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, 2021

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. ☒

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 $390,167,685 based on the closing sale price of the registrant's American Depositary Shares as reported by the Nasdaq Global Market on June 30, 2021. Such market value excludes 513,155 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 March 11, 2022 was 59,032,237.

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, 2021, 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:

- We cannot be certain that our lead product candidate or future product candidates will receive marketing approval. Without marketing approval, we will not be able to commercialize our lead product candidate or future product candidates.
- Our business is significantly dependent on the successful development, regulatory approval and commercialization of FT218, our only product candidate.
- Our lead product candidate and future product candidates may not reach the commercial market for a number of reasons.
- If we are not able to use the 505(b)(2) regulatory approval pathway for the regulatory approval of FT218 or if the U.S. Food and Drug Administration (“FDA”) requires additional clinical or nonclinical data to support an New Drug Application under Section 505(b)(2) than we previously anticipated, it will likely take significantly longer, cost significantly more and be significantly more complicated to gain FDA approval for FT218, and in any case may not be successful.
- We incurred a net loss in 2021 and we will likely incur a net loss in 2022, and if we are not able to regain 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 American Depositary Shares (“ADSs”).
- The distribution and sale of FT218, if approved, will be subject to significant regulatory restrictions, including the requirements of a Risk Evaluation and Mitigation Strategy (“REMS”) and safety reporting requirements, and these regulatory requirements will subject us to risks and uncertainties, any of which could negatively impact sales of FT218, if approved.
- Disruptions at the 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.
- FT218, if approved by the FDA, may not obtain desired regulatory exclusivities, including orphan drug exclusivity.
- We rely, and intend to continue to rely, on single source providers for the development, manufacture and supply of FT218, 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 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 establish effective sales, marketing and distribution capabilities, or enter into agreements with third parties to market, sell and distribute FT218, if approved, our business, results of operations, financial condition and prospects will be materially adversely affected.
- COVID-19 may materially and adversely affect our business and our financial results.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and 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 belief 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 reliance on a single lead product candidate, FT218;
- Our ability to obtain regulatory approval of and successfully commercialize FT218, including any delays in approval;
- The ability of FT218, if approved, to gain market acceptance;
- Our ability to enter into strategic partnerships for the commercialization, manufacturing and distribution of FT218, if approved;
- Our dependence on a limited number of suppliers for the manufacturing of FT218 and certain raw materials in FT218 and any failure of such suppliers to deliver sufficient quantities of these raw materials, which could have a material adverse effect on our business;
- Our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;
- Our expectations about the potential market size and market participation for FT218;
- Our ability to continue to service the our Exchangeable Senior Notes due February 2023 (the "February 2023 Notes") and our Exchangeable Senior Notes due October 2023 (the "October 2023 Notes", together with the February 2023 Notes, the "2023 Notes"), including making the ongoing interest payments on the 2023 Notes, settling exchanges of the 2023 Notes in cash or completing any required repurchases of the 2023 Notes;
- The potential impact of COVID-19 on our business and future operating results;
- Our ability to hire and retain key members of our leadership team and other personnel; and
- Competition existing today or that will likely 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.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to revise any forward-looking statements to reflect events or developments occurring after the date of this Annual Report, even if new information becomes available in the future.

NOTE REGARDING TRADEMARKS

We own various trademark registrations and applications, and unregistered trademarks, including Avadel®, Micropump®, LiquiTime® and Medusa®. All other 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 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 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. Our lead product candidate, FT218, is an investigational once-nightly, extended-release formulation of sodium oxybate for the treatment of excessive daytime sleepiness ("EDS") or cataplexy in adults with narcolepsy. We are primarily focused on the development and potential United States ("U.S.") Food and Drug Administration ("FDA") approval of FT218. In December 2020, we submitted a New Drug Application ("NDA") to the FDA for FT218 to treat excessive daytime sleepiness or cataplexy in adults with narcolepsy. In February 2021, the NDA for FT218 was accepted by the FDA and was assigned a Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021. On October 15, 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this Annual Report, the FDA's review of our NDA for FT218 remains ongoing.

Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio. As of the date of this Annual Report, we do not have any approved or commercialized products in our portfolio.

