- Our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness, issuance of equity, royalty-based financings, or through strategic financing or commercialization partnerships;
- Our expectations regarding the pricing and reimbursement of, and the extent to which patient financial assistance programs are utilized for, LUMRYZ;
- Our expectations about the potential market size and market participation for LUMRYZ;
- Our expectations regarding litigation related to LUMRYZ;
- Our expectations regarding our cash runway to support the commercialization of LUMRYZ in the U.S.;
- The potential impacts of inflation and rising interest rates on our business and future operating results;
- Our ability to hire and retain key members of our leadership team and other personnel;
- The potential impacts due to global political instability and conflicts, such as terrorism, civil unrest, war and natural disasters in foreign countries on our business, financial condition and results of operations; and
- Competition existing today or that may arise in the future.

These forward-looking statements are neither promises nor guarantees of future performance due to a variety of risks and uncertainties and other factors more fully discussed in the "Risk Factors" section in Part I, Item 1A of this Annual Report on Form 10-K and the risk factors and cautionary statements described in other documents that we file from time to time with the SEC. Given these uncertainties, readers should not place undue reliance on our forward-looking statements. These forward-looking statements speak only as of the date on which the statements were made and are not guarantees of future performance. Except as may be required by applicable law, we do not undertake to update any forward-looking statements after the date of this Annual Report or the respective dates of documents incorporated by reference herein or therein that include forward-looking statements, even if new information becomes available in the future.

NOTE REGARDING TRADEMARKS

We own various trademark registrations and applications, and unregistered trademarks, including, but not limited to, AVADEL™, LUMRYZ™ and RYZUP™. Trade names, trademarks and service marks of other companies appearing in this Annual Report are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Annual Report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

From time to time, we may use our website, LinkedIn or our X, formerly known as Twitter, account (@AvadelPharma) to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.avadel.com. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website, our LinkedIn posts or our Twitter posts are not incorporated into, and does not form a part of, this Annual Report.

PART I

Item 1. Business.

(Dollar amounts in thousands, except per-share amounts and as otherwise noted)

General Overview

Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel," the "Company," "we," "our," or "us") is a biopharmaceutical company. LUMRYZ is an extended-release formulation of sodium oxybate indicated to be taken once at bedtime for the treatment of cataplexy or EDS in adults with narcolepsy.

As of the date of this Annual Report, LUMRYZ is the only commercialized product in our portfolio. We continue to evaluate opportunities to expand our product portfolio.

LUMRYZ

LUMRYZ was approved by the FDA on May 1, 2023 for the treatment of cataplexy or EDS in adults with narcolepsy. In approving LUMRYZ, the FDA required a REMS for LUMRYZ to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in adults with narcolepsy outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of the drug. Under this REMS, healthcare providers who prescribe the drug must be specially certified; pharmacies that dispense the drug must be specially certified; and the drug must be dispensed only to patients who have enrolled in the LUMRYZ REMS and completed all REMS requirements including documentation of safe use conditions, among other requirements. 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, the 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. The orphan exclusivity will continue until May 1, 2030. In June 2023, we announced the U.S. commercial launch of LUMRYZ for the treatment of cataplexy or EDS in adults living with narcolepsy.

Numerous 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. We currently have numerous Orange Book listed patents.

We submitted a Supplemental New Drug Application ("sNDA") for LUMRYZ in the pediatric narcolepsy population in November 2023. The sNDA was accepted by the FDA in January 2024 and an approval decision is expected in September 2024.

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. Positive top line data from the REST-ON trial were announced on April 27, 2020.

Additionally, our open-label extension/switch study of LUMRYZ ("RESTORE") examined the long-term safety and maintenance of efficacy of LUMRYZ in patients with narcolepsy who participated in the REST-ON trial, as well as dosing and preference data for patients who switched from twice-nightly sodium oxybate to once-at-bedtime LUMRYZ, regardless of whether they participated in the REST-ON trial. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study. An interim safety analysis from the ongoing RESTORE study showed that LUMRYZ has generally been well-tolerated, with some patients receiving therapy for more than 18 months. In addition, interim data from RESTORE were presented demonstrating that a high proportion of patients switching from twice-nightly 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 switching from twice-nightly oxybate formulations had a stable dose equal to their starting dose. Subsequent interim data showed a preference (94.0%) for the once-at-bedtime dosing regimen. The last patient visit occurred in October 2023.

A discrete choice experiment ("DCE") 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.

Additional peer-reviewed publications have included data on improvement on disturbed nocturnal sleep ("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 over twenty years that sodium oxybate has been available.

At the 2023 SLEEP meeting, additional LUMRYZ data, including post-hoc analyses from the pivotal REST-ON trial, interim data from the open-label RESTORE study and real-world evidence regarding sodium oxybate utilization and co-morbidities were presented. At the World Sleep meeting in October 2023, these data were presented as encores, along with new post-hoc analyses from the REST-ON trial showing additional clinical efficacy data for LUMRYZ.

A second DCE among clinicians was published in May 2023, showing the dosing regimen was the most important driver of choice, with once-nightly preferred. Post-hoc analyses of narcolepsy Type 1 ("NT1") and Type 2 ("NT2") were also published, demonstrating consistent improvements regardless of narcolepsy type. A third plain language summary has been published; most recently evaluated the improvements of LUMRYZ on DNS.

We believe LUMRYZ has the potential to demonstrate improved dosing compliance, safety, and patient satisfaction over other treatment options 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.

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. A version of our MICROPUMP technology is being employed in LUMRYZ.

- 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.

Competition

Competition in the pharmaceutical and biotechnology industry continues to be intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies who have approved, or who are developing, niche branded or generic specialty pharmaceutical products or drug delivery platforms. 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.

LUMRYZ competes with 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. Generic pharmaceutical products will continue to play a large role in the U.S. healthcare system. LUMRYZ may face competition from manufacturers of generic twice-nightly oxybate formulations. In January 2023, Hikma Pharmaceuticals plc, announced that it launched an authorized generic version of Jazz Pharmaceuticals plc's ("Jazz") Xyrem (sodium oxybate). In July 2023, Amneal Pharmaceuticals, Inc. announced that it launched an authorized generic version of Jazz's Xyrem (sodium oxybate).

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.

Corporate Information

The Company was incorporated on December 1, 2015 as an Irish private limited company, and re-registered as an Irish public limited company, or plc, on November 21, 2016. Our registered address is at 10 Earlsfort Terrace, Dublin 2, Ireland and our phone number is +353-1-901-5201. We file annual, quarterly and current reports, proxy statements and other documents with the SEC under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our website is www.avadel.com, where we make available free of charge our reports (and any exhibits and amendments thereto) on Forms 10-K, 10-Q and 8-K as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. These filings are also available to the public at www.sec.gov. We do not incorporate the information on or accessible through our website into this Annual Report on Form 10-K.

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. Avadel France Holding SAS is the holding entity of Avadel Research SAS. A complete list of our subsidiaries can be found in Exhibit 21.1 to this Annual Report on Form 10-K.

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. We seek patent protection for our inventions and also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and develop competitive positions.

- Numerous 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 USPTO, as well as foreign 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 "Risk Factors" included in Part I, Item 1A of this Annual Report on Form 10-K.

Supplies and Manufacturing

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

The API in LUMRYZ, sodium oxybate, is a Schedule I controlled substance in the U.S., and the finished FDA-approved formulation of LUMRYZ is 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 both sodium oxybate and LUMRYZ in the U.S. Similar rules, restrictions and controls would apply to LUMRYZ in the event LUMRYZ is marketed outside of the U.S.

The API for LUMRYZ is currently manufactured by two source contract development and manufacturing organizations ("CDMOs") in the U.S. The LUMRYZ drug product for commercial lots is manufactured by one source CDMO in the U.S. and

one source CDMO outside of the U.S. We expect to continue to outsource the production of sodium oxybate and drug product for LUMRYZ to current good manufacturing practices ("cGMP") -compliant, DEA- and FDA-audited CDMOs pursuant to supply agreements. We may establish supply relationships with additional CDMOs to manufacture API and/or LUMRYZ.

Government Regulation

Government authorities in the U.S. at the federal, state, and local level and in other countries extensively regulate, among other things, the research and clinical development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, pricing, and export and import of drug products, such as those we are developing. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety, and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review, and approved by the regulatory authority.

Drugs are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable regulatory requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the regulatory authority's refusal to approve pending applications, withdrawal of an approval, clinical holds, untitled or warning letters, voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, debarment, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

U.S. Drug Development

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. Drugs are also subject to other federal, state, and local statutes and regulations. Drug candidates must be approved by the FDA through the New Drug Application ("NDA") process before they may be legally marketed in the U.S. The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of extensive preclinical, sometimes referred to as nonclinical, laboratory tests, animal studies, and formulation studies all performed in accordance with applicable regulations, including the FDA's good laboratory practice ("GLP") regulations;
- submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may begin and must be updated annually;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as good clinical practices ("GCPs") to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA for a new drug;
- a determination by the FDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the API and finished drug product are produced to assess compliance with the FDA's cGMP requirements;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the U.S.

The data required to support an NDA are generated in two distinct development stages: preclinical and clinical. The preclinical development stage generally involves synthesizing the active component, developing the formulation, and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology, and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the preclinical tests must comply with federal regulations, including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information,

analytical data, any available clinical data or literature, and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on patient safety and the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. The FDA also may impose a partial clinical hold that would limit a trial, for example, to certain doses, for a certain length of time or to a certain number of subjects. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the drug candidate to human subjects under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection, and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board ("IRB") at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

Clinical trials are generally conducted in three sequential phases that may overlap or be combined, known as Phase 1, Phase 2, and Phase 3 trials. Phase 1 trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the drug candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effects, tolerability, and safety of the drug. Phase 2 clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetics and pharmacodynamics information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase 3 trials generally involve large numbers of patients at multiple sites (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the efficacy of the drug for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the drug and provide an adequate basis for physician labeling. The duration of treatment is often extended to mimic the actual use of a drug during marketing. Generally, two adequate and well-controlled Phase 3 trials are required by the FDA for approval of an NDA. Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Additionally, written IND safety reports must be submitted to both the FDA and the qualified investigators for serious and unexpected adverse reactions, any findings from other clinical studies, tests in laboratory animals, *in vitro* testing that suggests a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2, and Phase 3 trials may not be completed successfully within any specified period, if at all. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies usually complete additional animal

studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, cGMPs impose extensive procedural, substantive, and recordkeeping requirements to ensure and preserve the long-term stability and quality of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

NDA and the FDA Review Process

Following trial completion, trial data are analyzed to assess safety and efficacy. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA, along with proposed labeling for the drug and information about the manufacturing process and facilities that will be used to ensure drug quality, results of analytical testing conducted on the chemistry of the drug, and other relevant information. The NDA is a request for approval to market the drug and must contain adequate evidence of safety and efficacy, which is demonstrated by extensive preclinical and clinical testing. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a drug, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug product for a particular indication or indications to the satisfaction of the FDA. FDA approval of an NDA must be obtained before a drug may be offered for sale in the U.S.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual prescription drug product program fee for human drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of an original NDA, the FDA reviews the application to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission, including for failure to pay required fees, and may request additional information. In this event, the application must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. The FDA typically makes a decision on whether to accept an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth, substantive review of the NDA. Under the performance goals established under the PDUFA, the FDA has agreed to review 90% of standard NDAs for new molecular entities ("NMEs") in ten months from the filing date and 90% of priority NME NDAs in six months from the filing date. The goals for reviewing standard and priority non-NME NDAs are ten months and six months, respectively, measured from the receipt date of the application. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMP to assure and preserve the drug's identity, strength, quality, and purity. The FDA may refer applications for novel drugs or drug candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. In the course of its review, the FDA may re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete.

Before approving an NDA, the FDA typically conducts a pre-approval inspection of the manufacturing facilities for the new drug to determine whether they comply with cGMPs. The FDA will not approve the drug unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process, and manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or additional pivotal clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies, or

manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, challenge the determination set forth in the letter by requesting a hearing, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret the same data differently than the applicant.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the U.S. If a drug receives marketing approval, the approval may be significantly limited to specific diseases, dosages, or patient subgroups, or the indications for use may otherwise be limited, which could restrict the commercial value of the drug. Further, the FDA may require that certain contraindications, warnings, precautions, or adverse events be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials, and surveillance to monitor the effects of approved drugs. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's safety and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription, or dispensing of drugs. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Pediatric Information and Exclusivity

Under the Pediatric Research Equity Act ("PREA"), as amended, an NDA or supplement to an NDA for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

A sponsor who is planning to submit a marketing application for a drug subject to PREA must submit an initial Pediatric Study Plan ("PSP") within 60 days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints, and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and/or other clinical development programs.

A drug product can also obtain pediatric exclusivity in the U.S., which is another type of regulatory market exclusivity in the U.S. Pediatric exclusivity, if granted, adds an additional six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued written request for such a trial.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects 200,000 or more individuals in the U.S., there is no reasonable expectation that the cost of developing and marketing the drug for this type of disease or condition will be recovered from sales in the U.S. Orphan drug designation entitles a party to potential financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

505(b)(2) New Drug Applications

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA pursuant to an NDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant, and for which the applicant has not obtained a right of reference. In addition, if the 505(b)(2) applicant can establish that reliance on the FDA's previous findings of safety and effectiveness is scientifically and legally appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional bridging studies or measurements, including clinical trials, to support the change from the previously approved reference drug. The FDA may then approve the new drug candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Post-Marketing Requirements

Following approval of a new drug, a pharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, establishment registration and drug listing, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse events with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as off-label promotion), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, the FDA takes the position that manufacturers may not market or promote such off-label uses. Modifications or enhancements to the drug or its labeling or changes of the site or process of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Prescription drug advertising is subject to federal, state, and foreign regulations. In the U.S., the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drugs and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act ("PDMA"), a part of the FDCA. The Drug Supply Chain Security Act ("DSCSA") was enacted in 2013 with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the U.S. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that culminated in November 2023. The FDA established a one-year stabilization period from November 2023 to November 2024 for trading partners to continue to build and validate interoperable systems and processes to meet certain requirements of the DSCSA. The law's requirements include the quarantine and prompt investigation of a suspect product to determine if it is illegitimate, and notifying trading partners and the FDA of any illegitimate product. Drug manufacturers and other parties involved in the supply chain for prescription drug products must also comply with product tracking and tracking requirements, such as placing a unique product identifier on prescription drug packages. This identifier consists of the National Drug Code, serial number, lot number, and expiration date, in the form of a 2-dimensional data matrix barcode that can be read by humans and machines.

In the U.S., once a drug is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. FDA regulations require that drugs be manufactured in specific facilities per the NDA approval and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our approved drug and drug candidates in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural, and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories, or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute drugs manufactured, processed, or tested by them.

The FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may require revisions to the approved labeling to add new safety information, including the addition of new warning and contraindications; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- mandated corrective advertising or communications with doctors;
- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals;
- drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

U.S. Marketing Exclusivity

Marketing exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications for competing products. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA") or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) applications for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Other Regulatory Matters

Manufacturing, sales, promotion, and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the U.S., the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services ("HHS"), the DEA for controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. In the U.S., sales, marketing, and scientific/educational programs must also comply with state and federal fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (or collectively, the "ACA"). If drugs are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion, and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

We are subject to numerous foreign, federal, state, and local environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. In addition, our leasing and operation of real property may subject us to liability pursuant to certain U.S. environmental laws and regulations, under which current or previous owners or operators of real property and entities that disposed or arranged for the disposal of hazardous substances may be held strictly, jointly, and severally liable for the cost of investigating or remediating contamination caused by hazardous substance releases, even if they did not know of and were not responsible for the releases.

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

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines, or other penalties, injunctions, voluntary recall or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with the FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of our approved drug or any future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our product; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other Regulation

Controlled Substances Regulations

Narcotics and other APIs, such as sodium oxybate, are "controlled substances" under the CSA. The CSA Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, regulates the manufacture and distribution of narcotics and other controlled substances, including stimulants, depressants and hallucinogens in the U.S. The CSA is administered by the DEA, a division of the U.S. Department of Justice, and is intended to prevent the abuse or diversion of controlled substances into illicit channels of commerce. The DEA classifies controlled substances into five schedules. Schedule I substances by definition have a high potential for abuse, have 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. may be 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. The API in LUMRYZ, sodium oxybate, is a Schedule I controlled substance in the U.S., and the FDA-approved LUMRYZ product is a Schedule III controlled substance in the U.S.

For drugs manufactured in the U.S., the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the U.S. based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The quotas apply equally to the manufacturing of the API and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year, and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether to make such adjustments for individual companies.

The DEA limits the quantity of certain Schedule I controlled substances that may be manufactured and procured in the U.S. in any given calendar year through a quota system and, as a result, quotas from the DEA are required in order to manufacture sodium oxybate in the U.S.

The FDA-approved LUMRYZ product is classified as a Schedule III controlled substance and subject to DEA quota requirements as well as state and federal regulations relating to manufacturing, storage, distribution and physician prescription procedures, including limitations on prescription refills. In addition, the third parties who perform our clinical and commercial manufacturing, distribution, dispensing and clinical studies for LUMRYZ are required to maintain necessary DEA registrations and state licenses. The DEA periodically inspects facilities for compliance with its rules and regulations.

Any person or firm that manufactures, distributes, dispenses, imports, or exports any controlled substance (or proposes to do so) must register with the DEA. The applicant must register for a specific business activity related to controlled substances, including manufacturing or distributing, and may engage in only the activity or activities for which it is registered. The DEA

conducts periodic inspections of registered establishments that handle controlled substances. Failure to comply with relevant DEA regulations, particularly as manifested in the loss or diversion of controlled substances, can result in regulatory action including civil penalties, refusal to renew necessary registrations, or proceedings to revoke those registrations. In certain circumstances, violations can lead to criminal prosecution. In addition to these federal statutory and regulatory obligations, there may be state and local laws and regulations relevant to the handling of controlled substances or listed chemicals. Governments outside of the U.S. have similar controlled substance laws, regulations and requirements in their respective jurisdictions.

Healthcare Laws

Healthcare providers and third-party payors in the U.S. and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act ("FCA"), which may constrain the business or financial arrangements and relationships through which companies research, sell, market and distribute pharmaceutical products. In addition, transparency laws and patient privacy laws can apply to the activities of pharmaceutical manufactures. The applicable federal, state and foreign healthcare laws and regulations that can affect a pharmaceutical company's operations include without limitation:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but such exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;

- The federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement, including providing inaccurate billing or coding information to customers or promoting a product off-label, material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose, among other things, specified

requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- The federal legislation commonly referred to as the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- Analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

In the U.S., to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the ACA's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the Office of Inspector General ("OIG") of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use

of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance.

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, operations and financial condition. Factors that payors consider in determining reimbursement are based on whether the product is (i) a covered benefit under its health plan; (ii) safe, effective, and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational. Additionally, a third-party payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company’s revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

In both the U.S. and certain foreign jurisdictions, there have been, and continue to be, a number of legislative and regulatory changes to the health care system. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In particular, in 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected

manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

In addition, other legislative and regulatory changes have been proposed and adopted in the U.S. since the ACA was enacted:

- The U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031.

- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

- On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.

These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for our product and any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product or product candidate is prescribed or used.