FT218

FT218 is a once-nightly formulation of sodium oxybate that uses our Micropump controlled release drug-delivery technology for the treatment of EDS or cataplexy in adults suffering from narcolepsy. Sodium oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid. Immediate release sodium oxybate is approved in the U.S. for the treatment of EDS or cataplexy in patients with narcolepsy and is approved in Europe for the treatment of cataplexy in patients with narcolepsy. Since 2002, sodium oxybate has only been available as a formulation that must be taken twice nightly, first at bedtime, and then again 2.5 to 4 hours later.

On December 16, 2020, we announced the submission of our NDA to the FDA for FT218. On February 26, 2021, the FDA notified us of formal acceptance of the NDA and assigned a PDUFA target action date of October 15, 2021. On October 15, 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this Annual Report, the FDA's review of our NDA for FT218 remains ongoing.

We conducted a Phase 3 clinical trial of FT218, the REST-ON trial, which was a randomized, double-blind, placebo-controlled study that enrolled 212 patients who received at least one dose of FT218 or placebo, and was conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient, last visit was completed at the end of the first quarter of 2020, and positive top line data from the REST-ON trial was announced on April 27, 2020. Patients who received 9 g of once-nightly FT218, the highest dose administered in the trial, demonstrated statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test ("MWT"), clinical global impression-improvement ("CGI-I"), and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g also demonstrated statistically significant and clinically meaningful improvement on all three co-primary endpoints compared to placebo. We observed the 9 g dose of once-nightly FT218 to be generally well tolerated. Adverse reactions commonly associated with sodium oxybate were observed in a small number of patients (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3% and enuresis 9%), and 3.9% of the patients who received 9 g of FT218 discontinued the trial due to adverse reactions.

In January 2018, the FDA granted FT218 orphan drug designation for the treatment of narcolepsy, which makes FT218 potentially eligible for certain development and commercial incentives, including potential U.S. market exclusivity for up to seven years. Additionally, several FT218-related U.S. patents have been issued, and there are additional patent applications currently in development and/or pending at the U.S. Patent and Trademark Office ("USPTO"), as well as foreign patent offices.

In July 2020, we announced that the first patient was dosed in our open-label extension ("OLE")/switch study of FT218 as a potential treatment for EDS or cataplexy in patients with narcolepsy. The OLE/switch study is examining the long-term safety and maintenance of efficacy of FT218 in patients with narcolepsy who participated in the REST-ON study, as well as dosing and preference data for patients switching from twice-nightly sodium oxybate to once-nightly FT218, regardless of whether they participated in REST-ON. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study.

New secondary endpoints from the REST-ON trial were presented at the American Academy of Neurology, beginning April 17, 2021. The first poster described FT218 improvements in disturbed nocturnal sleep ("DNS"), defined in REST-ON as the number of shifts from stages N1, N2, N3, and rapid eye movement ("REM") sleep to wake and from stages N2, N3, and REM sleep to stage N1. FT218 also decreased the number of nocturnal arousals as measured on polysomnography. Improvements in DNS were further supported by post-hoc analyses demonstrating increased time in deep sleep (N3, also known as slow wave sleep), and less time in N1. A second poster described the statistically significant improvements in the Epworth Sleepiness Scale, both the quality of sleep and the refreshing nature of sleep, and a decrease in sleep paralysis. These clinically relevant improvements were observed for all doses, beginning at week 3, for the lowest 6 g dose, compared to placebo. FT218 did not demonstrate significant improvement for hypnagogic hallucinations compared to placebo.

Additional data supportive of the efficacy findings in REST-ON were presented at the 35th Annual Meeting of the Associated Professional Sleep Societies, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, also known as SLEEP 2021, beginning June 10, 2021. New data included post-hoc analyses demonstrating endpoints improvements, regardless of concomitant stimulant use, in both narcolepsy Type 1 or Type 2. Additionally, a post-hoc analysis showed that FT218 was associated with decreased body mass index compared to placebo, which may be relevant as people with narcolepsy often have co-morbid obesity. In August 2021, the primary results from the REST-ON trial were published by Kushida et al. in the journal SLEEP. New data was presented at the American College of Chest Physicians annual meeting, beginning October 17, 2021, including additional post-hoc analyses from the REST-ON trial, demonstrating a greater proportion of patients receiving FT218 experienced reductions in weekly cataplexy attacks and improvement in mean sleep latency compared to placebo, as well as the results of a discrete choice experiment, indicating that the overall driver of patient preference between sodium oxybate treatments is a once-nightly, versus twice-nightly, formulation.