There has been heightened governmental scrutiny in the U.S. of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. In August 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. The IRA includes several provisions that may impact our business, depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

In addition, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through the FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

Individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical 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.

Human Capital Resources

At Avadel, the way we work is as important as the results we achieve. Our global organization fosters an entrepreneurial environment, where purpose, innovation, integrity, and collaboration come together to transform medicines to transform lives. Our organization fosters our culture based on being relentless for patients, having confidence with humility, being courageous, taking insight to impact and togetherness (the "Avadel Values"). In everything we do, we live the Avadel Values so we can be the best for our patients, our community, and each other. Success for us is defined through how we improve the lives of patients and how we achieve our objectives as one team.

We are committed to offering employees a rewarding and entrepreneurial work experience where patients are at the center of everything we do. Our people are our greatest competitive advantage, and our values serve as the foundation of our culture. We consider our relations with our employees to be good and are focused on maintaining a highly engaged and motivated workforce.

Employee Demographics

As of December 31, 2023, we had 154 full-time employees. None of our employees are subject to a union or other collective bargaining agreement. In addition to our employees, we contract with third parties in certain areas of the business such as clinical, regulatory, and manufacturing. We expect to continue to build and grow our organizational capabilities with a focus on talent attraction, development, engagement, and retention.

Diversity, Equity, and Inclusion

Avadel is committed to fostering a diverse workforce and a culture of inclusion. Avadel pursues fair employment practices in every aspect of its business and is committed to a productive work environment for its employees. We strive to create a level of connectivity that goes beyond working together. Rooted in the trust we earn every day, our team is inclusive, valuing diverse perspectives and work every day to lift each other up in pursuit of improving the lives of the patients we serve.

Avadel is committed to facilitating an open, honest, inclusive, transparent, and productive work environment where we work together as ONE team and ONE culture to be our best for patients, customers, and each other. Avadel is committed to equal employment opportunities and non-discrimination in employment. We believe that all employees and applicants should be treated with courtesy, dignity, and respect. Avadel does not discriminate in employment on the basis of race, color, religion, sex, sexual orientation, national origin, age, disability, genetic information, marital status, ancestry, gender, gender identity, pregnancy, status as a covered veteran, or any other characteristic protected by federal, state, and/or local law. It is our intent to comply with federal, state, and local laws, regulations, and guidelines in our employment practices and in our service to our clients. This policy applies to all terms and conditions of employment including, but not limited to, hiring, placement, promotion, termination, layoff, recall, transfer, leaves of absence, compensation, and training.

Compensation and Benefits

At Avadel, we prioritize the well-being of our employees by offering a comprehensive benefits package. We know that benefits play an important role in helping to ensure the health and financial security of our employees.

Our commitment to our employees includes benefit and compensation programs that value the contributions our employees make. We strive to provide pay, benefits, and services that are competitive and create incentives to attract and retain employees. In addition to competitive pay, we offer bonus and share-based compensation packages for all levels of employees within the organization as well as a company match for employee retirement programs.

Health and Wellness

Our healthcare plans allow employees to choose what works best for them and their families. We offer competitive health, dental, vision and life insurance for all employees as well as competitive vacation packages along with time off for holidays and other forms of leave for all employees. Further, we offer a variety of tools allowing employees to prioritize wellness, including retirement planning, employee stock purchase program, legal services, employee assistance programs, and more.

Career Growth and Development

We are invested in the development of each of our employees. We provide opportunities to lead and participate in cross-functional teams, coaching, leadership development, and more. We provide reimbursement to our employees for seminars, conferences and educational and professional training. In alignment with our business strategy, it is our goal to empower all employees to take full advantage of their professional growth opportunities, to lead them to long-term job satisfaction and organizational success. Through professional development, our employees can broaden their skills for their current and future roles.

Item 1A. Risk Factors.

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 or incorporated by reference in this Annual Report on Form 10-K, 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. In addition, please read "Cautionary Disclosure Regarding Forward-Looking Statements" in this Annual Report on Form 10-K, where we describe additional uncertainties associated with Avadel's business and with the forward-looking statements included or incorporated by reference in this Annual Report on Form 10-K. Please note that additional risks not presently known to us or that we currently deem immaterial may also impair Avadel's business and operations.

Risks Related to the Commercialization of Our Lead Product

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 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.

In May 2023, LUMRYZ was approved by the FDA for treatment of cataplexy or EDS in adults with narcolepsy. 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. 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 have built 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 and challenges in 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 and generate sufficient revenues to result in a profit, include:

- the acceptance of LUMRYZ by patients and the medical community;
- the differentiation of LUMRYZ from other available approved or investigational drugs and treatments for cataplexy or EDS in adults with narcolepsy;
- 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 in the absence of coverage and/or adequate reimbursement from third-party payors;
- 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, to 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 prevalence, duration and severity of potential side effects or other safety issues that patients may experience with LUMRYZ;
- 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; 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 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. 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.

On March 29, 2023, we entered into a royalty purchase agreement ("RPA") with RTW Investments, L.P. ("RTW") that could provide us up to $75,000 of royalty financing in two tranches. The first tranche of $30,000 became available upon satisfaction of certain conditions which included our first shipment of LUMRYZ. The second tranche is available to use, at our election, if we achieve quarterly net revenue of $25,000 by the quarter ending June 30, 2024. The second tranche expires if we do not elect to use it by August 31, 2024. On August 1, 2023, we received the first tranche of $30,000. As a result of receiving the first tranche, we are required to make quarterly royalty payments calculated as 3.75% of worldwide net product revenue of LUMRYZ, up to a total payback of $75,000. Even if we are able to successfully commercialize LUMRYZ, certain obligations we have to third parties, including, without limitation, our obligation to pay RTW royalties on certain LUMRYZ revenues under the RPA may reduce our profitability. 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.

If we are unable to establish effective sales, marketing and distribution capabilities for LUMRYZ or enter into agreements with third parties to market, sell and distribute LUMRYZ, 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 received final approval from the FDA for LUMRYZ in May 2023 for the treatment of cataplexy or EDS in adults with narcolepsy. We are continuing to build the systems, processes, policies, relationships and materials necessary for the successful commercialization of LUMRYZ in the U.S. for the treatment of cataplexy or EDS in adults with narcolepsy. 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 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 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 a formulation of sodium oxybate approved by the FDA 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, and our expectations with regard to LUMRYZ's potential to take

share of this market segment as well as attract oxybate-naïve patients and patients who have previously discontinued twice-nightly oxybate treatment. 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 and our ability to achieve and maintain profitability and, as a consequence, our business may suffer.

LUMRYZ may not gain market acceptance.

LUMRYZ may not gain market acceptance among physicians, patients, healthcare payors and medical communities. The degree of market acceptance of LUMRYZ 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, including the REMS or any other equivalent obligation by other regulatory authorities, patient registry requirements or labeling restrictions;
- the prevalence of narcolepsy-related EDS and cataplexy in adults in the U.S.;
- scheduling classification of sodium oxybate as a controlled substance regulated by the DEA;
- demonstration of the clinical safety and efficacy of LUMRYZ;
- the absence of evidence of undesirable side effects of LUMRYZ that delay or extend trials for additional indications or in geographies outside the U.S.;
- acceptance by physicians and patients of LUMRYZ 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;
- 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 fails to achieve market acceptance, our ability to generate revenue will be limited, which would have a material adverse effect on our business.

LUMRYZ is 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 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.

LUMRYZ, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for LUMRYZ, is 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 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 or any future product candidates we may develop, if approved, would adversely affect sales of our products. For example, 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. In January 2023, Hikma Pharmaceuticals plc, announced that they launched an authorized generic version of Jazz's Xyrem (sodium oxybate). In July 2023, Amneal Pharmaceuticals, Inc. announced that it launched an authorized generic version of Jazz's Xyrem (sodium oxybate). 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 LUMRYZ or any future product candidates, the sales of LUMRYZ and any future 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 product or any future 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 product or any future 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. Competition from generic equivalents to our product or any future product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our product or any future product candidates.

With the passage of the CREATES Act, we are exposed to possible litigation and damages by competitors who may claim that we are not providing sufficient quantities of our approved products on commercially reasonable, market-based terms for testing in support of their ANDAs and 505(b)(2) applications.

In December 2019, former President Trump signed legislation intended to facilitate the development of generic and biosimilar products. The bill, previously known as the CREATES Act, authorizes sponsors of ANDAs and 505(b)(2) applications to file lawsuits against companies holding NDAs that decline to provide sufficient quantities of an approved reference drug on commercially reasonable, market-based terms. Drug products on FDA's drug shortage list are exempt from these new provisions unless the product has been on the list for more than six continuous months or the FDA determines that the supply of the product will help alleviate or prevent a shortage. For the purposes of the statute, the term "commercially reasonable, market-based terms" is defined as (1) the nondiscriminatory price at or below the most recent wholesale acquisition cost for the product, (2) a delivery schedule that meets the statutorily defined timetable, and (3) no additional conditions on the sale.

To bring an action under the statute, an ANDA or 505(b)(2) sponsor must take certain steps to request the reference product, which, in the case of products covered by a REMS with elements to assure safe use (such as LUMRYZ), include obtaining authorization from the FDA for the acquisition of the reference product. If the sponsor does bring an action for failure to provide a reference product, there are certain affirmative defenses available to the NDA holder, which must be shown by a preponderance of evidence. If the sponsor prevails in litigation, it is entitled to a court order directing the NDA holder to provide, without delay, sufficient quantities of the applicable product on commercially reasonable, market-based terms plus reasonable attorney fees and costs.

Additionally, the statutory provisions authorize a U.S. federal court to award the product developer an amount "sufficient to deter" the NDA holder from refusing to provide sufficient product quantities on commercially reasonable, market-based terms if the court finds, by a preponderance of the evidence, that the NDA holder did not have a legitimate business justification to delay providing the product or failed to comply with the court's order.

Although we intend to comply fully with the terms of these new statutory provisions, we are still exposed to potential litigation and damages by competitors who may claim that we are not providing sufficient quantities of our approved products on commercially reasonable, market-based terms for testing in support of ANDAs and 505(b)(2) applications. Such litigation

would subject us to additional costs, damages and reputational harm, which could lead to lower revenues. The CREATES Act may enable generic competition with LUMRYZ and any of our future product candidates, if approved, which could impact our ability to maximize product revenue.

If we cannot keep pace with the rapid technological change in our industry, we may lose business, and LUMRYZ or future 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 and any future product candidates. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our product and any future product candidates or technologies obsolete or noncompetitive.

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 U.S. 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. See the section entitled, "*Business — Government Regulation — Healthcare laws*".

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 LUMRYZ or any future products, if approved, which could make it difficult for us to sell LUMRYZ or any future products profitably.

The success of LUMRYZ or any future products, 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 products or assure that coverage and reimbursement will be available for any product that we may develop, such as LUMRYZ. See the section entitled, "*Business — Government Regulation — Coverage and Reimbursement*".

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 U.S., 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 U.S., 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 products 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 future product candidates, once approved.

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 U.S. 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 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 U.S. 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 products. 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 may be adopted in the future that may result in more rigorous coverage criteria and in additional downward pressure on the price 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 products, if any, may be.

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 company 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 our product or any of our future products. 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. See the section entitled, "*Business — Government Regulation — Healthcare Reform*".

Moreover, increasing efforts by governmental and third-party payors in the U.S. 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 or any future products. 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 product and any future products or put pressure on our product 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 our product and any future products or the frequency with which any such products are prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

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

We participate in the U.S. Department of Veterans Affairs, Federal Supply Schedule ("FSS") pricing program, and the Tricare Retail ("Tricare") Pharmacy program and have obligations to report the average sales price for certain of our drugs. Pricing and rebate calculations are complex, varying across products and programs, and are often subject to interpretation by us,

governmental or regulatory agencies and the courts, which can change and evolve over time. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price or if we fail to submit the required price data on a timely basis. We cannot assure you that our submissions will not be found to be incomplete or incorrect.

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

LUMRYZ may be found to cause undesirable side effects that limit the commercial profile or result in other significant negative consequences or delay or prevent further development or regulatory approval with respect to new indications, or cause regulatory authorities to require labeling statements, such as boxed warnings.

Undesirable side effects caused by LUMRYZ 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, denial or withdrawal 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. For example, we anticipate initiating a clinical trial for LUMRYZ in idiopathic hypersomnia. If any participants in the trial report any serious adverse events 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 adversely affected. If we or others identify undesirable side effects caused by LUMRYZ (or any other drug), a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their marketing approval of such drug;
- 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 drug;
- we may be required to change the way such drugs are distributed or administered, conduct additional clinical trials or change the labeling of the drug;
- 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 the drug from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking the drug; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of LUMRYZ 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, we may not promote LUMRYZ in the U.S. for any indications other than for the treatment of cataplexy or EDS in adults with narcolepsy. 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, while the FDA granted full approval of LUMRYZ in May 2023 for the treatment of cataplexy or EDS in adults with narcolepsy in the U.S., comparable regulatory authorities in foreign jurisdictions may not approve LUMRYZ in those countries for the same or similar indication, if at all. 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") and its Irish equivalent, prohibits any 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 company to maintain books and records that accurately and fairly reflect all transactions of the company, 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 LUMRYZ to other available therapies. If we seek approval for LUMRYZ outside of the U.S. and reimbursement of LUMRYZ 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.

We may expend our limited resources to pursue a particular indication and fail to capitalize on indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial, managerial and research and development resources, we must prioritize our research programs and will need to focus LUMRYZ on the potential treatment of certain indications or in certain populations. As a result, we may forego or delay pursuit of opportunities for other populations or indications that later prove to have greater commercial potential. For example, we anticipate initiating a clinical trial for LUMRYZ in idiopathic hypersomnia in 2024. Our resource allocation decisions may cause us to fail to capitalize on profitable market opportunities. Our spending on current and future research and development programs, including evaluating LUMRYZ in additional indications, may not yield any commercially viable products or result in additional approvals for LUMRYZ. If we do not accurately evaluate the commercial potential or target market for LUMRYZ, we may also relinquish valuable rights to LUMRYZ through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to LUMRYZ. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Product Candidate Development

Clinical development of drugs is costly and time-consuming, and the outcomes are uncertain. A failure to prove that LUMRYZ or any future product candidates are 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.

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 our candidates for use in clinical trials.

We cannot be certain that a product candidate will receive marketing approval. Without marketing approval, we will not be able to commercialize a product candidate.

We may devote significant financial resources and business efforts to the development of product candidates. We cannot be certain that any current 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 a product candidate 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 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 a 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 candidate. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. Any delay or setback in obtaining final approval or the commercialization of a product candidate may 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 may select, as applicable, for a product candidate;
- could determine that the information provided was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of a 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 a 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 a 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 a 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 a 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 a 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 a 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 received marketing approval from the FDA for LUMRYZ in the U.S. and will evaluate filing potentially elsewhere. We 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, was the appropriate pathway for the LUMRYZ NDA. There can be no assurances, however, that similar approval pathways outside of the U.S., will be available for LUMRYZ or that the FDA or other regulatory authorities will approve any future product candidates through an application based on such pathways. We have also submitted a sNDA for LUMRYZ in the pediatric narcolepsy population in November 2023. The sNDA was accepted by the FDA in January 2024 and an approval decision is expected in September 2024. We cannot be certain this sNDA will be approved by the FDA.

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 analysis, 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 a product candidate.

Our current 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 successful commercialization of new drugs and products that utilize our drug delivery technologies.

Even if product candidates and 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;
- 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
- 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.

Risks Related to Our Financial Position and Capital Requirements

We incurred a net loss in 2023 and may incur a net loss in 2024, 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 $160,276 for the year ended December 31, 2023. We may not 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 in the U.S. We have devoted significant financial resources to research and development, including our clinical development activities, the pursuit of regulatory approval and commercial launch for LUMRYZ. Our future revenues will depend upon the size of any markets in which LUMRYZ and any future products receive 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 have significantly increased our sales organization and supporting commercial infrastructure to support the commercial launch of LUMRYZ and, accordingly, we will continue to incur significant expenses related to the commercialization of LUMRYZ. Because of the numerous risks and uncertainties associated with the commercialization of 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:

- 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;
- the timely receipt of approval for the commercialization of LUMRYZ outside the U.S.;
- the potential expansion of LUMRYZ into other populations;
- 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; and
- general economic conditions.

Even though the FDA granted final approval of our NDA for LUMRYZ in May 2023 for the treatment of cataplexy or EDS in adults with narcolepsy, 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 successfully commercialize LUMRYZ 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 commercialization of LUMRYZ and possible development or 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 commercialize LUMRYZ. 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 our product or future 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, future debt agreements or other financing arrangements may include 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 or 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. If we are unable to obtain renewal of such authorization from our shareholders, our ability to use our authorized but unissued share capital to effect or to obtain additional financing, could be adversely affected. 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 $160,276 in 2023. We reported cash used in operating activities of $128,511. Cash and marketable securities as of December 31, 2023 totaled $105,111. Our business strategy is to primarily focus on the commercialization of LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy in the U.S. 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. 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.

Risks Related to Regulation

The distribution and sale of LUMRYZ are subject to significant regulatory restrictions, including the requirements of a REMS and safety reporting requirements, and these regulatory requirements subject us to risks and uncertainties, any of which could negatively impact sales of LUMRYZ.

The API of LUMRYZ is sodium oxybate, 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, maintain a REMS to help ensure that the benefits of the drug outweigh the serious risks of the drug. As a part of the final approval granted by the FDA for LUMRYZ, the FDA required a REMS for LUMRYZ, which, among other requirements, imposes controls and restrictions on the distribution of the product in the U.S. Any failure to demonstrate our substantial compliance with such REMS obligations, including as a result of business or other interruptions, 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 in the future. 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 in the U.S.

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 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 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.

LUMRYZ may not maintain regulatory exclusivities, including orphan drug exclusivity, or the benefits of such exclusivities, which may adversely affect the sales of the product.

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 to the first approved orphan drug through greater safety, greater effectiveness, or a major contribution to patient care.

LUMRYZ obtained orphan drug designation for the treatment of narcolepsy from the FDA in January 2018. Upon the approval of LUMRYZ in May 2023 by the FDA for the treatment of cataplexy or EDS in adults with narcolepsy and a finding of clinical superiority of LUMRYZ relative to marketed oxybate products, the FDA granted LUMRYZ seven years of orphan drug exclusivity. Accordingly, the FDA cannot approve a subsequent sponsor's same drug as LUMRYZ for the same indication until May 2030, subject to certain exceptions. Even though we have obtained orphan drug exclusivity for LUMRYZ, that exclusivity may not effectively protect LUMRYZ from competition because different drugs can be approved for the same condition. Moreover, there can be no assurance that third parties will not attempt to disrupt the commercialization of LUMRYZ through litigation. 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, sodium oxybate, is regulated by the DEA as a Schedule I controlled substance, and FDA-approved products containing sodium oxybate, including LUMRYZ, 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 or future product candidate(s). 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 product and any future product 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. for additional indications beyond what the FDA has already approved, 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. The annual quota allocated to us or our U.S. manufacturing partners for sodium oxybate may not be sufficient to meet commercial demand of LUMRYZ. 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 commercial activities and future development/clinical activities, which could have a material adverse effect on our business, financial position and results of operations.

LUMRYZ is classified as a Schedule III substance based on current applicable regulations, which allows 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 are required 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 conduct 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, for example, 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 we will be able to use the same proprietary name for a product in each jurisdiction where we market that product. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product 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. Final acceptance of a proposed proprietary name occurs as part of the final approval of a 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 a product.

Risks Related to our Reliance on Third Parties

We rely, and intend to continue to rely on a limited number of 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 a limited number of providers for the development, supply of clinical materials and supply of commercial batches for our product, 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 on a 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 demand. 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, and delays related to the supply chain),our manufacturing, clinical development or commercial activities of LUMRYZ (or any future product or product candidate) 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.

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 commercialization, and expect to continue to do so for any future products and product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of LUMRYZ or any future products or product candidates, 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 and commercial manufacture of LUMRYZ as well as any other future products and product candidates we develop. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development and 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 LUMRYZ and any future products and product candidates. If our CDMOs cannot successfully manufacture materials that conform to our specifications and the strict regulatory requirements of the FDA and any other applicable regulatory authorities, 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 LUMRYZ or any future products or product candidates, 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 market LUMRYZ or any future product or develop and obtain regulatory approval for any future product candidates, if granted final approval by the FDA or other applicable regulatory authority.

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 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, 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 a product or product candidate 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 a product or product candidate according to the specifications previously submitted to or approved by the FDA or other regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to commercialize a product or develop a product candidate in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of a product or product candidate that such CDMO owns independently. This would increase our reliance on such CDMO and may require us to obtain a license from such CDMO in order to have another CDMO manufacture the product or product candidate. In addition, in the case of CDMOs that supply a product or product candidate, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our supply from the prior CDMO and that of any new manufacturer.

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, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of a product or product candidates.

We may be unable to establish 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 non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

A product or product candidate we develop may compete with other product candidates and approved products of other parties 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, marketing approval or commercialization efforts. 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 LUMRYZ and any future products may adversely affect our future profit margins and our ability to commercialize such products 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 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.

We have substantially increased our number of employees over the last year, and we expect to expand our organization as a result of the commercialization of LUMRYZ. As a result, we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2023, we had 154 full-time employees. Our full-time employee base increased substantially in 2023 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 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 execute our business strategy. Our future financial performance and our ability to commercialize LUMRYZ 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 any 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 trials 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 trial 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 any 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 or the clinical development of any future product candidates. If the FDA or other foreign regulatory authorities determine 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 any future products. Such strategy involves risks that could impair our prospects for realizing profits from such products.

We expect that commercialization of LUMRYZ and any future products outside of the U.S. 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 foreign regulatory authorities, the potential market for LUMRYZ or any future products, 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 products, 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 any future product or 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 any future 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 develop future drug candidates, commercialize LUMRYZ outside of the U.S. or bring any future products to market and generate product revenue.

In addition, any future collaborations 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 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 product development process or commercializing the applicable product and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither party 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 LUMRYZ, as well as future products, 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 LUMRYZ, future products and product candidates, and technologies.

To the extent our product and any future products and 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 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 or any future product or product candidate. 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 or any future product or product candidate, 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 LUMRYZ or a future product or product candidate. Further, patent protection once obtained is limited in time, after which competitors may use the claimed invention 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 inventions and proprietary information 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.

We rely, in part, on confidentiality agreements with our employees, suppliers, consultants, advisors and partners to protect trade secrets, know-how and proprietary information related to, for example, current and future products, product candidates, and manufacturing processes. These agreements may not provide adequate protection for our trade secrets, know-how 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 trade secrets, know-how or other proprietary information, or that they will not gain access to our trade secrets, know-how or other proprietary information or disclose same to the public. Therefore, we cannot guarantee we can maintain and protect our trade secrets, know-how and other proprietary information. 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 current and future 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 current and future products. We and our partners may not be able to protect these trademarks and trade names. In addition, if the trademark or trade name for a product infringes the valid rights of others, we or our partners may be forced to stop using the trademark or trade name, 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 current and future products.

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 current or future product infringes 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 such product.

Third parties may claim infringement of their patents and other intellectual property rights by the manufacture, use, import, offer for sale or sale of a commercial product. Further, 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, future products or future product candidates 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 any future product candidates.

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, import, use, offer for sale 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. 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, the patent is removed from FDA's orange book 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, if approved, 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 any future product candidates, if approved, 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 the competitive position of our product or any future products 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 utility 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 or any future products 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, if approved, 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 and any future products and 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 and any future products, 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 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 Our Business and Industry

Our business could be adversely affected by the effects of health epidemics, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations.

Health epidemics in regions where we have concentrations of potential clinical trial sites or other business operations could adversely affect our business, including by causing significant disruption in the operations of third parties upon whom we rely. For example, the COVID-19 pandemic presented a substantial public health and economic challenge around the world and affected employees, patients, communities and business operations, as well as the economy and financial markets.

Health epidemics could continue to produce significant and prolonged disruption of, or volatility in, global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, to the extent the lingering effects of the COVID-19 pandemic adversely affect our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, ongoing military conflicts, including the conflict between Russia and Ukraine and the conflict in Israel, and high inflation and rising interest rates, any of which could have a material adverse effect on our business, financial condition and results of operations.

U.S. and global markets are experiencing volatility and disruption caused by economic uncertainty, including as a result of the ongoing Russia-Ukraine conflict and the effects of sanctions imposed on Russia as a result of the conflict, as well as the recent conflict in Israel and the Gaza Strip. In February 2022, a full-scale military invasion of Ukraine by Russian troops began. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine has led to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, which has contributed to record inflation globally. In addition, global markets may experience additional disruptions as a result of the current armed conflict in Israel and the Gaza Strip, with Israel having declared war on Hamas, a U.S. designated Foreign Terrorist Organization, due to recent attacks. We are continuing to monitor inflation, the situations in Ukraine and Israel and global capital markets and assessing their potential impact on our business, including the impact on the supply chains we rely on for the manufacture of LUMRYZ or other future product candidates.

Although, to date, our business has not been materially impacted by the events described above, geopolitical tensions, or record inflation, it is impossible to predict the extent to which our operations will be impacted in the short and long term, or the ways in which such matters may impact our business. The extent and duration of the conflicts in Ukraine and Israel, geopolitical tensions, record inflation and resulting market disruptions are impossible to predict but could be substantial. Any such disruptions may also magnify the impact of other risks we face.

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 or any future product or product candidate, 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 future product candidates, if approved, 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 any future products or technologies and subcontractors we engage or may engage for services related to the development and manufacturing of our product or any 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 may license any future product or 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 our product or future products, or claims related to clinical trials for any future product candidates.

The testing, including through clinical trials, manufacturing and marketing, and the use of our product and any future products and 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 manufacturing our current product or developing, or will develop, any 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, development and manufacturing activities involve the controlled use of potentially harmful biological and/or chemical materials, and are subject to U.S., EU, state, 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 representing our ordinary shares 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 December 31, 2023, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged from $6.41 to $16.48. During the year ended December 31, 2022, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged from $1.07 to $10.00. 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;
- the success of our LUMRYZ sales and anticipated product revenue;
- the success of competitive products or technologies;
- 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 technologies;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- adverse events related to LUMRYZ or any future products or product candidates;

- lack of efficacy of LUMRYZ or any future products or product candidates;
- litigation;
- decisions by our pharmaceutical and biotechnology company partners relating to 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 25%) 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.

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 Company 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 Company 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 company 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 company. Directors must not put themselves in a position in which their duties to the company and their personal interests conflict and must disclose any personal interest in any contract or arrangement with the company or any of our subsidiaries. A director or officer can be held personally liable to the company in respect of a breach of duty to the company.

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 Company.

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 U.S., 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 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 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 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 LUMRYZ, to fund 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 be at the sole discretion of our Board of Directors and 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 December 31, 2023, we had $212,426 of net operating losses in the U.S. Of the $212,426 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 $195,595 are due to the losses at Avadel US Holdings, Inc. The portion due to the acquisition of FSC will expire in 2034 through 2035 and will not be fully utilized before they expire.

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 December 31, 2023, we had approximately $111,647 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 December 31, 2023 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 2023 taxable year, but that our non-U.S. subsidiaries were CFCs in the 2023 taxable year. We anticipate that our non-U.S. subsidiaries will remain CFCs in the 2024 taxable year, and it is possible that we may become a CFC in the 2024 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 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 material weaknesses.

As a company, publicly-listed in the U.S., 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.

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 February 26, 2024, we had outstanding 90,577 ordinary shares, 5,194 ordinary shares issuable upon conversion of our preferred shares, options to purchase 10,246 ordinary shares or ADSs, with an average exercise price of $7.30, and unsettled restricted shares and performance shares relating to 38 ordinary shares. 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 any future product candidate development, commercialization activities for LUMRYZ and any future products, 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 and commercial materials.

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 Company'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.

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, the Federal Deposit Insurance Corporation ("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 Company, the financial institutions with which the Company 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 Company 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 Company'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 Company 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.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

At Avadel, we recognize the importance of assessing, identifying, and managing risks from cybersecurity threats. We have implemented a cybersecurity risk management process in accordance with our risk profile and business that is informed by industry standards.

We maintain cybersecurity policies and procedures as part of our overall risk management process. We leverage the support of third-party information technology and security providers, including for periodic security testing and risk assessments which are designed to identify, assess, and manage cybersecurity risks. We perform cybersecurity risk analyses of select third-party service providers and maintain an incident response and notification plan designed to assist us in identifying, responding to, and recovering from cybersecurity incidents.

We did not experience any material cybersecurity threats or incidents for the year ended December 31, 2023.

Governance Related to Cybersecurity Risk

Our Senior Director of Information Technology ("IT"), who reports to the Chief Financial Officer, is responsible for the strategic leadership and direction of the Company's cybersecurity program. The Senior Director of IT has over 30 years of professional experience in IT, including the development of data protection strategies, identification of cybersecurity matters, management of IT environments, (including corresponding data relied on in the environment), and timely deployment of responses to cybersecurity incidents. Further, the Senior Director of IT has education related qualifications specific to cybersecurity, including a Master of Science in Cybersecurity Management.

As part of the Company's incident response and notification plan, the Senior Director of IT has a process to assess potential cybersecurity incidents through a cybersecurity incident decision matrix. The Senior Director of IT escalates cybersecurity incidents to our Cybersecurity Response Committee, which consists of key members of executive management. The Cybersecurity Response Committee, informed by information and recommendations from the Senior Director of IT, determines appropriate actions and responses, as needed.

The audit committee of our Board of Directors has responsibility for oversight of the Company's cybersecurity risk management and receives cybersecurity updates from management at regularly scheduled meetings.

Item 2. Properties.

We have commercial and administrative activities located in Chesterfield, Missouri. Our current office space consists of 24,236 square feet, and the lease expires in 2025.

See "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this Annual Report on Form 10-K for more information regarding our investment activities and principal capital expenditures over the last two years.

Item 3. Legal Proceedings.

For information regarding legal proceedings we are involved in, see *Note 14: Contingent Liabilities and Commitments* to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Common Stock Data (per share):

The principal trading market for our securities in ADSs is the Nasdaq Global Market under the symbol "AVDL". There is no foreign trading market for our ordinary shares, ADSs or any other equity security issued by us. Each ADS represents one ordinary share, nominal value $0.01. The Bank of New York Mellon is the Depositary for the ADSs.

As of February 26, 2024, there were 90,577 ordinary shares outstanding, and our closing stock price was $12.99 per share.

Holders

As of February 26, 2024, there were 58 holders of record of our ordinary shares and accounts registered with The Bank of New York Mellon, the Depositary of our ADS program, as holders of ADSs, one of which is registered to the Depositary Trust Corporation ("DTC"). Because our ADSs are generally held of record by brokers, nominees and other institutions as participants in DTC on behalf of the beneficial owners of such ADSs, we are unable to estimate the total number of beneficial owners of the ADSs held by these record holders.

Dividends

We have never declared or paid a cash dividend on any of our shares and do not anticipate declaring cash dividends in the foreseeable future.

Equity Compensation Plan

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2023.

Recent Sales of Unregistered Securities

None.

Irish taxes applicable to U.S. holders

The following is a general summary of the main Irish tax considerations applicable to the purchase, ownership and disposition of our ordinary shares by U.S. holders. It is based on existing Irish law and practices in effect on February 26, 2024, and on correspondence with the Irish Revenue Commissioners. Legislative, administrative or judicial changes may modify the tax consequences described below.

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

Withholding tax on dividends

While we have no current plans to pay dividends, dividends on our ordinary shares would generally be subject to Irish dividend withholding tax ("DWT") at 25%, unless an exemption applies. In advance of payment of any dividends, we intend to seek confirmation from the Irish Revenue Commissioners that dividends on our ordinary shares that are owned by residents of the U.S. and held beneficially through the Depositary Trust Company ("DTC") would not be expected to be subject to DWT provided that the address of the beneficial owner of the ordinary shares in the records of the broker is in the U.S.

Dividends on our ordinary shares that are owned by residents of the U.S. and held directly (outside of DTC) will not be subject to DWT provided that the shareholder (a) where the shareholder is a body corporate, is not under the control of persons resident in Ireland and (b) has completed the appropriate Irish DWT form and this form remains valid. Such shareholders must provide the appropriate Irish DWT form to our transfer agent at least seven business days before the record date for the first dividend payment to which they are entitled.

If any shareholder who is resident in the U.S. receives a dividend subject to DWT, he or she should generally be able to make an application for a refund from the Irish Revenue Commissioners on the prescribed form.

Income tax on dividends

Irish income tax, if any, may arise in respect of dividends paid by us. However, a shareholder who is neither resident nor ordinarily resident in Ireland and who is entitled to an exemption from DWT, generally has no liability for Irish income tax or to the universal social charge on a dividend from us, unless he or she holds his or her ordinary shares through a branch or agency in Ireland which carries out a trade on his or her behalf.

Irish tax on capital gains

A shareholder who is neither resident nor ordinarily resident in Ireland and does not hold our ordinary shares in connection with a trade or business carried on by such shareholder in Ireland through a branch or agency, should not be within the scope of the charge to Irish tax on capital gains on a disposal of our ordinary shares.

A shareholder who is an individual and who is temporarily not resident in Ireland may, under Irish anti-avoidance legislation, still be liable for Irish tax on capital gains on any chargeable gain realized upon the disposal of our ordinary shares during the period in which such individual is a non-resident.

Capital acquisitions tax

Irish capital acquisitions tax ("CAT") is comprised principally of gift tax and inheritance tax. CAT could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares are regarded as property situated in Ireland as our share register must be held in Ireland. The person who receives the gift or inheritance has primary liability for CAT.

CAT is levied at a rate of 33% above certain tax-free thresholds. The appropriate tax-free threshold is dependent upon (i) the relationship between the donor and the recipient, and (ii) the aggregation of the values of previous gifts and inheritances received by the recipient from persons within the same category of relationship for CAT purposes. Gifts and inheritances passing between spouses are exempt from CAT. Children currently have a tax-free threshold of €335,000 in respect of taxable gifts or inheritances received from their parents. Our shareholders should consult their own tax advisers as to whether CAT is creditable or deductible in computing any domestic tax liabilities.

Stamp duty

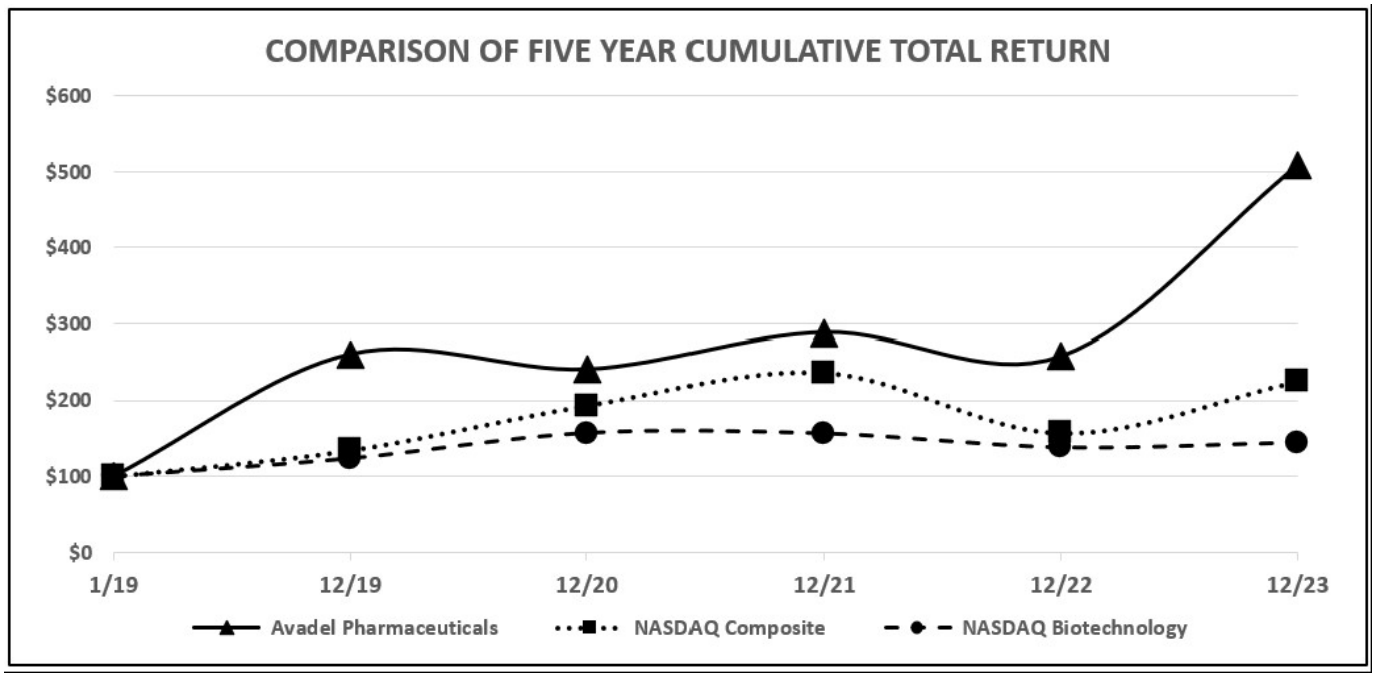
Irish stamp duty may become payable in respect of ordinary share transfers. However, a transfer of our ordinary shares from a seller who holds shares through DTC to a buyer who holds the acquired shares through DTC should not be subject to Irish stamp duty. A transfer of our ordinary shares (i) by a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

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

owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC, and in exactly the same proportions or vice-versa, as a result of the transfer and there is no agreement for the sale of the related book-entry interest or the ordinary shares or an interest in the ordinary shares, as the case may be, by the shareholder to a third party being contemplated.

Share Performance Graph

The following graph compares the cumulative 5-year return provided to shareholders of Avadel's ADSs relative to the cumulative total returns of the Nasdaq Composite Index and the Nasdaq Biotechnology Index. We believe these indices are the most appropriate indices against which the total shareholder return of Avadel should be measured. The Nasdaq Biotechnology Index has been selected because it is an index of U.S. quoted biotechnology and pharmaceutical companies. An investment of $100 (with reinvestment of all dividends) is assumed to have been made in our ADSs and in each of the indexes on January 1, 2019 and our relative performance is tracked through December 31, 2023. The comparisons shown in the graph are based upon historical data and we caution that the stock price performance shown in the graph is not indicative of, or intended to forecast, the potential future performance of our stock.