We believe FT218 has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standards of care for EDS or cataplexy in patients with narcolepsy, which are twice-nightly oxybate formulations.

Micropump Drug-Delivery Technology

Our Micropump drug-delivery technology allows for the controlled delivery of small molecule drugs taken orally, which has the potential to improve dosing compliance, reduce toxicity and improve patient compliance. Beyond FT218, we believe there could be other product development opportunities for our Micropump drug-delivery technology, representing either life cycle opportunities, whereby additional intellectual property can be added to a pharmaceutical product to extend the commercial viability of a currently marketed product, or innovative formulation opportunities for new chemical entities.

Previously Approved FDA Products

On June 30, 2020 ("Closing Date"), we announced the sale of our portfolio of sterile injectable drugs used in the hospital setting (the "Hospital Products"), including our three FDA-approved commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, to Exela Sterile Medicines LLC ("Exela Buyer").

Our Drug Delivery Technologies

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

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

- Micropump. Our Micropump technology allows for the development of modified release solid, oral dosage formulations of drugs. Micropump-carvedilol and Micropump-aspirin formulations have been approved in the U.S. Further, Micropump technology is being employed in our investigational FT218 product.

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

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

Competition and Market Opportunities

Competition

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

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

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

Potential competition for FT218

If FT218 receives FDA approval, it will compete with the currently approved twice-nightly oxybate formulations, as well as a number of daytime wake promoting agents including lisdexamfetamine, detroamphetamine, methylphenidate, amphetamine, modafinil, and armodafinil, which are widely prescribed, as well as solriamfetol and pitolisant, all of which may be prescribed concomitantly with sodium oxybate. If approved, we anticipate FT218 may face competition from manufacturers of generic twice-nightly sodium oxybate formulations, who have reached settlement agreements with the current marketer, which allows for entry of an authorized generic in 2023. 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 $GABA_B$ agonists.

Corporate Information

We are an Irish public limited company. 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 is an Irish limited company, 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. As a matter of policy, we seek patent protection of our inventions and also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and develop competitive positions.

- FT218 Patents. We have been awarded several FT218-related U.S. patents having expiry dates from mid-2037 to early-2040. We have a number of additional FT218-related patent applications pending at the USPTO as well as at non-U.S. patent offices.

- Drug Delivery Technology Patents. Our drug delivery technologies are the subject of certain patents, including: (i) for Micropump, patents relating to coating technologies that provide for controlled release of an active ingredient (expiring in 2025 in the U.S. and 2022 in non-U.S. jurisdictions); (ii) for LiquiTime, patents relating to film-coated microcapsules and a method comprising orally administering such microcapsules to a patient (expiring in 2023); and (iii) for Medusa, patents relating to an aqueous colloidal suspension of low viscosity based on submicronic particles of water-soluble biodegradable polymer PO (polyolefin) carrying hydrophobic groups (expiring in 2023).

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. Nevertheless, for FT218, we currently rely on one supplier for sourcing active pharmaceutical ingredients (“APIs”).

The API in FT218, sodium oxybate, is a Schedule I controlled substance in the U.S., and FT218, if approved by the FDA, will be a Schedule III controlled substance in the U.S. As a result, FT218 is subject to regulation by the U.S. Drug Enforcement Administration (“DEA”) under the Controlled Substances Act (“CSA”), and its manufacturing and distribution are highly restricted. Quotas from the DEA are required in order to manufacture and package sodium oxybate and FT218 in the U.S. Similar rules, restrictions and controls apply to FT218 in relevant jurisdictions outside of the U.S.

The API for FT218 is currently manufactured by a single source contract manufacturing organization (“CMO”) in the U.S. The drug product for commercial lots is manufactured outside of the U.S. by a single source CMO. We will continue to outsource the production of FT218 to current good manufacturing practices (“cGMP”) -compliant, DEA and FDA-audited CMOs pursuant to supply agreements and have no present plans to acquire manufacturing facilities. We are establishing, and may continue to establish, additional CMOs for the manufacture FT218, including drug product manufacturing in the U.S.

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. Our drug candidates must be approved by the FDA through the 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 a NDA for a new drug;
- a determination by the FDA within 60 days of its receipt of a NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient ("API") and finished drug product are produced to assess compliance with the FDA's current good manufacturing practice requirements ("cGMPs");
- 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 a 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 or 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 ("PK") and pharmacodynamics ("PD") 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 a 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 and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse reactions, any finding from other clinical studies, tests in laboratory animals, or *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 a 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 a NDA must be obtained before a drug may be offered for sale in the U.S.