This performance graph shall not be deemed "filed" for purposes of Section 18 of the Exchange Act. Notwithstanding any statement to the contrary set forth in any of our filings under the Securities Act or the Exchange Act that might incorporate future filings, including this Annual Report on Form 10-K, in whole or in part, this performance graph shall not be incorporated by reference into any such filings except as may be expressly set forth by specific reference in any such filing.

Item 6. Reserved.

Not Applicable.

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

(In thousands, except per share data)

You should read the discussion and analysis of our financial condition and results of operations set forth in this Item 7 together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties, and reference is made to the "Cautionary Disclosure Regarding Forward-Looking Statements" set forth immediately following the Table of Contents of this Annual Report on Form 10-K for further information on the forward looking statements herein. In addition, you should read the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this Annual Report on Form 10-K.

Information pertaining to fiscal year 2021 was included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, on pages 69 through 82, under Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," which was filed with the SEC on March 29, 2023.

Overview

Nature of Operations

Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel," the "Company," "we," "our," or "us") is a biopharmaceutical company. LUMRYZ is an extended-release formulation of sodium oxybate indicated to be taken once at bedtime for the treatment of cataplexy or EDS in adults with narcolepsy.

As of the date of this Annual Report, LUMRYZ is the only commercialized product in our portfolio. We continue to evaluate opportunities to expand our product portfolio.

LUMRYZ

LUMRYZ was approved by the FDA on May 1, 2023 for the treatment of cataplexy or EDS in adults with narcolepsy. In approving LUMRYZ, the FDA required a REMS for LUMRYZ to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in adults with narcolepsy outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of the drug. Under this REMS, healthcare providers who prescribe the drug must be specially certified; pharmacies that dispense the drug must be specially certified; and the drug must be dispensed only to patients who have enrolled in the LUMRYZ REMS and completed all REMS requirements including documentation of safe use conditions, among other requirements. 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, the 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. The orphan exclusivity will continue until May 1, 2030. In June 2023, we announced the U.S. commercial launch of LUMRYZ for the treatment of cataplexy or EDS in adults living with narcolepsy.

Numerous 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. We currently have numerous Orange Book listed patents.

We submitted a Supplemental New Drug Application ("sNDA") for LUMRYZ in the pediatric narcolepsy population in November 2023. The sNDA was accepted by the FDA in January 2024 and an approval decision is expected in September 2024.

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. Positive top line data from the REST-ON trial were announced on April 27, 2020.

Additionally, our open-label extension/switch study of LUMRYZ ("RESTORE") examined the long-term safety and maintenance of efficacy of LUMRYZ in patients with narcolepsy who participated in the REST-ON trial, as well as dosing and preference data for patients who switched from twice-nightly sodium oxybate to once-at-bedtime LUMRYZ, regardless of whether they participated in the REST-ON trial. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study. An interim safety analysis from the ongoing RESTORE study showed that LUMRYZ has generally been well-tolerated, with some patients receiving therapy for more than 18 months. In addition, interim data from RESTORE were presented demonstrating that a high proportion of patients switching from twice-nightly 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 switching from twice-nightly oxybate formulations had a stable dose equal to their starting dose. Subsequent interim data showed a preference (94.0%) for the once-at-bedtime dosing regimen. The last patient visit occurred in October 2023.

A discrete choice experiment ("DCE") 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.

Additional peer-reviewed publications have included data on improvement on disturbed nocturnal sleep ("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 over twenty years that sodium oxybate has been available.

At the 2023 SLEEP meeting, additional LUMRYZ data, including post-hoc analyses from the pivotal REST-ON trial, interim data from the open-label RESTORE study and real-world evidence regarding sodium oxybate utilization and co-morbidities were presented. At the World Sleep meeting in October 2023, these data were presented as encores, along with new post-hoc analyses from the REST-ON trial showing additional clinical efficacy data for LUMRYZ.

A second DCE among clinicians was published in May 2023, showing the dosing regimen was the most important driver of choice, with once-nightly preferred. Post-hoc analyses of narcolepsy Type 1 ("NT1") and Type 2 ("NT2") were also published, demonstrating consistent improvements regardless of narcolepsy type. A third plain language summary has been published; most recently evaluated the improvements of LUMRYZ on DNS.

We believe LUMRYZ has the potential to demonstrate improved dosing compliance, safety, and patient satisfaction over other treatment options for cataplexy or EDS in patients with narcolepsy.

Key Business Trends and Highlights

In operating our business and monitoring our performance, we consider a number of performance measures, as well as trends affecting our industry as a whole, which include the following:

- **Healthcare and Regulatory Reform:** Various health care reform laws in the U.S. may impact our ability to successfully commercialize our products and technologies. The success of our commercialization efforts may depend on the extent to which the government health administration authorities, the health insurance funds in the E.U. Member States, private health insurers and other third-party payers in the U.S. will reimburse consumers for the cost of healthcare products and services.

- **Competition and Technological Change:** Competition in the pharmaceutical and biotechnology industry continues to be intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing niche branded or generic specialty pharmaceutical products or drug delivery platforms. 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.

- **Pricing Environment for Pharmaceuticals:** The pricing environment continues to be in the political spotlight in the U.S. As a result, the need to obtain and maintain appropriate pricing for pharmaceutical products may become more challenging due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide.

- **Generics Playing a Larger Role in Healthcare:** Generic pharmaceutical products will continue to play a large role in the U.S. healthcare system. LUMRYZ may face competition from manufacturers of generic twice-nightly sodium oxybate formulations. In January 2023, Hikma Pharmaceuticals plc, announced that it launched an authorized generic version of Jazz Pharmaceuticals plc's ("Jazz") Xyrem (sodium oxybate). In July 2023, Amneal Pharmaceuticals, Inc. announced that it launched an authorized generic version of Jazz's Xyrem (sodium oxybate).

- **Access to and Cost of Capital:** Similar to other businesses in our industry and at our stage of development, we will continue to rely on external sources of capital to fund our business. The process of raising capital and the associated cost of such capital for a company of our financial profile can be difficult and potentially expensive. If the need were to arise to raise additional capital, access to that capital may be difficult, expensive and/or dilutive and, as a result, could create liquidity challenges for us.

- **Continuing Net Loss from Operations:** We have a recent history of generating losses from operations and expect to continue generating losses until we are able to generate revenues sufficient to generate positive cash flow from the commercialization of LUMRYZ. LUMRYZ is the only commercialized product in our portfolio, and we will incur substantial expenses to continue our commercial launch of LUMRYZ.

Financial Highlights

Highlights of our consolidated results for the year ended December 31, 2023 are as follows:

- Net product revenue was $27,963 for the year ended December 31, 2023. LUMRYZ was approved by the FDA on May 1, 2023 and we began shipping product to our customers in June 2023.

- Operating loss was $137,849 for the year ended December 31, 2023 compared to operating loss of $98,561 for the year ended December 31, 2022. Selling, general & administrative expenses increased $77,189 during the year ended December 31, 2023, driven by increased headcount and costs associated with the commercial launch of LUMRYZ and higher legal fees. Research and development expenses decreased $7,439 during the year ended December 31, 2023, driven by lower pre-commercial LUMRYZ related costs of $11,500 that we began capitalizing to inventory in May 2023 upon FDA approval of LUMRYZ. Prior to FDA approval these costs were recorded as research and development expense. This was offset by an increase of $3,300 in pre-commercial product related costs for new research and development activity.

- Net loss was $160,276 for the year ended December 31, 2023 compared to net loss of $137,464 in the same period last year.

- Diluted net loss per share was $2.00 for the year ended December 31, 2023 compared to diluted net loss per share of $2.29 in the same period last year.

- Cash, cash equivalents and marketable securities increased by $8,612 to $105,111 at December 31, 2023 from $96,499 at December 31, 2022. This increase was driven primarily by net proceeds of $134,151 received in exchange for issuing 12,205 ordinary shares, nominal value $0.01 per share ("Ordinary Shares") in the form of ADSs and 4,706 Series B Non-Voting Convertible Preferred Shares ("Series B Preferred Shares") in the April 3, 2023 public offering, proceeds of $30,000 received for the first tranche of the royalty purchase agreement, net proceeds of $11,913 from the sale of ADSs through an Open Market Sale Agreement[SM] with Jefferies LLC ("Jefferies") with respect to an at-the-market offering program ("ATM Program") under which we may offer and sell our ADSs through Jefferies as our sales agent and $2,293 of proceeds from stock option exercises and employee share purchase plan issuances, offset by net cash used in operating activities of $128,511, cash settlement of $17,500 for our 4.50% exchangeable senior notes that matured in February 2023 (the "February 2023 Notes"), cash settlement of $21,165 for our 4.50% exchangeable senior notes that matured in October 2023 (the "October 2023 Notes") and debt issuance costs of $4,357.

Critical Accounting Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to use judgment in making estimates and assumptions that affect the reported amounts of assets and liabilities, disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the periods presented.

We have identified certain policies and estimates as critical to our business operations and the understanding of our past or present results of operations. These policies and estimates are considered critical because they had a material impact, or they have the potential to have a material impact, on our consolidated financial statements and because they require us to make significant judgments, assumptions or estimates. We believe that the estimates, judgments and assumptions made when accounting for the items described below were reasonable, based on information available at the time they were made. However, actual results may differ from those estimates, and these differences may be material. For a complete list of significant accounting policies, see *Note 1: Summary of Significant Accounting Policies* to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Revenue. We sell products to specialty pharmacies and consider those specialty pharmacies to be our customers. Under ASC 606, revenue from product sales is recognized when the customer obtains control of the product, which occurs typically upon receipt by the customer. Our gross product sales are subject to a variety of price adjustments to arrive at reported net product revenue. These adjustments include estimates of payment discounts, specialty pharmacy fees, patient financial assistance programs, rebates and product returns and are estimated based on contractual arrangements, historical trends, expected utilization of such products and other judgments and analysis.

Product Sales

Revenue from product sales are recognized when the customer obtains control of our product and our performance obligations are met, which occurs typically upon receipt of delivery to the customer. As is customary in the pharmaceutical industry, our gross product sales are subject to a variety of price adjustments in arriving at reported net product revenue. These adjustments include estimates of payment discounts, specialty pharmacy fees, patient financial assistance programs, rebates and product returns and are estimated based on contractual arrangements, historical trends, expected utilization of such products and other judgments and analysis.

Reserves for Variable Consideration

Revenues from product sales are recorded at the estimated net selling price, which includes reserves for estimated variable consideration to reduce gross product sales to net product revenue resulting from payment discounts, specialty pharmacy fees, patient financial assistance programs, rebates and product returns. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable if the amount is payable to the customer. The reserves are classified as a liability if the amount is payable to a party other than a customer. Where appropriate, these estimated reserves take into consideration relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, historical trends, current and expected patient demand and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates to reduce gross selling price to net selling price. The actual net selling price ultimately may differ from our estimates.

Payment Discounts and Specialty Pharmacy Fees

Payment discounts and specialty pharmacy fees represent the estimated obligations resulting from contractual commitments with our customers. We offer customers discounts off of list price and fees for the distribution of our products. Reserves for these discounts and fees are established in the same period that the related revenue is recognized, resulting in a reduction of gross product sales and accounts receivable.

Patient Assistance Programs

We offer certain patient assistance programs. We have multiple programs to assist patients, including patient financial assistance programs. We estimate a reserve for these patient financial assistance programs primarily based on expected utilization by patients. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of gross product sales.

Rebates

Rebates and other fees represent the estimated obligations resulting from agreements with payors. We estimate a reserve for rebates and other fees based on contractual rates and estimates regarding our expectations of future patient utilization rates. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of gross product sales.

Product Returns

We maintain a returns policy that offers customers a right to return product within a defined period before and after the expiration date of that product. We record the estimate of product returns as a reduction of gross product sales in the period the related product revenue was recognized.

Income Taxes. Our income tax (benefit) provision, deferred tax assets and liabilities, and liabilities for unrecognized tax benefits reflect management's best estimate of current and future taxes to be paid. We are subject to income taxes in Ireland, France and the U.S. Significant judgments and estimates are required in the determination of the consolidated income tax (benefit) provision.

Deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. In evaluating our ability to recover our deferred tax assets in the jurisdiction from which they arise, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income or loss, tax-planning strategies, and results of recent operations. The assumptions about future taxable income or loss require the use of significant judgment and are consistent with the plans and estimates we are using to manage the underlying businesses. The Company's cumulative loss position is 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 Company continues to record a full valuation allowance on its deferred tax assets in 2023. The Company 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 Company'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 calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in a multitude of jurisdictions across our global operations. A tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

We record unrecognized tax benefits as liabilities and adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available.

We have not recorded a deferred tax liability for any income or withholding taxes that may arise as the result of the distribution of unremitted earnings within our Company. As of December 31, 2023, we had unremitted earnings of $3,854 outside of Ireland as measured on a U.S. GAAP basis. Based on our estimates that future domestic cash generation will be sufficient to meet future domestic cash needs along with our specific plans for reinvestment, we have not recorded a deferred tax liability for any income or withholding taxes that may arise from a distribution that would qualify as a dividend for tax purposes. It is not practicable to estimate the amount of deferred tax liability on such remittances, if any. We believe that our estimates for deferred income taxes and the amount of benefits recognized for uncertain tax positions are appropriate based on current facts and circumstances.

Goodwill. Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. We elected to make November 30 the annual impairment assessment date for goodwill. However, we could be required to evaluate the recoverability of goodwill outside of the required annual assessment if, among other things, we experience disruptions to the business, unexpected significant declines in operating results, divestiture of a significant component of the business or a sustained decline in market capitalization.

We can test for goodwill impairment by first performing a qualitative assessment to determine whether a quantitative goodwill test is necessary or we can elect to forgo the qualitative assessment and perform the quantitative goodwill test. We elected to perform a qualitative assessment of goodwill in 2023. Upon performing the qualitative assessment of goodwill, qualitative factors are assessed to determine whether it is more likely than not that the fair value is less than the carrying amount. We elected to perform a quantitative goodwill test in 2022. Upon performing the quantitative goodwill test, if the carrying value of the reporting unit exceeds its fair value, an impairment loss is recognized in an amount equal to that excess, not to exceed the carrying amount of goodwill.

Based on the results of the annual qualitative assessment of goodwill for 2023, we concluded it is not more likely than not that the fair value of the reporting unit is less than the carrying amount and therefore, did not perform a quantitative goodwill test or record an impairment.

The Company continuously monitors for events and circumstances that could negatively impact the key assumptions in determining fair value. While the Company believes the judgments and assumptions used in the goodwill impairment assessment are reasonable, different assumptions or changes in general industry or market and macro-economic conditions could change the estimated fair values and, therefore, future impairment charges could be required, which could be material to the consolidated financial statements.

Results of Operations

The following is a summary of our financial results (in thousands, except per share amounts):

	Years Ended December 31,		Change 2023 vs. 2022	
Comparative Statements of Loss:	**2023**	**2022**	**$**	**%**
Net product revenue	$ 27,963	$ —	$ 27,963	n/a
Cost of products sold	846	—	846	n/a
Gross profit	27,117	—	27,117	n/a
Operating expenses:			—	
Research and development expenses	13,261	20,700	(7,439)	(35.9)%
Selling, general and administrative expenses	151,705	74,516	77,189	103.6 %
Restructuring expense	—	3,345	(3,345)	(100.0)%
Total operating expenses	164,966	98,561	66,405	67.4 %
Operating loss	(137,849)	(98,561)	(39,288)	39.9 %
Investment and other income (expense), net	87	(536)	623	(116.2)%
Interest expense	(9,886)	(12,342)	2,456	(19.9)%
Loss on extinguishment of debt	(13,129)	—	(13,129)	n/a
Loss before income taxes	(160,777)	(111,439)	(49,338)	44.3 %
Income tax (benefit) provision	(501)	26,025	(26,526)	(101.9)%
Net loss	$ (160,276)	$ (137,464)	$ (22,812)	16.6 %
Net loss per share - diluted	$ (2.00)	$ (2.29)	$ 0.29	(12.7)%

	Years Ended December 31,		Change 2023 vs. 2022	
Gross Profit:	**2023**	**2022**	**$**	**%**
Net product revenue	$ 27,963	$ —	$ 27,963	n/a
Cost of products sold	846	—	846	n/a
Gross profit	$ 27,117	$ —	$ 27,117	n/a
Gross profit as a percentage of net product revenue	97.0 %	n/a	97.0 %	n/a

Net product revenue was $27,963 during the year ended December 31, 2023. LUMRYZ was approved by the FDA on May 1, 2023 and we began shipping product to our customers in June 2023. Products sold during the year ended December 31, 2023 includes inventory that was expensed as research and development prior to FDA approval.

	Years Ended December 31,		Change 2023 vs. 2022	
Research and Development Expenses:	**2023**	**2022**	**$**	**%**
Research and development expenses	$ 13,261	$ 20,700	$ (7,439)	(35.9)%

Research and development expenses decreased $7,439 or 35.9% during the year ended December 31, 2023 as compared to the same period in 2022. This decrease was driven by lower pre-commercial LUMRYZ related costs of $11,500 that we began capitalizing to inventory in May 2023 upon FDA approval of LUMRYZ. Prior to FDA approval these costs were recorded as research and development expense. This was offset by an increase of $3,300 in pre-commercial product related costs for new research and development activity.

	Years Ended December 31,		Change 2023 vs. 2022	
Selling, General and Administrative Expenses:	**2023**	**2022**	**$**	**%**
Selling, general and administrative expenses	$ 151,705	$ 74,516	$ 77,189	103.6 %

Selling, general and administrative expenses increased $77,189 or 103.6% during the year ended December 31, 2023 as compared to the same period in 2022. This increase was driven primarily by higher costs associated with the commercial launch of LUMRYZ of $18,800, higher compensation costs of $18,700 due to increased headcount, higher marketing and market research activities of $17,000, and higher legal fees of $15,900. Selling, general, and administrative expenses during the year ended December 31, 2023 also includes a $7,800 cumulative adjustment for certain compensation awards tied to the achievement of performance conditions, which became probable during the year. We also incurred costs related to financing activities of approximately $1,300 in the current period.

In the prior period, we incurred costs of approximately $5,450 related to the exchange of $117,375 of our February 2023 Notes for a new series of October 2023 Notes that did not recur in the current period. In the prior period, we realized benefit from the reversal of approximately $2,300 of previously recorded compensation costs for employees affected by our 2022 corporate restructuring plan that was implemented in June 2022 and did not recur in the current period.

	Years Ended December 31,		Change 2023 vs. 2022	
Interest Expense:	**2023**	**2022**	**$**	**%**
Interest expense	$ (9,886)	$ (12,342)	$ 2,456	(19.9)%

Interest expense decreased $2,456 or 19.9% for the year ended December 31, 2023 as compared to the same period in 2022. This decrease was driven primarily by a $6,400 decrease in amortization of debt discount and debt issuance costs as a result of the extinguishment of $96,188 of our October 2023 Notes, offset by $3,743 increase in interest expense for our royalty financing obligation. See *Note 10: Long-term debt* and *Note 11: Royalty Financing Obligation* to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for further details.

	Years Ended December 31,		Change 2023 vs. 2022	
Loss on Extinguishment of Debt:	**2023**	**2022**	**$**	**%**
Loss on extinguishment of debt	$ (13,129)	$ —	$ (13,129)	n/a

Over the course of April 3 and April 4, 2023, we completed an exchange of $96,188 of our $117,375 October 2023 Notes for $106,268 of a new series of 6.0% exchangeable notes due April 2027 (the "April 2027 Notes"). We accounted for the exchange of the October 2023 Notes for the April 2027 Notes as an extinguishment of $96,188 of our October 2023 Notes. We recorded a loss on the extinguishment of $13,129 as a result of the exchange. See *Note 10: Long-term debt* to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for further details.

	Years Ended December 31,		Change 2023 vs. 2022	
Income Tax (Benefit) Provision:	**2023**	**2022**	**$**	**%**
Income tax (benefit) provision	$ (501)	$ 26,025	$ (26,526)	(101.9)%
Percentage of loss before income taxes	0.3 %	(23.4)%		

The income tax benefit was $501 for the year ended December 31, 2023 resulting in an effective tax rate of 0.3%. The income tax provision was $26,025 for the year ended December 31, 2022 resulting in an effective tax rate of (23.4)%. The change in the effective tax rate for the year ended December 31, 2023 when compared to the same period in 2022 is primarily driven by the valuation allowances recorded against net deferred tax assets established beginning in the second quarter of 2022.

Liquidity and Capital Resources

Overview of Sources and Uses of Cash

Our ability to generate revenue started following the launch of LUMRYZ in June 2023. For the twelve month period ending December 31, 2024, we project that our fixed commitments will include (i) payments on our royalty financing obligation, (ii) capital commitments, and (iii) lease payments. We project that our long-term fixed commitments will include (i) payments on our royalty financing obligation, (ii) capital commitments, and (iii) lease payments.

Risk Management

The adequacy of our cash resources depends on the outcome of certain business conditions including the cost of our LUMRYZ ongoing commercial launch, our cost structure, and other factors set forth in "Risk Factors" within Part I, Item 1A of this Annual Report on Form 10-K. We will need to commit substantial resources to support the commercialization of LUMRYZ 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 impacts of inflation, and rising interest rates, which may have a material adverse impact on our business.

We believe our existing cash, cash equivalents and marketable securities, along with cash anticipated from sales of LUMRYZ, provides sufficient capital to meet our operating, royalty obligation and capital requirements for the next twelve months following the date of this Annual Report.

Debt Arrangements

On February 1, 2023, we paid $17,500 in cash to settle the remaining principal balance of our February 2023 Notes.

Over the course of April 3 and April 4, 2023, we completed an exchange of $96,188 of our $117,375 October 2023 Notes for $106,268 of the April 2027 Notes. The remaining $21,187 aggregate principal amount of the October 2023 Notes matured on October 2, 2023 and were settled with a combination of cash and ADSs in October 2023. The aggregate amount of cash and ADSs delivered to holders for the October 2023 Notes, including accrued interest was $21,641 and 408 ADSs, respectively.

On May 31, 2023, we exercised our option to exchange (the "Mandatory Exchange") $106,268 of aggregate principal amount of the April 2027 Notes, which represents all of the April 2027 Notes outstanding under the Indenture. The aggregate amount of ADSs and cash in respect of accrued and unpaid interest delivered to holders of Notes in the Mandatory Exchange was 12,347 ADSs and $1,470, respectively. The Mandatory Exchange closed on June 26, 2023.

On March 29, 2023, we entered into a royalty purchase agreement ("RPA") with RTW Investments, L.P. ("RTW") that could provide the Company up to $75,000 of royalty financing in two tranches. On August 1, 2023, the Company received the first tranche of $30,000. As a result of receiving the first tranche, we are required to make quarterly royalty payments calculated as 3.75% of worldwide net product revenue of LUMRYZ, up to a total payback of $75,000.

Capital Commitments

We have a five year commitment with a contract manufacturer of approximately $2,700 to $4,200 per year as determined by the terms of the agreement with the contract manufacturer.

At December 31, 2023, we have leases for office space and a production suite. We have a current obligation of $1,091 due within one year and a long-term obligation of $1,953 due between January 1, 2025 and December 31, 2028. See *Note 9: Leases* to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for further details for further details.

Consolidated Statement of Cash Flows

Our cash flows from operating, investing and financing activities, as reflected in the consolidated statements of cash flows, are summarized in the following table:

Net Cash (Used In) Provided By	Years Ended December 31, 2023	2022	Change $	Change %
Operating activities	$ (128,511)	$ (70,304)	$ (58,207)	82.8 %
Investing activities	(50,093)	79,698	(129,791)	(162.9)%
Financing activities	135,335	14,543	120,792	830.6 %

Operating Activities

Net cash used in operating activities was $128,511 for the year ended December 31, 2023, compared to cash used in operating activities of $70,304 in the prior year. Net cash used in operating activities for the year ended December 31, 2023 was driven by net loss of $160,276 and unfavorable changes in working capital of $2,999, offset by favorable non-cash adjustments of $34,764 due to the loss on extinguishment of debt and share-based compensation expense. For the year ended December 31, 2022, net cash used in operating activities was driven by net loss of $137,464, partially offset by favorable non-cash adjustments of $42,625 and favorable changes in working capital of $24,535.

The December 31, 2022 net favorable change in working capital was driven by the receipt of $29,058 of tax refund claims associated with the carryback of 2019 losses during the period which was offset by the timing of payments made related to our accounts payable and accrual balances.

Investing Activities

Net cash used in investing activities was $50,093 for the year ended December 31, 2023 compared to cash provided by investing activities of $79,698 in the prior year. Net cash used in investing activities for the year ended December 31, 2023 was due to net purchases of marketable securities in excess of proceeds received from the excess of sales of $50,093. Net cash provided by investing activities for the year ended December 31, 2022 was driven by net proceeds from sales of marketable securities of $80,414.

Financing Activities

Net cash provided by financing activities was $135,335 for the year ended December 31, 2023 compared to cash provided by financing activities of $14,543 in the prior year. Net cash provided by financing activities for the year ended December 31, 2023 was a result of net proceeds of $134,151 received in exchange for issuing 12,205 ordinary shares and 4,706 Series B Preferred Shares in the April 3, 2023 public offering, proceeds of $30,000 received for the first tranche of the RPA, net proceeds of $11,913 from the sale of ADSs through the ATM Program and $2,293 of proceeds from stock option exercises and employee share purchase plan issuances, offset by settlement of the October 2023 Notes of $21,165, settlement of the February 2023 Notes of $17,500 and debt issuance costs of $4,357. Net cash provided by financing activities for the year ended December 31, 2022 was driven by net proceeds of $25,318 from the sale of ADSs through the ATM program and $2,682 of proceeds from stock option exercises and employee share purchase plan issuances, offset by the payment of $8,653 for the early extinguishment of a portion of the February 2023 Notes in November 2022 and payment of $4,804 of debt issuance costs.

Other Matters

Litigation

We are 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. We accrue 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 December 31, 2023 and December 31, 2022, 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 our consolidated financial position, results of operations, cash flows or liquidity. For information regarding legal proceedings we are involved in, see *Note 14: Contingent Liabilities and Commitments* to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are 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 accumulated other comprehensive loss in shareholders' equity (deficit). 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 December 31, 2023 would have had an immaterial impact on net loss for the year ended December 31, 2023.

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 income (expense), net in the consolidated statements of loss. As of December 31, 2023, 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 December 31, 2023.

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 products. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the year ended December 31, 2023. 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 commercially launch 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.

Item 8. Financial Statements and Supplementary Data.

AVADEL PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF LOSS
(In thousands, except per share data)

	Years ended December 31,		
	2023	**2022**	**2021**
Net product revenue	$ 27,963	$ —	$ —
Cost of products sold	846	—	—
Gross profit	27,117	—	—
Operating expenses:			
Research and development expenses	13,261	20,700	17,104
Selling, general and administrative expenses	151,705	74,516	68,495
Restructuring expense (income)	—	3,345	(53)
Total operating expenses	164,966	98,561	85,546
Operating loss	(137,849)	(98,561)	(85,546)
Investment and other income (expense), net	87	(536)	2,343
Interest expense	(9,886)	(12,342)	(9,942)
Loss on extinguishment of debt	(13,129)	—	—
Loss before income taxes	(160,777)	(111,439)	(93,145)
Income tax (benefit) provision	(501)	26,025	(15,816)
Net loss	$ (160,276)	$ (137,464)	$ (77,329)
Net loss per share - basic	$ (2.00)	$ (2.29)	$ (1.32)
Net loss per share - diluted	(2.00)	(2.29)	(1.32)
Weighted average number of shares outstanding - basic	80,174	60,094	58,535
Weighted average number of shares outstanding - diluted	80,174	60,094	58,535

See accompanying notes to consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Years ended December 31,		
	2023	**2022**	**2021**
Net loss	$ (160,276)	$ (137,464)	$ (77,329)
Other comprehensive income (loss), net of tax:			
Foreign currency translation gain (loss)	331	(597)	(1,228)
Net other comprehensive income (loss), net of income tax benefit of $0, $0, and $214, respectively	2,843	(1,804)	(1,661)
Total other comprehensive income (loss), net of tax	3,174	(2,401)	(2,889)
Total comprehensive loss	$ (157,102)	$ (139,865)	$ (80,218)

See accompanying notes to consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,167	$ 73,981
Marketable securities	73,944	22,518
Accounts receivable, net	12,103	—
Inventories	10,380	—
Research and development tax credit receivable	1,322	2,248
Prepaid expenses and other current assets	5,286	2,096
Total current assets	134,202	100,843
Property and equipment, net	585	839
Operating lease right-of-use assets	2,591	1,713
Goodwill	16,836	16,836
Research and development tax credit receivable	332	1,232
Other non-current assets	10,152	11,322
Total assets	$ 164,698	$ 132,785
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term debt	$ —	$ 37,668
Current portion of operating lease liability	934	960
Accounts payable	11,433	7,890
Accrued expenses	24,227	7,334
Other current liabilities	261	1,941
Total current liabilities	36,855	55,793
Long-term debt	—	91,614
Long-term operating lease liability	1,690	780
Royalty financing obligation	32,760	—
Other non-current liabilities	5,654	5,743
Total liabilities	76,959	153,930
Shareholders' equity (deficit):		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 5,194 issued and outstanding at December 31, 2023 and 488 issued and outstanding at December 31, 2022	52	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 89,825 issued and outstanding at December 31, 2023 and 62,878 issued and outstanding at December 31, 2022	898	628
Additional paid-in capital	855,452	589,783
Accumulated deficit	(745,496)	(585,220)
Accumulated other comprehensive loss	(23,167)	(26,341)
Total shareholders' equity (deficit)	87,739	(21,145)
Total liabilities and shareholders' equity (deficit)	$ 164,698	$ 132,785

See accompanying notes to consolidated financial statements.

AVADEL PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
(In thousands)

	Ordinary shares		Preferred shares		Additional	Accumulated	Accumulated other comprehensive	Total shareholders'
	Shares	Amount	Shares	Amount	paid-in capital	deficit	loss	equity (deficit)
Balance, December 31, 2020	58,396	$ 583	488	$ 5	$ 566,916	$ (384,187)	$ (21,051)	$ 162,266
Impact of the adoption of ASU 2020-06	—	—	—	—	(26,699)	13,760	—	(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 share issuance	17	—	—	—	94	—	—	94
Share-based compensation expense	—	—	—	—	8,872	—	—	8,872
Balance, December 31, 2021	58,620	$ 586	488	$ 5	$ 549,349	$ (447,756)	$ (23,940)	$ 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	62,878	$ 628	488	$ 5	$ 589,783	$ (585,220)	$ (26,341)	$ (21,145)
Net loss	—	—	—	—	—	(160,276)	—	(160,276)
Other comprehensive income	—	—	—	—	—	—	3,174	3,174
Issuance of common stock under at-the-market offering program, net of issuance costs	1,564	16	—	—	11,897	—	—	11,913
Amortization of deferred issuance costs	—	—	—	—	(16)	—	—	(16)
April 2023 public offering, net of issuance costs	12,205	122	4,706	47	133,982	—	—	134,151
Mandatory Exchange of April 2027 Notes, net of issuance costs	12,347	123	—	—	101,689	—	—	101,812
Settlement of October 2023 Notes	408	4	—	—	18	—	—	22
Exercise of stock options	343	4	—	—	2,058	—	—	2,062
Vesting of restricted shares	33	—	—	—	—	—	—	—
Employee share purchase plan share issuance	47	1	—	—	230	—	—	231
Share-based compensation expense	—	—	—	—	15,811	—	—	15,811
Balance, December 31, 2023	89,825	$ 898	5,194	$ 52	$ 855,452	$ (745,496)	$ (23,167)	$ 87,739

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2023	**2022**	**2021**
Cash flows from operating activities:			
Net loss	$ (160,276)	$ (137,464)	$ (77,329)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,766	1,493	815
Amortization of debt discount and debt issuance costs	2,796	6,052	1,248
Changes in deferred taxes	—	26,025	(15,666)
Share-based compensation expense	15,811	7,013	8,872
Loss on extinguishment of debt	13,129	—	—
Other adjustments	1,262	2,042	1,055
Net changes in assets and liabilities			
Accounts receivable	(12,103)	—	—
Inventories	(9,532)	—	—
Prepaid expenses and other current assets	(3,127)	30,815	(439)
Research and development tax credit receivable	1,884	30	2,796
Accounts payable & other current liabilities	1,545	(3,108)	4,232
Accrued expenses	16,892	227	895
Other assets and liabilities	1,442	(3,429)	(3,789)
Net cash used in operating activities	(128,511)	(70,304)	(77,310)
Cash flows from investing activities:			
Purchases of property and equipment	—	(716)	(26)
Proceeds from the disposition of the Hospital Products	—	—	16,500
Proceeds from sales of marketable securities	187,136	83,828	102,224
Purchases of marketable securities	(237,229)	(3,414)	(61,769)
Net cash (used in) provided by investing activities	(50,093)	79,698	56,929
Cash flows from financing activities:			
Proceeds from April 2023 public offering, net of issuance costs	134,151	—	—
Payments for February 2023 Notes	(17,500)	(8,653)	—
Payments for October 2023 Notes	(21,165)	—	—
Payments for debt issuance costs	(4,357)	(4,804)	—
Proceeds from royalty purchase agreement	30,000	—	—
Proceeds from issuance of shares off the at-the-market offering program	11,913	25,318	—
Proceeds from stock option exercises and employee share purchase plan	2,293	2,682	263
Net cash provided by financing activities	135,335	14,543	263
Effect of foreign currency exchange rate changes on cash and cash equivalents	455	(664)	(896)
Net change in cash and cash equivalents	(42,814)	23,273	(21,014)
Cash and cash equivalents at January 1	73,981	50,708	71,722
Cash and cash equivalents at December 31	$ 31,167	$ 73,981	$ 50,708
Supplemental disclosures of cash flow information:			
Interest paid	$ 5,250	$ 9,660	$ 6,469
Income taxes (refunded) paid, net	—	(29,058)	76

See accompanying notes to consolidated financial statements.

NOTE 1: Summary of Significant Accounting Policies

Nature of Operations. Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel," the "Company," "we," "our," or "us") is a biopharmaceutical company. The Company is registered as an Irish public limited company. The Company's headquarters are in Dublin, Ireland with operations in Dublin, Ireland and St. Louis, Missouri, United States ("U.S.").

LUMRYZ 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. LUMRYZ was approved by the U.S. Food and Drug Administration ("FDA") on May 1, 2023. The FDA also granted Orphan Drug Exclusivity to LUMRYZ for a period of seven years until May 1, 2030. In June 2023, the Company commercially launched LUMRYZ in the U.S.

In approving LUMRYZ, the FDA required 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 adults with narcolepsy outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of the drug. Under this REMS, healthcare providers who prescribe the drug must be specially certified; pharmacies, that dispense the drug must be specially certified; and the drug must be dispensed only to patients who have enrolled in the LUMRYZ REMS and completed all REMS requirements including documentation of safe use conditions, among other requirements.

As of the date of this Annual Report, the Company's only commercialized product is LUMRYZ. The Company continues to evaluate opportunities to expand its product portfolio.

Liquidity. The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP") applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

On March 29, 2023, the Company and Avadel CNS Pharmaceuticals, LLC, an indirect wholly-owned subsidiary of the Company ("Avadel CNS"), entered into a royalty purchase agreement ("RPA") with RTW Investments, L.P. ("RTW") that could provide the Company up to $75,000 of royalty financing in two tranches. The first tranche of $30,000 became available upon satisfaction of certain conditions which included the Company's first shipment of LUMRYZ. The second tranche is available to use, at the Company's election, if it achieves quarterly net revenue of $25,000 by the quarter ending June 30, 2024. The second tranche expires if the Company does not elect to use it by August 31, 2024. On August 1, 2023, the Company received the first tranche of $30,000.

At March 31, 2023, the Company had outstanding $117,375 aggregate principal amount of its 4.50% exchangeable senior notes due October 2023 (the "October 2023 Notes"). Over the course of April 3 and April 4, 2023, Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of the Company (the "Issuer"), completed an exchange of $96,188 of its $117,375 October 2023 Notes for $106,268 of a new series of 6.0% exchangeable notes due April 2027 (the "April 2027 Notes"). The Issuer settled, with a combination of cash and American Depositary Shares ("ADSs"), the remaining $21,187 aggregate principal amount of the October 2023 Notes in October 2023. The aggregate amount of cash and ADSs delivered to holders for the October 2023 Notes, including accrued interest was $21,641 and 408 ADSs, respectively.

On April 3, 2023, the Company completed the sale of 12,205 ordinary shares, nominal value $0.01 per share ("Ordinary Shares") in the form of ADSs and 4,706 Series B Non-Voting Convertible Preferred Shares ("Series B Preferred Shares") in an underwritten public offering. The Company received proceeds, net of underwriter fees and issuance costs of $134,151.

On May 31, 2023 and in accordance with the terms of the Indenture of the April 2027 Notes (the "Indenture"), dated as of April 3, 2023, the Issuer exercised its option to exchange (the "Mandatory Exchange") $106,268 of aggregate principal amount of the April 2027 Notes, which represents all of the April 2027 Notes outstanding under the Indenture. The Mandatory Exchange consideration per one thousand dollars of principal April 2027 Notes exchanged consisted of 116.1846 of the Company's ADSs, representing a corresponding number of the Company's ordinary shares, nominal value $0.01 per share, plus accrued and unpaid interest thereon. The aggregate amount of ADSs and cash in respect of accrued and unpaid interest delivered to holders of Notes in the Mandatory Exchange was 12,347 ADSs and $1,470, respectively. The Mandatory Exchange closed on June 26, 2023.

Basis of Presentation. These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S., the requirements of Form 10-K and Article 10 of Regulation S-X. The consolidated financial statements include the accounts of the Company and all subsidiaries. All intercompany accounts and transactions have been eliminated.

Reclassifications

Certain reclassifications are made to prior year amounts whenever necessary to conform with the current year presentation. Certain reclassifications have been made within *Note 13: Other Assets and Liabilities* for the year ended December 31, 2022 to condense line items of the same nature into a single line.

Concentrations of Risk. A significant portion of the Company's cash, cash equivalents and marketable securities are held at two financial institutions. Due to their size, the Company believes these financial institutions represent minimal credit risk. The Company has not experienced any losses on its cash, cash equivalents, or marketable securities.