Under the 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 a 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 a NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving a 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 a 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 an 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 data differently than we interpret the same data.

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 Risk Evaluation and Mitigation Strategy (“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, a NDA or supplement to a 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. is another type of regulatory market exclusivity in the U.S. Pediatric exclusivity, if granted, adds 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 a 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 experiences 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, 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 is expected to culminate in November 2023. 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 also may require post-approval testing, sometimes referred to as Phase 4 testing, risk minimization action plans, and post-marketing surveillance to monitor the effects of an approved drug or place conditions on an approval that could restrict the distribution or use of the drug.

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 AEs 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 a 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 a 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 Drug Enforcement Administration 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 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 U.S. federal Controlled Substances Act (“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 Drug Enforcement Administration (“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 FT218, sodium oxybate, is a Schedule I controlled substance in the U.S., and FT218, if approved by the FDA, will be 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 active pharmaceutical ingredient 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 or not 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 and FT218 in the U.S. Accordingly, we require DEA quotas for sodium oxybate and FT218, until approved, if ever, by the FDA.

If approved by the FDA, FT218 will be a Schedule III controlled substance and subject to DEA import volume limits and state 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 FT218 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 United States 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. 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 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) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1,

2022, covered manufacturers also are required to report information regarding their payments and other transfers of value to physician assistants, and nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;

- 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.

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, our 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 United States 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 United States 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 United States, 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.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative efforts to expand, repeal, replace or modify the ACA, some of which have been successful, in part, in modifying the law, as well as court challenges to the constitutionality of the law. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

Prior to the Biden administration, on October 13, 2017, former President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The former Trump administration concluded that cost-sharing reduction (" CSR"), payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. Several state attorneys general filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the U.S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued the payments were owed to them. On April 27, 2020, the United States Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is unclear what impact these rulings will have on our business.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- On August 2, 2011, 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 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the temporary suspension, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022.

- 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.

- 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 December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation ("MFN") Model under which Medicare Part B reimbursement rates would have been be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021 CMS rescinded the Most Favored Nations rule. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. 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.

There have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the FYs 2019 and 2018 reimbursement formula on specified covered outpatient drugs ("SCODs"). The court ruled this change was not an "adjustment" which was within the secretary of HHS's discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. Plaintiffs-appellees filed a petition for a writ of certiorari at the Supreme Court on February 10, 2021. On Friday July 2, 2021, the Supreme Court granted the petition. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

Individual states in the United States 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 action 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, 2021, we had approximately 66 employees, all of which were full-time. 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.

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 Our Lead Product Candidate, Future Product Candidates Clinical Development and Commercialization

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

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

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

An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. An NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. For example, we submitted an NDA to the FDA for FT218 for the treatment of EDS or cataplexy in adults with narcolepsy to the FDA in December 2020 through the Section 505(b)(2) regulatory pathway. In February 2021, the FDA assigned FT218 a PDFUA target action date of October 15, 2021. In October, the FDA notified us that its review was still ongoing and action would not be taken by the PDUDFA date. Any delay or setback in the regulatory approval or commercialization of our lead product candidate will adversely affect our business.

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

- could determine that we cannot rely on the Section 505(b)(2) regulatory pathway or other pathways we have selected, as applicable, for our lead product candidate;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of our product candidate for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the U.S., including any findings that the clinical and other benefits of our product candidate outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for our product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously approved drugs with the same conditions of approval as our product candidate, as applicable;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidate;

- may audit some or all of our clinical research study sites to determine the integrity of our data and may reject any or all of such data;
- may approve our lead 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 change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our lead product candidate.

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

We have submitted a NDA for FT218 in the U.S. and will evaluate filing potentially elsewhere. We have determined, following FDA consultation, that the 505(b)(2) approval pathway, which permits an NDA applicant to rely on the FDA's previous findings of safety or effectiveness and data from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, is the appropriate pathway for a FT218 NDA. There can be no assurances, however, that the 505(b)(2) approval pathway in the U.S., or similar approval pathways outside of the U.S., will be available for FT218 or that the FDA or other regulatory authorities will approve FT218 through an application based on such pathways.

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

Our business is significantly dependent on the successful development, regulatory approval and commercialization of FT218, our only product candidate.