The Company is subject to credit risk from its accounts receivable related to the sale of LUMRYZ. The Company extends credit to its customers, specialty pharmacies. Customer creditworthiness is monitored, and collateral is not required. Amounts owed to the Company are presented net of an allowance that includes an 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 Company identifies that any individual customer's credit quality has deteriorated, the Company establishes allowances based on the individual risk characteristics of that customer. The Company 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. As of December 31, 2023, the Company did not recognize any allowances for credit losses. As of December 31, 2023, three customers accounted for 100% of gross accounts receivable, Caremark LLC ("Caremark"), which accounted for 52% of gross accounts receivable; Accredo Health Group, Inc. ("Accredo"), which accounted for 28% of gross accounts receivable; and Optum Frontier Therapies LLC ("Optum"), which accounted for 20% of gross accounts receivable. As of December 31, 2022, the Company did not have accounts receivable.

The Company attempts to maintain multiple suppliers for its active pharmaceutical ingredient ("API") and manufacturing in order to mitigate the risk of shortfall and inability to supply market demand, but is subject to risk due to a limited number of providers. The API is currently manufactured by two source contract development and manufacturing organizations ("CDMOs") in the U.S. The drug product for commercial lots is manufactured by one source CDMO in the U.S. and one source CDMO outside of the U.S.

Revenue. Revenue includes sales of LUMRYZ. ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when the performance obligations to the customer have been satisfied through the transfer of control of the goods or services. To determine the appropriate revenue recognition for arrangements that the Company believes are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company applies the five-step model to contracts only when the Company and its customer's rights and obligations under the contract can be determined, the contract has commercial substance, and it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. For contracts that are determined to be within the scope of ASC 606, the Company identifies the promised goods or services in the contract to determine if they are separate performance obligations or if they should be bundled with other goods and services into a single performance obligation. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Sales

The Company sells LUMRYZ to specialty pharmacies and considers those specialty pharmacies to be its customers. Under ASC 606, revenue from product sales is recognized when the customer obtains control of the product, which occurs typically upon receipt by the customer. The Company's gross product sales are subject to a variety of price adjustments to arrive at reported net product revenue. These adjustments include estimates of payment discounts, specialty pharmacy fees, patient financial assistance programs, rebates and product returns and are estimated based on contractual arrangements, historical trends, expected utilization of such products and other judgments and analysis.

Reserves for Variable Consideration

Revenues from product sales are recorded at the estimated net selling price, which includes reserves for estimated variable consideration to reduce gross product sales to net product revenue resulting from payment discounts, specialty pharmacy fees, patient financial assistance programs, rebates and product returns. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable if the amount is payable to the customer. The reserves are classified as a liability if the amount is payable to a party other than a customer. Where appropriate, these estimated reserves take into consideration relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, historical trends, current and expected patient demand and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates to reduce gross selling price to net selling price. The actual net selling price ultimately may differ from our estimates.

Cost of Products Sold. Cost of products sold includes the cost of the API, manufacturing and distribution costs, packaging costs and freight. LUMRYZ was approved by the FDA on May 1, 2023 and the Company began shipping product to its customers in June 2023. Products sold includes inventory purchased or produced that was expensed as research and development costs prior to FDA approval.

Inventories. Inventories consist of raw materials, work in process and finished products, which are stated at lower of cost or net realizable value, using the first-in, first- out method. Raw materials used in the production of pre-clinical and clinical products are expensed as research and development costs. The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow-moving on a case by case basis.

The Company capitalizes inventory costs associated with products when future commercialization is considered probable and the future economic benefit is expected to be realized, which is typically when regulatory approval is obtained for a drug candidate. As such, the Company began capitalizing costs related to inventory in May 2023 upon FDA approval of LUMRYZ. Manufacturing costs associated with inventory purchased or produced prior to FDA approval were recorded as research and development expense in prior periods. Accordingly, cost of products sold in the near term will likely be lower than in later periods given the sales of pre-approval inventory will carry little to no manufacturing costs as such costs were previously expensed to research and development.

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 Company recognizes refundable R&D tax credits received for spending on innovative R&D as an offset of R&D expenses.

Advertising Expenses. The Company expenses the costs of advertising as incurred. Branded advertising expenses were $6,452 for the year ended December 31, 2023. Branded advertising expenses were immaterial for the years ended December 31, 2022 and 2021, respectively.

Share-based Compensation. The Company 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 Company estimates the expected term using a simplified method, as the Company does not have enough historical exercise data for a majority of such options upon which to estimate an expected term. The Company recognizes compensation cost, net of an estimated forfeiture rate, using the accelerated method over the requisite service period of the award.

Income Taxes. The Company 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 Company 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 Company recognizes deferred tax assets to the extent that the Company believes that these assets are more likely than not to be realized. In making such a determination, the Company 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 Company determines that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. As of December 31, 2023, the Company'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 Company continues to record a full valuation allowance on its deferred tax assets. The Company 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 Company'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 Company records uncertain tax positions on the basis of a two-step process in which (1) the Company 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 Company 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 Company recognizes interest and penalties related to unrecognized tax benefits in the income tax expense line in the consolidated statements of loss. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheets.

Cash and Cash Equivalents. Cash and cash equivalents consist of cash on hand, cash on deposit and fixed term deposits which are highly liquid investments with original maturities of less than three months.

Marketable Securities. The Company’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 accumulated other comprehensive loss in shareholders’ equity (deficit), 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.

For available-for-sale debt securities in an unrealized loss position, the Company assesses whether it intends to sell or if it is more likely than not that the Company 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 Company 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.

Property and Equipment. Property and equipment is stated at historical cost less accumulated depreciation. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

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

Goodwill. Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. The Company 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 Company tests goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. The Company determined that no impairment of goodwill existed at December 31, 2023 and 2022.

Long-Lived Assets. Long-lived assets include fixed assets and right of use assets at contract manufacturing organizations. 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 December 31, 2023, 2022 and 2021 was $588, $391 and $0, respectively.

Lease Obligations. The Company 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 Company considers only payments that are fixed and determinable at the time of commencement. The Company 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 statements of loss on a straight-line basis over the lease term. The Company's lease contracts do not provide a readily determinable implicit rate. The Company's estimated incremental borrowing rate is based on information available at the inception of the lease. The Company'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 statements of loss.

Use of Estimates. The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses during the periods presented. These estimates and assumptions are based on the best information available to management 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 the Company's consolidated statements of loss and balance sheets. Actual results could differ from those estimates under different assumptions or conditions.

NOTE 2: Newly Issued 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 impacted ASC 740, *Income Taxes*, and may impact both interim and annual reporting periods. ASU 2019-12 was effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years and early adoption was permitted. The Company adopted the provisions of ASU 2019-12 on January 1, 2021. Adoption of ASU 2019-12 did not have any impact on the Company'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 reduced 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 required 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 was effective for fiscal years beginning January 1, 2022 and interim periods therein. Early adoption was permitted, but no earlier than fiscal years beginning after December 15, 2020. The amendments may be adopted through either a modified retrospective method, or a fully retrospective method.

The Company elected to early adopt ASU 2020-06 as of January 1, 2021 using a modified retrospective method. The Company's 4.50% exchangeable senior notes due 2023 were a convertible instrument with a cash-conversion feature that was accounted for within the scope of Subtopic 470-20. The Company calculated the cumulative-effect adjustment as of January 1, 2021 by comparing (i) the historical amortization schedule for the 2023 Notes through December 31, 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 $26,699 decrease in additional paid-in capital, a $12,939 increase in long-term debt, and a $13,760 increase to the opening balance of retained earnings.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures,* to enhance the transparency and decision usefulness of income tax disclosures. The ASU is effective for annual periods beginning

after December 15, 2024. Adoption of ASU 2023-09 will not have a material effect on the Company's financial position or results of operations.

NOTE 3: Revenue Recognition

The Company's source of net product revenue during the year ended December 31, 2023 consists solely of sales of LUMRYZ in the U.S.

For the year ended December 31, 2023, three customers accounted for 100% of sales. The following table presents a summary of the percentage of total gross sales to customers:

	Twelve Months Ended December 31,
Sales by Customer:	**2023**
Accredo	41 %
Caremark	39 %
Optum	20 %

The Company had no net product revenue during the years ended December 31, 2022 and 2021.

NOTE 4: Fair Value Measurements

The Company is required to measure certain assets and liabilities at fair value, either upon initial recognition or for subsequent accounting or reporting. For example, the Company uses 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, the Company 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 sheets:

	As of December 31, 2023			As of December 31, 2022		
Fair Value Measurements:	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Marketable securities (see *Note 5)*						
Mutual and money market funds	$ —	$ —	$ —	$ 22,518	$ —	$ —
Government securities - U.S.	73,944	—	—	—	—	—
Total assets	$ 73,944	$ —	$ —	$ 22,518	$ —	$ —

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 financial assets or liabilities. During the twelve months ended December 31, 2023, there were no transfers in and out of Level 1, 2, or 3. During the twelve months ended December 31, 2023, 2022, and 2021, the Company did not recognize any allowances for credit losses.

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

Royalty Financing Obligation

As of December 31, 2023, the carrying value of the royalty financing obligation under the RPA approximated its fair value and was measured using the estimates of forecasted net product revenue based on current contractual and statutory requirements, specific known market events and trends, industry data, historical trends, current and expected patient demand and forecasted customer buying and payment patterns (Level 3 inputs). See *Note 11: Royalty Financing Obligation* for additional information regarding the Company's royalty financing obligation.

NOTE 5: Marketable Securities

The Company has 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 as accumulated other comprehensive loss in shareholders' equity (deficit), net of income tax effects. As of December 31, 2023, the Company considered any decreases in fair value on its marketable securities to be driven by factors other than credit risk, including market risk.

The following tables show the Company's available-for-sale securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category as of December 31, 2023 and 2022, respectively:

	2023			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Government securities - U.S.	$ 72,990	$ 954	$ —	$ 73,944
Total	$ 72,990	$ 954	$ —	$ 73,944

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

The Company determines realized gains or losses on the sale of marketable securities on a specific identification method. The Company reflects these gains and losses as a component of investment and other income (expense), net in the accompanying consolidated statements of loss.

The Company recognized gross realized gains of $988, $584 and $174 for the twelve months ended December 31, 2023, 2022 and 2021, respectively. These realized gains were offset by realized losses of $2,791, $2,338 and $275 for the twelve-months ended December 31, 2023, 2022 and 2021, respectively.

The following table summarizes the estimated fair value of the Company's investments in marketable debt securities, accounted for as available-for-sale debt securities and classified by the contractual maturity date of the securities as of December 31, 2023:

	Maturities				
Marketable Debt Securities:	**Less than 1 Year**	**1-5 Years**	**5-10 Years**	**Greater than 10 Years**	**Total**
Government securities - U.S.	$ 73,944	$ —	$ —	$ —	$ 73,944
Total	$ 73,944	$ —	$ —	$ —	$ 73,944

The Company has classified its investment in available-for-sale marketable debt securities as current assets in the consolidated balance sheets 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 Company's investment portfolio.

NOTE 6: Inventories

The principal categories of inventories at December 31, 2023 were comprised of the following:

Inventory:	**2023**
Raw materials and supplies	$ 5,291
Work in process	2,037
Finished goods	3,052
Total	$ 10,380

The Company had no capitalized inventories at December 31, 2022. The Company capitalizes inventory costs associated with products when future commercialization is considered probable and the future economic benefit is expected to be realized, which is typically when regulatory approval is obtained for a drug candidate. As such, the Company began capitalizing costs related to inventory in May 2023 upon FDA approval of LUMRYZ. Manufacturing costs associated with inventory purchased or produced prior to FDA approval were recorded as research and development expense in prior periods.

NOTE 7: Property and Equipment, net

The principal categories of property and equipment, net at December 31, 2023 and 2022, respectively, are as follows:

Property and Equipment, net:	**2023**	**2022**
Software, office and computer equipment	$ 832	$ 832
Furniture, fixtures and fittings	634	634
Less - accumulated depreciation	(881)	(627)
Total	$ 585	$ 839

Depreciation expense for the years ended December 31, 2023, 2022 and 2021 was $254, $162 and $97, respectively.

NOTE 8: Goodwill

The Company's goodwill is $16,836 at December 31, 2023 and 2022.

No impairment loss related to goodwill was recognized during the years ended December 31, 2023 or 2022.

NOTE 9: Leases

The Company leases office space and a production suite. All leased facilities are classified as operating leases with remaining lease terms between one and five years. The Company determines if a contract is a lease at the inception of the arrangement. The Company 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 Company's lease agreements do not contain any material residual value guarantees or material variable lease payments. For the Company'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 statements of loss for the years ended December 31, 2023, 2022 and 2021 were as follows:

Lease cost:	2023	2022	2021
Operating lease costs	$ 1,039	$ 1,028	$ 821
Sublease income	(123)	(116)	(110)
Total lease cost	$ 916	$ 912	$ 711

During the year ended December 31, 2023, the Company increased its operating lease liabilities by $1,803 due to an increase in the lease term for the production suite, offset by $1,036 for cash paid. During the year ended December 31, 2022, the Company reduced its operating lease liabilities by $963 for cash paid.

As of December 31, 2023, the Company's operating leases have a weighted-average remaining lease term of 3.7 years and a weighted-average discount rate of 7.8%. The Company's lease contracts do not provide a readily determinable implicit rate. The Company's estimated incremental borrowing rate is based on information available at the inception of the lease.

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

Maturities:	Operating Leases
2024	$ 1,091
2025	683
2026	477
2027	477
2028	316
Thereafter	—
Total lease payments	3,044
Less: interest	(420)
Present value of lease liabilities	$ 2,624

NOTE 10: Long-Term Debt

The Company had no exchangeable senior notes as of December 31, 2023. Long-term debt as of December 31, 2022 is summarized as follows:

Exchangeable Senior Notes:	2022
Principal amount of 4.50% exchangeable senior notes due October 2023	$ 117,375
Principal amount of 4.50% exchangeable senior notes due February 2023	17,500
Less: unamortized debt discount and issuance costs, net	(5,593)
Net carrying amount of liability component	129,282
Less: current maturities, net of $1,019 unamortized debt discount and issuance costs	(37,668)
Long-term debt	$ 91,614

For the years ended December 31, 2023, 2022 and 2021, the total interest expense for exchangeable senior notes was $6,143, $12,342 and $9,942, respectively, with coupon interest expense of $3,347, $6,405 and $6,469 for each period, respectively, and the amortization of debt issuance costs and debt discount of $2,796, $6,052 and $1,248 for each period, respectively.

February 2023 Notes

On February 16, 2018, the Issuer issued $125,000 aggregate principal amount of its 4.50% exchangeable senior notes due February 2023 (the "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 February 16, 2018. Net proceeds received by the Company, after issuance costs and discounts, were approximately $137,560. The February 2023 Notes were the Company's senior unsecured obligations and ranked equally in right of payment with all of the Company's existing and future senior unsecured indebtedness and effectively junior to any of the Company's existing and future secured indebtedness, to the extent of the value of the assets securing such indebtedness.

October 2023 Notes

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

The Company accounted for the October 2023 Notes as a modification to the February 2023 Notes. The Company 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 Company paid approximately $5,450 in fees to third parties that were expensed as part of the completed 2022 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 was amortized over the remaining term of the October 2023 Notes as a component of interest expense.

Over the course of April 3 and April 4, 2023, the Issuer completed an exchange of $96,188 of its $117,375 October 2023 Notes for $106,268 of the April 2027 Notes. The remaining $21,187 aggregate principal amount of the October 2023 Notes matured on October 2, 2023. The Issuer settled, with a combination of cash and ADSs, the remaining $21,187 aggregate principal amount of the October 2023 Notes in October 2023. The aggregate amount of cash and ADSs delivered to holders for the October 2023 Notes and accrued and unpaid interest was $21,641 and 408 ADSs, respectively.

April 2027 Notes

The Company accounted for the exchange of the October 2023 Notes for the April 2027 Notes as an extinguishment of $96,188 of its October 2023 Notes. The Company recorded a loss on the extinguishment of $13,129 as a result of the exchange.

On June 26, 2023, and in accordance with the terms of the Indenture, the Company completed the Mandatory Exchange of $106,268 of aggregate principal amount of the April 2027 Notes, which represents all of the April 2027 Notes outstanding under the Indenture. The Mandatory Exchange consideration per one thousand dollars of principal Notes exchanged consisted of 116.1846 of ADSs representing a corresponding number of the Company's ordinary shares, nominal value $0.01 per share, plus accrued and unpaid interest thereon. The aggregate amount of ADSs and cash in respect of accrued and unpaid interest delivered to holders of Notes in the Mandatory Exchange was 12,347 ADSs and $1,470, respectively.

NOTE 11: Royalty Financing Obligation

On March 29, 2023, the Company and Avadel CNS entered into the RPA with RTW that could provide the Company up to $75,000 of royalty financing in two tranches. The first tranche of $30,000 became available upon satisfaction of certain conditions which included the Company's first shipment of LUMRYZ. The second tranche is available to use, at the Company's election, if it achieves quarterly net revenue of $25,000 by the quarter ending June 30, 2024. The second tranche expires if the Company does not elect to use it by August 31, 2024.

On August 1, 2023, the Company received the first tranche of $30,000. As a result of receiving the first tranche, the Company is required to make quarterly royalty payments calculated as 3.75% of worldwide net product revenue of LUMRYZ, up to a total payback of $75,000.

The RPA is recorded as a royalty financing obligation on the consolidated balance sheet based on the Company's evaluation of the terms of the RPA. The accounts receivable and inventory balances of LUMRYZ are pledged as collateral for the RPA. There are no subjective acceleration clauses or provisions, and there are no covenants in violation or other clauses that would cause the full amount of the royalty financing obligation to be callable. As such, the RPA is recorded as a long-term obligation on the consolidated balance sheet.

The Company imputes interest using the effective interest method and records interest expense based on the unamortized royalty financing obligation. The Company's estimate of the interest rate under the RPA is based primarily on forecasted net revenue and the calculated amounts and timing of net royalty payments to reach the total payback of $75,000. As of

December 31, 2023 the effective interest rate is estimated as 30.4%. The Company will account for changes in the imputed interest rate resulting from changes in forecasted net product revenue using the prospective method.

The following table shows the activity within the royalty financing obligation account for the period ended December 31, 2023.

Royalty Financing Obligation:	**2023**
Royalty financing obligation – beginning balance	$ —
Receipt of the first tranche of the royalty financing obligation	30,000
Accretion of imputed interest expense on royalty financing obligation	3,743
Less: royalty payments made to RTW	(253)
Royalty financing obligation – ending balance	33,490
Less: royalty payable to RTW classified within accrued expenses	(730)
Royalty financing obligation, non-current	$ 32,760

The accretion of imputed interest expense is reflected as interest expense in the consolidated statements of loss.