We have invested substantially all of our efforts and financial resources in the development of FT218, which has not yet been approved for sale or commercial use. Currently, FT218 is our only product candidate and we have not licensed, acquired, or invented any other product candidates for preclinical or clinical evaluation. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and that therefore may be able to better sustain a failure of a lead candidate. The success of our business, including our ability to finance our company and generate any revenue in the future, will, at this point, depend entirely on the regulatory approval and commercialization of FT218, which may never occur. Any failure to obtain regulatory approval of FT218 would have a material and adverse impact on our business. Even if we successfully obtain regulatory approvals to market FT218, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of FT218, even if approved.

The commercial success of FT218 will depend on a number of factors, including the following:

- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- our ability to raise any additional required capital to support the commercialization on acceptable terms, or at all;
- our ability to consistently manufacture FT218 on a timely basis;
- our ability to secure and maintain from the U.S. DEA our annual quota for FT218 APIs;
- our ability to successfully to develop and implement a REMS for the safe use of FT218;
- the prevalence, duration and severity of potential side effects or other safety issues that patients may experience with FT218;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to FT218;

- the differentiation of FT218 from other available approved, or investigational, drugs and treatments of excessive daytime sleepiness or cataplexy in adults with narcolepsy, and the willingness of physicians, operators of hospitals and clinics and patients to adopt and utilize FT218's once nightly formulation;
- our ability to successfully develop a commercial strategy and thereafter commercialize FT218 in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid and similar foreign authorities) and other third-party payors for FT218;
- patients' ability and willingness to pay out-of-pocket for FT218 in the absence of coverage and/or adequate reimbursement from third-party payor;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of FT218, if approved;
- patient demand for FT218, if approved;
- our ability to establish and enforce intellectual property rights in and to FT218; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize FT218. Even if regulatory approvals are obtained, we may never be able to successfully commercialize FT218. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of FT218 to continue our business or achieve profitability.

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

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

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

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

If we are not able to use the 505(b)(2) regulatory approval pathway for the regulatory approval of FT218 or if the FDA requires additional clinical or nonclinical data to support an NDA under Section 505(b)(2) than we previously anticipated, it will likely take significantly longer, cost significantly more and be significantly more complicated to gain FDA approval for FT218, and in any case may not be successful.

We submitted an NDA to the FDA for FT218 for the treatment of cataplexy or EDS in adults with narcolepsy in December 2020 through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984,

also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act, or the FDCA. In general, Section 505(b)(2) allows an applicant to rely on the FDA's prior findings of safety or effectiveness for a listed drug only to the extent that the proposed product in the 505(b)(2) application shares common characteristics with the listed drug, or on published literature that the applicant believes supports the safety or efficacy of its proposed product but for which it does not have a right of reference for the underlying data. The 505(b)(2) application must include sufficient data to support differences between the listed drug and the proposed drug in the 505(b)(2) application. If the FDA does not agree that the 505(b)(2) regulatory pathway is appropriate or scientifically justified for FT218, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. Specifically, the FDA may not agree that we have provided a scientific bridge, through, for example, comparative bioavailability data, to demonstrate that reliance on the prior findings of safety or efficacy for a listed drug is justified. Although the active ingredient in FT218, sodium oxybate, is approved for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy, it has not previously been approved or demonstrated to be safe for once nightly administration in these indications. If we are unable to establish a bridge between FT218 and the listed drug upon which we rely to demonstrate that such reliance is justified, we may be required to show safety and efficacy through one or more additional clinical trials. In addition, if we are unable to utilize the 505(b)(2) pathway, the time and financial resources required to obtain FDA approval for FT218 would likely increase substantially. Moreover, the inability to utilize the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than FT218, which could materially adversely impact its competitive position and prospects.

Even if we are successful in pursuing the 505(b)(2) regulatory pathway for FT218, we cannot assure you that we will receive the requisite or timely approval for commercialization of FT218. Although the Section 505(b)(2) pathway allows us to rely in part on the FDA's prior findings of safety or efficacy for approved listed drugs or on published literature for which we do not have a right of reference, the FDA may determine that prior findings by the FDA or the published literature that we believe supports the safety or efficacy of FT218 is insufficient or not applicable to our application or that additional studies will need to be conducted. To the extent that we are relying on the 505(b)(2) regulatory pathway based on the approval of a listed drug for a similar indication, the FDA may require that we include in the labeling of FT218, if approved, some or all of the safety information that is included in the labeling of the approved listed drug. For example, the labels of current FDA-approved sodium oxybate products include a black box warning regarding risks of central nervous system depression and abuse and misuse. Moreover, even if FT218 is approved via the 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, such as a Risk Evaluation and Mitigation Strategy, or REMS, which is a risk mitigation plan which could include medication guides, physician communication plans, or elements to assure safe use, or ETASU, such as restricted distribution methods, patient registries and other risk minimization tools.