NOTE 12: Income Taxes

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

(Loss) Income Before Income Taxes:	**2023**	**2022**	**2021**
Ireland	$ (45,689)	$ (53,717)	$ (36,631)
U.S.	(114,942)	(57,755)	(56,687)
France	(146)	33	173
Total loss before income taxes	$ (160,777)	$ (111,439)	$ (93,145)

The income tax (benefit) provision consists of the following for the years ended December 31:

Income Tax (Benefit) Provision:	**2023**	**2022**	**2021**
Current:			
U.S. - State	$ (661)	$ —	$ 60
Total current	(661)	—	60
Deferred:			
U.S. - Federal	—	25,896	(15,876)
U.S. - State	160	129	—
Total deferred	160	26,025	(15,876)
Income tax (benefit) provision	$ (501)	$ 26,025	$ (15,816)

The reconciliation between income taxes at the statutory rate and the Company's (benefit) provision for income taxes is as follows for the following years ended December 31:

Reconciliation to Effective Income Tax Rate:	2023	2022	2021
Income tax (benefit) provision - at statutory tax rate	$ (20,097)	$ (13,916)	$ (11,642)
Differences in international tax rates	(6,341)	(9,921)	(8,950)
Change in valuation allowances	24,332	48,734	4,296
Nondeductible share-based compensation	798	1,424	645
Unrealized tax benefits	160	258	239
State and local taxes (net of federal)	(5,614)	(4,467)	60
Nondeductible interest expense	4,362	4,239	2,173
Orphan drug and R&D tax credit	899	—	(1,524)
Other	1,000	(326)	(1,113)
Income tax (benefit) provision - at effective income tax rate	$ (501)	$ 26,025	$ (15,816)

In 2023, the income tax benefit was $501, a change of $26,526 from income tax provision of $26,025. The change in the effective tax rate for the year ended December 31, 2023 is primarily driven by the valuation allowances recorded against our deferred tax assets during the prior period. The effective tax rate for 2021 was impacted by the geographic mix of earnings.

Unrecognized Tax Benefits

The Company or one of its subsidiaries files income tax returns in Ireland, France, U.S. and various states. The Company is no longer subject to Irish, French, U.S. Federal, and state and local examinations for years before 2019.

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

Unrecognized Tax Benefit Activity	2023	2022	2021
Balance at January 1:	$ 3,143	$ 3,143	$ 3,143
Increases for tax positions of prior years	—	—	—
Statute of limitations expiration	(108)	—	—
Settlements	—	—	—
Balance at December 31:	$ 3,035	$ 3,143	$ 3,143

The Company 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 December 31, 2023, 2022 and 2021, there are $3,035, $3,143,and $2,483 of unrecognized tax benefits that if recognized would affect the annual effective tax rate.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits in income tax provision. During the years ended December 31, 2023, 2022 and 2021, the Company recognized approximately $268, $258 and $239 in interest and penalties. The Company had approximately $2,372, $2,103, and $1,777 for the payment of interest and penalties accrued at December 31, 2023, 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 December 31, 2023 and 2022 resulted from the following temporary differences:

Net Deferred Tax Assets and Liabilities:	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 71,051	$ 53,393
Royalty income	8,378	—
Share-based compensation	7,347	4,684
Orphan drug and R&D tax credit	4,065	4,964
Capitalized research costs	1,738	2,108
Interest expense carryforward	1,368	1,216
Other	1,322	1,521
Amortization	1,159	3,541
Gross deferred tax assets	96,428	71,427
Deferred tax liabilities:		
Prepaid expenses	—	(86)
Gross deferred tax liabilities	—	(86)
Less: valuation allowances	(96,428)	(71,341)
Net deferred tax assets	$ —	$ —

At December 31, 2023, the Company had $111,647 of net operating losses in Ireland that do not have an expiration date and $212,426 of net operating losses and $5,469 163(j) carryforwards in the U.S. Of the $212,426 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 $195,595 are due to the losses at US Holdings, of which $6,466 are state net operating losses. The portion due to the acquisition of FSC will expire in 2034 through 2035. The remaining U.S. net operating loss and 163(j) carryforwards do not have an expiration date. 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 December 31, 2023, the Company recorded a net increase to the valuation allowance related primarily to current year net operating losses of $25,087. 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. In addition to net operating losses and 163(j) carryforwards, the Company has U.S. Orphan Drug tax credit carryforwards of $3,059 as well as U.S. Research and Development credits of $1,005. The Orphan Drug Credit and Research and Development credits will expire in 2040 through 2043.

The Company's cumulative loss position is 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 Company has recorded a full valuation allowance on its deferred tax assets. The Company 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 Company'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 Company recorded a valuation allowance against all of its net operating losses in Ireland, France and the U.S. as of December 31, 2023 and 2022. The Company intends to continue maintaining a full valuation allowance on the Irish, French and U.S. net operating losses until there is sufficient evidence to support the reversal of all or some portion of these allowances.

At December 31, 2023, the Company has unremitted earnings of $3,854 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 Company were to sell its 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 December 31, 2023, the Company's net research tax credit receivable amounts to $1,654 and represents a French gross research tax credit of $837 and an Irish gross research tax credit of $817. As of December 31, 2022, the Company'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.

NOTE 13: Other Assets and Liabilities

Various other assets and liabilities are summarized for the years ended December 31, as follows:

Prepaid Expenses and Other Current Assets:	**2023**	**2022**
Prepaid and other expenses	$ 4,373	$ 1,523
Other	913	573
Total	$ 5,286	$ 2,096

Other Non-Current Assets:	**2023**	**2022**
Right of use assets at contract manufacturing organizations	$ 9,905	$ 10,686
Other	247	636
Total	$ 10,152	$ 11,322

Accrued Expenses:	**2023**	**2022**
Accrued professional fees	$ 11,767	$ 4,040
Accrued compensation	7,492	1,613
Reserve for variable consideration	4,044	—
Royalty payable to RTW	730	—
Accrued outsourced contract costs	194	1,208
Accrued restructuring	—	473
Total	$ 24,227	$ 7,334

Other Current Liabilities:	**2023**	**2022**
Other	$ 261	$ 292
Accrued interest	—	1,649
Total	$ 261	$ 1,941

Other Non-Current Liabilities:	**2023**	**2022**
Tax liabilities	$ 5,407	$ 5,246
Other	247	497
Total	$ 5,654	$ 5,743

NOTE 14: Contingent Liabilities and Commitments

Litigation

The Company is subject to potential liabilities generally incidental to its 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 Company 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 December 31, 2023 and December 31, 2022, 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 Company's consolidated financial position, results of operations, cash flows or liquidity.

First Jazz Complaint

On May 12, 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 ("Avadel CNS") will infringe at least one claim of U.S. 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 June 3, 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 June 18, 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 June 21, 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 July 21, 2021.

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

On October 18, 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 CNS's NDA.

On January 4, 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 February 25, 2022, Jazz filed an amended Answer to the Avadel Parties' 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 June 23, 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 August 31, 2022. On July 7, 2022, Jazz filed a response styled as Objections to Avadel CNS' Motion for Judgment on the Pleadings. On July 14, 2022, Avadel CNS replied to Jazz's response, and on July 21, 2022, Avadel CNS requested oral argument on its delisting motion simultaneous with the *Markman*

hearing. On August 24, 2022, the Court ordered Jazz to respond substantively to Avadel CNS' motion, which Jazz did on August 26, 2022. Avadel CNS filed its reply on August 28, 2022.

On August 23, 2022, the *Markman* hearing was postponed. On September 7, 2022, the case was reassigned to a new judge, and the *Markman* hearing was held on October 25, 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 October 28, 2022, the Court granted Avadel CNS' request and scheduled the hearing for November 15, 2022.

The Court held the *Markman* hearing on November 15, 2022 and issued a claim construction ruling on November 18, 2022. Also on November 18, 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 November 22, 2022, Jazz appealed that decision and on December 14, 2022, the Federal Circuit issued a stay of the delisting order until further notice. Oral argument was held February 14, 2023. On February 24, 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 March 7, 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.

On March 15, 2023, the parties submitted a Stipulation and Proposed Order Modifying the Case Schedule to accommodate additional claim construction proceedings. That stipulation remains pending before the Court. On April 26, 2023, the parties filed their Supplemental Joint Claim Construction Brief.

On July 3, 2023, the Court issued a modified scheduling order establishing a new trial date of February 26, 2024.

On July 21, 2023, in response to a Court order, the parties submitted a Stipulation and Proposed Order Modifying the Case Schedule with an updated proposed schedule to accommodate additional claim construction proceedings. On August 4, 2023, the Court entered a modified version of the parties' proposed schedule, which was revised on August 28, 2023. The parties' Second Supplemental Joint Claim Construction Brief was filed on October 10, 2023, and a *Markman* hearing regarding the disputed terms occurred on November 1, 2023. The Court issued its claim construction order on December 15, 2023.

On August 15, 2023, Avadel renewed its request to consolidate this litigation with the litigation described in the Avadel Complaint below. On November 3, 2023, the Court denied that request.

On November 30, 2023, the parties filed cross motions for summary judgment. The parties filed opposition briefs on December 15, 2023. The parties filed reply briefs on December 22, 2024. On February 14, 2024, the Court denied the parties' summary judgment motions. On February 15, 2024, the Court held its Pretrial Conference, in advance of the ongoing February 26, 2024 trial.

Second Jazz Complaint

On August 4, 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 will infringe at least one claim of U.S. 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 September 9, 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 October 22, 2021, the Court issued an oral order stating that this case should proceed on the same schedule as the case filed on May 12, 2021.

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

Third Jazz Complaint

On November 10, 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

will infringe at least one claim of U.S. 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 December 21, 2021, the Court entered a revised schedule for the First, Second and Third Complaints, setting a new claim construction date of August 31, 2022.

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

Fourth Jazz Complaint

On July 15, 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 September 7, 2022, the case was reassigned to a new judge.

On September 21, 2022, Jazz served the Fourth Complaint. On October 21, 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 December 9, 2022, Jazz filed a Motion to Dismiss Avadel's Antitrust Counterclaims. Avadel filed its opposition brief on December 27, 2022, and Jazz filed its reply brief on January 6, 2022. On January 11, 2023, Avadel filed a request for oral argument on the motion, which is still pending.

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

On May 19, 2023, the Court issued a scheduling order establishing timing for litigation events including i) completion of fact discovery by March 14, 2024, and ii) a deadline for case dispositive motions of September 20, 2024. On January 23, 2024, the parties submitted a stipulation to extend the case schedule. On January 24, 2024, the Court ordered an extension of the case schedule, including i) completion of fact discovery by June 20, 2024 and ii) a deadline for case dispositive motions by January 31, 2025. On January 24, 2024, the Court issued an order setting a pretrial conference for October 30, 2025 and a 5-day trial to begin on November 3, 2025.

On June 29, 2023, Jazz filed a Motion to Stay the case, pending resolution of its Motion to Dismiss. Briefing on that Motion to Stay closed on August 10, 2023.

Avadel Complaint

On April 14, 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 June 2, 2022, Jazz answered the Avadel Complaint. The Answer generally denies the allegations set forth in the Avadel Complaint and includes various affirmative defenses.

On July 8, 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 August 5, 2022. On February 2, 2023, the Court held a hearing on Jazz's Motion for Judgment on the Pleadings.

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

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

On July 18, 2023, the Court denied Jazz's Motion for Judgment on the Pleadings.

On August 15, 2023, the parties submitted competing proposed scheduling orders, and Avadel requested consolidation with the above First Jazz Complaint litigation. That request for consolidation was denied on November 3, 2023.

On November 17, 2023, the parties submitted an updated joint proposed scheduling order. On January 30, 2024, the parties agreed to a 6-week stay of discovery and submitted a proposed stipulation extending certain case deadlines to accommodate the same. On February 9, 2024, the parties submitted an updated proposed scheduling order consistent with that stipulation, setting the close of fact discovery for August 9, 2024 and a trial date of December 15, 2025. That proposed scheduling order remains pending before the Court as of the date of this Annual Report on Form 10-K.

Jazz's Administrative Procedure Act Complaint

On June 22, 2023, Jazz 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. This suit alleges that the FDA's approval of LUMRYZ was an unlawful agency action and asks the DC Court to set aside FDA's approval of LUMRYZ. On June 28, 2023, the DC Court granted Avadel CNS's unopposed motion to intervene in the case to defend the FDA's decision. On August 14, 2023, the Court entered a scheduling order establishing timing for litigation events including early summary judgment briefing closing December 22, 2023. On September 22, 2023, Jazz filed its Motion for Summary Judgment. On October 20, 2023, the FDA and Avadel filed their Cross Motions for Summary Judgment. Briefing on the parties' motions closed January 4, 2024. On February 14, 2024, the Court set hearing for oral argument on the parties' motions for February 27, 2024. On February 21, 2024, the Court rescheduled the oral argument to April 9, 2024.

Material Commitments

The Company has a five year commitment with a contract manufacturer of approximately $2,700 to $4,200 per year as determined by the terms of the agreement with the contract manufacturer.

Guarantees

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

Deerfield Guarantee

In connection with the Company's February 2018 divestiture of its pediatric assets, including four pediatric commercial stage assets – Karbinal™ ER, Cefaclor, Flexichamber™ and AcipHex® Sprinkle™ ("FSC products"), to Cerecor, Inc. ("Cerecor"), the Company guaranteed to Deerfield a quarterly royalty payment of 15% on net sales of the FSC products through February 6, 2026 ("FSC Product Royalties"), in an aggregate amount of up to approximately $10,300. Given the Company's explicit guarantee to Deerfield, the Company recorded the guarantee in accordance with ASC 460. The balance of this guarantee liability was $501 at December 31, 2023. 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 Company's February 2018 divestiture of the pediatric assets, Armistice Capital Master Fund, Ltd., the majority shareholder of Cerecor, guaranteed to the Company the FSC Product Royalties. The Company recorded the guarantee in accordance with ASC 460. The balance of this guarantee asset was $495 at December 31, 2023. This asset is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield noted above.

NOTE 15: Equity Instruments and Transactions

Capital Shares

The Company has 500,000 shares of authorized ordinary shares with a nominal value of $0.01 per ordinary share. As of December 31, 2023, the Company had 89,825 ordinary shares issued and outstanding, respectively. The Board of Directors is authorized to issue preferred shares 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. The Company has 50,000 shares of authorized preferred shares, $0.01 nominal value, of which 5,194 are currently issued and outstanding as of December 31, 2023.

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, each of which may be represented by 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") in 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.

During the year ended December 31, 2022, the Company issued and sold 3,588 ADSs, resulting in net proceeds to the Company of approximately $25,318, pursuant to the Sales Agreement. No ADSs were issued and sold from the 2020 Base Prospectus during the year ended December 31, 2023.

The 2020 Shelf Registration Statement expired on February 14, 2023.

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.

As of December 31, 2023, the Company issued and sold 1,564 ADSs, resulting in net proceeds to the Company of approximately $11,913, pursuant to the Sales Agreement. The Company may offer and sell up to an additional $96,064 of ADSs under the ATM Program that remains available for sale pursuant to the 2022 Base Prospectus.

The transactions costs associated with the 2022 Shelf Registration Statement totaled $192, of which $135 remain recorded within prepaid expenses and other current assets at December 31, 2023.

April 2023 Public Offering

On April 3, 2023, the Company completed the sale of 12,205 Ordinary Shares in the form of ADSs and 4,706 Series B Preferred Shares in an underwritten public offering. The Company received proceeds, net of underwriter fees and issuance costs of $134,151.

NOTE 16: Share-Based Compensation

Compensation expense included in the Company's consolidated statements of loss for all share-based compensation arrangements was as follows for the periods ended December 31, 2023, 2022, and 2021, respectively:

Share-based Compensation Expense:	**2023**	**2022**	**2021**
Selling, general and administrative	$ 15,248	$ 6,844	$ 8,114
Research and development	563	169	758
Total share-based compensation expense	$ 15,811	$ 7,013	$ 8,872

As of December 31, 2023, the Company expects $13,962 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 2.5 years.

In 2022, the Company 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"). In May 2023, the achievement of the milestones related to the 2022 Performance Options became probable, and the Company recognized the compensation costs that would have been recognized had the performance factor been considered probable since the inception of the award. In June 2023, achievement of these milestones was met and 50% of the 2022 Performance Options vested. As of December 31, 2023, the Company has recognized $6,996 in share-based compensation for the 2022 Performance Options.

The excess tax benefit related to share-based compensation recorded by the Company was not material for the years ended December 31, 2023, 2022, and 2021.

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

At December 31, 2023, there were 6,883 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 Company to grant equity awards to induce highly-qualified prospective officers and employees who are not currently employed by the Company to accept employment and provide them with a proprietary interest in the Company. The maximum number of shares reserved and available for issuance under the Plan is 1,500 shares. As of December 31, 2023, the Company had 348 shares available for issuance under this Inducement Plan in subsequent periods.

Determining the Fair Value of Stock Options

The Company 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 Company and become exercisable ratably over four years following the grant date and expire ten years after the grant date. Prior to 2021, the Company 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 Company 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 December 31, 2023, 2022 and 2021 are as follows:

Stock Option Assumptions:	2023	2022	2021
Stock option grants:			
Expected term (years)	6.2	6.1	6.2
Expected volatility	100.1 %	93.4 %	73.9 %
Risk-free interest rate	3.9 %	2.7 %	1.1 %
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 Company'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 Company has not distributed any dividends since its inception and have no plan to distribute dividends in the foreseeable future.

Stock Options

A summary of the combined stock option activity and other data for the Company's stock option plans for the year ended December 31, 2023 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, January 1, 2023	9,304	$ 6.67		
Granted	1,437	11.34		
Exercised	(342)	6.02		
Forfeited	(96)	12.58		
Expired	(4)	7.36		
Stock options outstanding, December 31, 2023	10,299	$ 7.29	7.2	$ 811
Stock options exercisable, December 31, 2023	6,337	$ 6.82	6.3	$ 627

The aggregate intrinsic value of options exercised during the year ended December 31, 2023, 2022, and 2021 was $2,612, $877, and $249, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2023, 2022, and 2021 was $9.14, $4.02, and $5.36 per share, respectively.

Restricted Share Awards

Restricted share awards represent Company shares issued free of charge to employees of the Company as compensation for services rendered. The Company measures the total fair value of restricted share awards on the grant date using the Company's stock price at the time of the grant. Restricted share awards granted to employees vest over a four-year period; one-fourth (1/4) on each anniversary of the grant date. Compensation expense for such awards granted is recognized over the applicable vesting period.

A summary of the Company's restricted share awards as of December 31, 2023, 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, January 1, 2023	56	$ 7.95
Granted	—	—
Vested	(33)	7.77
Forfeited	—	—
Non-vested restricted share awards outstanding, December 31, 2023	23	$ 8.20

No restricted share awards were granted during the years ended December 31, 2023 and 2022. The weighted average grant date fair value of restricted share awards granted during the year ended December 31, 2021 was $8.22 per share.

Performance Share Units Awards

Performance share units awards ("PSUs") represent Company shares issued free of charge to employees of the Company as compensation for achieving specified results. The Company measures the total fair value of performance share unit awards on the grant date using the Company's stock price at the time of the grant. In 2021, the Company 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. The weighted average grant date fair value of performance share awards granted during the years ended December 31, 2021 was $8.20 per share. No performance share awards were granted during the year ended December 31, 2022.

As of December 31, 2023, there were 555 performance share awards that did not have an accounting grant date due to the discretionary nature of the performance criteria. Accordingly, no grant date fair value was established and there were no performance share awards considered granted during the year ended December 31, 2023.

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 December 31, 2023, 2022 and 2021 the Company issued 47, 75, and 17 ordinary shares to employees, respectively. Expense related to the ESPP for the years ended December 31, 2023, 2022 and 2021 was immaterial.

NOTE 17: Net Loss Per 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 February 2023 Notes and the October 2023 Notes (together, the "2023 Notes"), the conversion of the Company's preferred shares, the exercise of outstanding equity compensation awards, and ordinary shares expected to be issued under the Company's ESPP.

The Company had a choice to settle the conversion obligations under the 2023 Notes in cash, shares or any combination of the two. The Company utilized the if-converted method to reflect the impact of the conversion of the 2023 Notes, unless the result was anti-dilutive. This method assumed the conversion of the 2023 Notes into shares of the Company's ordinary shares and reflected 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 the Company's 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 December 31, 2023, 2022 and 2021, is as follows:

Net Loss Per Share:	2023	2022	2021
Net loss	$ (160,276)	$ (137,464)	$ (77,329)
Weighted average shares:			
Basic shares	80,174	60,094	58,535
Effect of dilutive securities—employee and director equity awards outstanding	—	—	—
Diluted shares	80,174	60,094	58,535
Net loss per share - basic	$ (2.00)	$ (2.29)	$ (1.32)
Net loss per share - diluted	$ (2.00)	$ (2.29)	$ (1.32)

Potential ordinary shares of 513, 17,941, 15,327 and were excluded from the calculation of weighted average shares for the years ended December 31, 2023, 2022 and 2021 respectively, because either their effect was considered to be anti-dilutive or they were related to shares from PSUs for which the contingent vesting condition had not been achieved. For the years ended December 31, 2023, 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 18: Comprehensive Loss

The following table shows the components of accumulated other comprehensive loss for the year ended December 31, net of immaterial tax effects:

Accumulated Other Comprehensive Loss:	2023	2022	2021
Foreign currency translation adjustment:			
Beginning balance	$ (24,452)	$ (23,855)	$ (22,627)
Net other comprehensive income (loss)	331	(597)	(1,228)
Balance at December 31,	$ (24,121)	$ (24,452)	$ (23,855)
Unrealized gain (loss) on marketable securities, net			
Beginning balance	$ (1,889)	$ (85)	$ 1,576
Net other comprehensive income (loss), net of income tax benefit of $0, $0, and $214, respectively	2,843	(1,804)	(1,661)
Balance at December 31,	$ 954	$ (1,889)	$ (85)
Accumulated other comprehensive loss at December 31,	$ (23,167)	$ (26,341)	$ (23,940)

The effect on the Company's consolidated financial statements of amounts reclassified out of accumulated other comprehensive loss was immaterial for all periods presented.

NOTE 19: Segment Information

The Company 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 Company'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 Company'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.

Non-monetary long-lived assets primarily consist of property and equipment, goodwill, intangible assets and operating right-of use-assets. The following table summarizes non-monetary long-lived assets by geographic region as of December 31, 2023 and 2022:

Long-lived Assets by Geographic Region:	**2023**	**2022**
U.S.	$ 18,413	$ 19,414
Ireland	11,751	11,296
Total	$ 30,164	$ 30,710

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Avadel Pharmaceuticals plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Avadel Pharmaceuticals plc (the "Company") as of December 31, 2023 and 2022 the related consolidated statements of loss, comprehensive loss, shareholders' equity (deficit), and cash flows, for each of the three years in the period ended December 31, 2023, and the related notes and the schedule listed in the Index at Item 15 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 29, 2024, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Net Product Revenue- Reserves for Variable Consideration– Patient Financial Assistance Programs and Rebates – Refer to Note 1 to the financial statements

Critical Audit Matter Description

As described in Note 1 to the financial statements, the Company's revenue from product sales is recognized in accordance with Accounting Standards Codification Topic 606 ("ASC 606") when the customer obtains control of the product. The Company’s gross product sales are subject to a variety of price adjustments to arrive at reported net product revenue. These adjustments include estimates of payment discounts, specialty pharmacy fees, patient financial assistance programs, rebates and product returns and are estimated based on contractual arrangements, historical trends, expected utilization of such products and other judgments and analysis. The Company estimates a reserve for patient financial assistance programs primarily based on expected utilization by patients. The Company estimates a reserve for rebates based on contractual rates and estimates regarding their expectations of future patient utilization rates. Where appropriate, these estimated reserves take into consideration relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, historical trends, current and expected patient demand and forecasted customer buying and payment patterns. Given the complexity and

judgment involved in determining the significant assumptions used in estimating the reserve for patient financial assistance programs and rebates, auditing such estimates required a high degree of auditor judgment and increased extent of audit effort.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the reserve for patient financial assistance programs and rebates included the following, among others:

- We tested the effectiveness of controls over management’s process to account for variable consideration associated with the reserve for patient financial assistance programs and rebates, including underlying assumptions and key inputs into the Company's process to calculate the patient financial assistance programs and rebate accruals.
- We evaluated the Company's methodology and assumptions in developing the reserves for patient financial assistance programs and rebates accrual models, including assessing the completeness and accuracy of the underlying data used by management in their estimates.
- We tested the mathematical accuracy of the reserve for patient financial assistance programs and rebates.
- We performed retrospective reviews comparing management’s estimates of the expected reserve for patient financial assistance programs and rebates to actual amounts incurred subsequent to the dates of estimation, to evaluate management's ability to accurately forecast the reserves.

/s/ Deloitte and Touche LLP
St. Louis, Missouri
February 29, 2024

We have served as the Company's auditor since 2016.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Avadel Pharmaceuticals plc

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Avadel Pharmaceuticals plc (the "Company") as of December 31, 2023, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2023, of the Company and our report dated February 29, 2024, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Deloitte and Touche LLP
St. Louis, Missouri
February 29, 2024

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of December 31, 2023, the end of the period covered by this Annual Report on Form 10-K.

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to provide reasonable assurance that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

Based on their evaluation, as of the end of the period covered by this Annual Report on Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of December 31, 2023.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles.

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

We assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, our management used the criteria set forth in *Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission*. Based on this assessment, management concluded that, as of December 31, 2023, the Company's internal control over financial reporting is effective based on those criteria.

The Company's independent auditors have issued their auditors' report on the Company's internal control over financial reporting. That report appears above in this Annual Report on Form 10-K.

Other Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 or 15d-15 that occurred during the year ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Item 9B. Other Information.

During the year ended December 31, 2023, none of the Company's directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934) adopted, terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we intend to file our definitive proxy statement for our 2024 annual general meeting of shareholders pursuant to Regulation 14A of the Securities Exchange Act of 1934 (our "Definitive 2024 Proxy Statement"), not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in our Definitive 2024 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

Information regarding Directors, Executive Officers and Corporate Governance is hereby incorporated by reference to our Definitive 2024 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2023.

Item 11. Executive Compensation.

Information regarding Executive Compensation is hereby incorporated by reference to our Definitive 2024 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2023.

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

Information regarding Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters is hereby incorporated by reference to our Definitive 2024 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2023.

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

Information regarding Certain Relationships and Related Transactions, and Director Independence is hereby incorporated by reference to our Definitive 2024 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2023.

Item 14. Principal Accountant Fees and Services.

Our independent public accounting firm is Deloitte and Touche LLP, St. Louis, Missouri (PCAOB Auditor ID: 34).

Information regarding Principal Accountant Fees and Services is hereby incorporated by reference to our Definitive 2024 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2023.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report:

1. *Financial Statements*

See Item 8 - Financial Statements and Supplementary Data of Part II of this Report.

2. *Financial Statement Schedules*

See below for Schedule II: Valuation and Qualifying Accounts. All other schedules are omitted as they are not applicable, not required or the information is included in the consolidated financial statements or related notes to the consolidated financial statements.

Schedule II

Valuation and Qualifying Accounts

(In thousands)

Deferred Tax Asset Valuation Allowance:	Balance, Beginning of Period	Additions (a)	Deductions (b)	Other Changes (c)	Balance, End of Period
2023	$ 71,341	$ 30,918	$ (6,586)	$ 755	$ 96,428
2022	$ 24,025	$ 48,734	$ —	$ (1,418)	$ 71,341
2021	$ 21,624	$ 4,235	$ (51)	$ (1,783)	$ 24,025

a. Additions to the deferred tax asset valuation allowance relate to movements on certain French, Irish and U.S. deferred tax assets where we continue to maintain a valuation allowance until sufficient positive evidence exists to support reversal.

b. Deductions to the deferred tax asset valuation allowance include movements relating to utilization of net operating losses and tax credit carryforwards, release in valuation allowance and other movements including adjustments following finalization of tax returns.

c. Other changes to the deferred tax asset valuation allowance including currency translation adjustments recorded directly in equity, account method changes and the impact of corporate restructuring.

3. Exhibits required by Item 601 of Regulation S-K

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Item 16. Form 10-K Summary

Not applicable.

Index to Exhibits

Exhibit Number	Exhibit Description
3.1	Constitution (containing the Memorandum and Articles of Association) of Avadel Pharmaceuticals plc (incorporated by reference to Appendix 15 of Exhibit 2.1 to the registrant's current report on Form 8-K, filed on July 1, 2016)
3.2	Certificate of Designation of Series A Non-Voting Convertible Preferred Shares of Avadel Pharmaceuticals plc, dated February 20, 2020 (incorporated by reference to Exhibit 3.1 to the registrant's current report on Form 8-K, filed on February 24, 2020)

3.3	Certificate of Designation of Series B Non-Voting Convertible Preferred Shares of Avadel Pharmaceuticals plc, dated March 29, 2023 (incorporated by reference to Exhibit 3.1 to the registrant's current report on Form 8-K, filed on March 30, 2023)
4.1	Deposit Agreement dated as of January 3, 2017 among Avadel Pharmaceuticals plc, The Bank of New York, as Depositary, and holders from time to time of American Depositary Shares issued thereunder (including as an exhibit the form of American Depositary Receipt) (incorporated by reference to Exhibit 1.1 to the registrant's current report on Form 8-K12B, filed on January 4, 2017 and amended January 6, 2017)
4.2	Description of Securities (filed herewith)
10.1*	Exclusive License Agreement by and between Perrigo Pharma International DAC (f/k/a Elan Pharma International Limited) and Flamel Ireland Limited dated September 30, 2015, as amended by the First Amendment to Exclusive License Agreement dated December 21, 2018 (incorporated by reference to Exhibit 10.1 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2020, filed on March 9, 2021)
10.2	Office Lease Agreement by and between Grove II LLC and Eclat Pharmaceuticals LLC dated October 5, 2015, as amended (incorporated by reference to Exhibit 10.2 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2020, filed on March 9, 2021)
10.3‡	December 2015 Stock Option Rules (incorporated by reference to Exhibit 10.25 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.4‡	Form of Stock Option Grant Letter (incorporated by reference to Exhibit 10.26 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.5‡	Rules Governing the Free Share Plan - August 2016 (incorporated by reference to Exhibit 99.1 to the registrant's Registration Statement (No. 333-213154) on Form S-8, filed on August 16, 2016)
10.6‡	August 2016 Stock Option Rules (incorporated by reference to Exhibit 99.2 to the registrant's Registration Statement (No. 333-213154) on Form S-8, filed on August 16, 2016)
10.7‡	August 2016 Stock Warrant Rules (incorporated by reference to Exhibit 99.3 to the registrant's Registration Statement (No. 333-213154) on Form S-8, filed on August 16, 2016)
10.8‡	Form of stock option grant letter for 2016 Stock Option Rules (incorporated by reference to Exhibit 10.31 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 28, 2017)
10.9‡	Amended Employment Agreement dated as of June 3, 2019 between Avadel Management Corporation and Gregory J. Divis (incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K, filed on June 5, 2019)
10.10‡	First Amendment to Employment Agreement, dated as of September 28, 2022, between Avadel Management Corporation and Gregory J. Divis (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on From 10-Q, for the quarter ended September 30, 2022, filed on November 9, 2022)
10.11‡	Employment Agreement dated as of May 15, 2020 between Avadel Management Corporation and Thomas S. McHugh (incorporated by reference to Exhibit 10.2 to the registrant's current report on Form 10-Q, filed on August 10, 2020)

10.12‡	First Amendment to Employment Agreement, dated as of September 28, 2022, between Avadel Management Corporation and Thomas S. McHugh (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on From 10-Q, for the quarter ended September 30, 2022, filed on November 9, 2022)
10.13*	Asset Purchase Agreement by and among Cerecor, Inc. and Avadel Pharmaceuticals (USA), Inc., Avadel Pediatrics, Inc., FSC Therapeutics, LLC, Avadel US Holdings, Inc. and Avadel Pharmaceuticals plc dated as of February 12, 2018 (incorporated by reference to Exhibit 10.43 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 16, 2018)
10.14*	Guarantee by Avadel US Holdings, Inc. and Avadel Pharmaceuticals plc in favor of Deerfield CSF, LLC, Peter Steelman and James Flynn dated as of February 16, 2018 (incorporated by reference to Exhibit 10.45 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 16, 2018)
10.15*	Guarantee by Armistice Capital Master Fund, Ltd. in favor of Avadel US Holdings, Inc. dated as of February 16, 2018 (incorporated by reference to Exhibit 10.46 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 16, 2018)
10.16‡	Avadel Pharmaceuticals plc 2017 Omnibus Incentive Compensation Plan and related equity award agreements (incorporated by reference to Exhibit 10.18 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2020, filed on March 9, 2021)
10.17‡	Avadel Pharmaceuticals plc 2020 Omnibus Incentive Compensation Plan (incorporated by reference to Exhibit 10.19 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2020, filed on March 9, 2021)
10.18‡	Amendment to the Avadel Pharmaceuticals plc 2020 Omnibus Incentive Compensation Plan (incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K, filed August 3, 2023)
10.19‡	Employment Agreement dated as of February 15, 2021 between Avadel Management Corporation and Richard Kim (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly report on Form 10-Q, for the quarter ended March 31, 2021, filed on May 10, 2021)
10.20‡	First Amendment to Employment Agreement, dated as of September 28, 2022, between Avadel Management Corporation and Richard Kim (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on From 10-Q, for the quarter ended September 30, 2022, filed on November 9, 2022)
10.21	Avadel Pharmaceuticals plc 2021 Inducement Plan and related equity award agreements (incorporated by reference to Exhibit 10.20 to the registrant's Annual Report on Form 10-K, for the year ended December 31, 2021, filed on March 16, 2022)
10.22+^	Manufacturing Agreement by and between Flamel Ireland Limited and Recipharm Pessac, dated as of October 1, 2022 (incorporated by reference to Exhibit 10.21 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, filed on March 29, 2023)
10.23+^	Generic API Supply Agreement by and between Euticals Inc. and Avadel CNS Pharmaceuticals, LLC, dated as of January 2, 2020 (incorporated by reference to Exhibit 10.22 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2022, filed on March 29, 2023)
10.24+^	Purchase and Sale Agreement, dated March 29, 2023, between Avadel CNS Pharmaceuticals, LLC, the Company, Flamel Ireland Ltd., and RTW Royalty II DAC (incorporated by reference to Exhibit 10.2 to the registrant's current report on Form 8-K, filed on March 30, 2023)
10.25+^	Generic API Supply Agreement and Manufacturing Agreement by and between Catalent Pharma Solutions LLC and Flamel Ireland Limited, dated as of March 29, 2018 (filed herewith)

14.1	Code of Business Conduct and Ethics (filed herewith)
14.2	Financial Integrity Policy (incorporated by reference to Exhibit 14.2 to the registrant's current report on Form 8-K, filed on March 7, 2017)
21.1	List of Subsidiaries (filed herewith)
23.1	Consent of Deloitte & Touche LLP (filed herewith)
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32.1	Certification of the Chief Executive Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)
32.2	Certification of the Principal Financial Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)
97.1‡	Avadel Pharmaceuticals plc Compensation Recovery Policy (filed herewith)
101.INS	Inline XBRL Instant Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*) (filed herewith)

***** Confidential treatment has been requested for the redacted portions of this agreement. A complete copy of the agreement, including the redacted portions, has been filed separately with the Securities and Exchange Commission.

The representations and warranties contained in this agreement were made only for purposes of the transactions contemplated by the agreement as of specific dates and may have been qualified by certain disclosures between the parties and a contractual standard of materiality different from those generally applicable under securities laws, among other limitations. The representations and warranties were made for purposes of allocating contractual risk between the parties to the agreement and should not be relied upon as a disclosure of factual information relating to the Company, the Investors or the transaction described in the Current Report on Form 8-K.

‡ Management contract or compensatory plan or arrangement filed pursuant to Item 15(b) of Form 10-K.

+ Certain exhibits and schedules to these agreements have been omitted pursuant to Item 601 of Regulation S-K. The registrant will furnish copies of any of the exhibits and schedules to the Securities and Exchange Commission upon request.

^ Certain portions of this exhibit have been omitted because they are not material and the registrant customarily and actually treats that information as private or confidential.

(1) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Avadel Pharmaceuticals plc

Dated: February 29, 2024

By: /s/ Gregory J. Divis

Name: Gregory J. Divis

Title: Chief Executive Officer

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each of Geoffrey M. Glass, Eric J. Ende, Mark A. McCamish, MD, Ph.D., Linda S. Palczuk, and Peter J. Thornton, by their respective signatures below, irrevocably constitutes and appoints Gregory J. Divis and Thomas S. McHugh, and each of them individually acting alone without the other, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Signature	Title	Date
/s/ Gregory J. Divis Gregory J. Divis	Director, Chief Executive Officer and Principal Executive Officer	February 29, 2024
/s/ Thomas S. McHugh Thomas S. McHugh	Chief Financial Officer and Principal Financial and Accounting Officer	February 29, 2024
/s/ Geoffrey M. Glass Geoffrey M. Glass	Non-Executive Chairman of the Board and Director	February 29, 2024
/s/ Dr. Eric J. Ende Dr. Eric J. Ende	Director	February 29, 2024
/s/ Mark A. McCamish, MD, Ph.D. Mark A. McCamish, MD, Ph.D.	Director	February 29, 2024
/s/ Linda S. Palczuk Linda S. Palczuk	Director	February 29, 2024
/s/ Peter J. Thornton Peter J. Thornton	Director	February 29, 2024

AVADEL PHARMACEUTICALS PLC
CORPORATE AND OTHER INFORMATION

Board of Directors

Geoffrey M. Glass
President and Chief Executive Officer, Kiniciti, LLC

Gregory J. Divis
Chief Executive Officer

Eric J. Ende, M.D.
President, Ende BioMedical Consulting Group

Mark A. McCamish, M.D., Ph.D.
President and Chief Executive Officer of IconOVir Bio, Inc.

Linda S. Palczuk
Chief Executive/Operating Officer of Life Sciences Companies

Peter J. Thornton
President and Chief Financial Officer of Envetec Sustainable Technologies Limited

Naseem S. Amin, M.D.
Chief Executive Officer of Orphalan SA

Executive Officers

Gregory J. Divis
Chief Executive Officer

Thomas S. McHugh
Chief Financial Officer

Richard J. Kim
Chief Commercial Officer

Jerad G. Seurer
General Counsel and Corporate Secretary

Form 10-K Report

Our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission, is printed as part of this Annual Report. Additional copies are available without charge upon written request to:

Jerad G. Seurer, Company Secretary
Avadel Pharmaceuticals plc
10 Earlsfort Terrace
Dublin 2, Ireland D02 T380
+1 636-730-1420.