Our business depends heavily on our ability to successfully commercialize FT218 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 FT218, if approved, will be successful or that we will be able to generate revenues at the levels or on the timing we expect, or at levels or on the timing necessary to support our goals.

Our business currently depends heavily on our ability to successfully commercialize FT218 for the treatment of cataplexy or EDS in adults with narcolepsy in the U.S. and in other jurisdictions where we may obtain marketing approval. Even if we obtain marketing approval for FT218, we may never be able to successfully commercialize our product or meet our expectations with respect to revenues. There is no guarantee that the infrastructure, systems, processes, policies, relationships, and materials we are building for the commercialization of FT218 in the U.S., or that we may build for other jurisdictions where we may obtain marketing approval, will be sufficient for us to achieve success at the levels we expect. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected. We may encounter issues, delays or other challenges in launching or commercializing FT218, if approved. For example, our results may be negatively impacted if we have not adequately sized our field teams or if our targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes.

We may encounter issues and challenges in commercializing FT218, if approved, and generating sufficient revenues to result in a profit. We may also encounter challenges related to reimbursement of FT218, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering FT218. 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 FT218. 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 FT218, if approved, and generate sufficient revenues to result in a profit, include:

- the acceptance of FT218 by patients and the medical community;
- the ability of our third-party manufacturer(s) to manufacture commercial supplies of FT218 in sufficient quantities at acceptable costs, to remain in good standing with regulatory agencies, maintain applicable registrations and licenses, and to maintain commercially viable manufacturing processes that are, to the extent required, compliant with current Good Manufacturing Practices, or cGMP, regulations;
- our ability to remain compliant with laws and regulations that apply to us and our commercial activities;
- FDA- or other foreign regulatory agency-mandated package insert requirements and successful completion of any related FDA or other foreign regulatory agency post-marketing requirements, including a REMS;
- the actual market size for FT218, which may be different than expected;
- the length of time that patients who are prescribed our drug remain on treatment;
- the sufficiency of our drug supply to meet commercial demand which could be negatively impacted if our projections regarding the potential number of patients are inaccurate, we are subject to unanticipated regulatory requirements, or our current drug supply is destroyed, or negatively impacted at our manufacturing sites, storage sites, or in transit;
- our ability to effectively complete with other therapies; and
- our ability to maintain, enforce, and defend third party challenges to our intellectual property rights in and to FT218.

Any of these issues could impair our ability to successfully commercialize our product, if approved, or to generate sufficient revenues to result in a profit or to meet our expectations with respect to the amount or timing of revenues or profits. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition, and prospects. Even if approved, there is no guarantee that we will be successful in our commercialization efforts with respect to FT218. We may also experience significant fluctuations in sales of FT218 from period to period and, ultimately, we may never generate sufficient revenues from FT218 to reach or maintain profitability or sustain our anticipated levels of operations. Any inability on our part to successfully commercialize FT218 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 adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected. We may encounter issues, delays or other challenges in launching or commercializing FT218, if approved. 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.

Clinical development of drugs is costly and time-consuming, and the outcomes are uncertain. A failure to prove that FT218 is safe and effective in clinical trials could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Clinical trials are expensive and can take many years to complete, and the outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical testing. For example, we are currently conducting an open-label extension (“OLE”) switch study of FT218, RESTORE, to examine the long-term safety and maintenance of efficacy of FT218 in patients with narcolepsy who participated in our REST-ON trial, as well as dosing and preference data for patients switching from twice-nightly sodium oxybate to once-nightly FT218 regardless if they participated in REST-ON or not. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study. If any participants in the OLE/switch study report any serious adverse events that are deemed to be related to FT218 or if FT218 is not observed to have long-term efficacy, our business, financial condition, results of operations and growth prospects could be material and adversely affected.

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

- obtaining regulatory approval to commence a trial;

- reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board or ethics committee approval at each site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial;
- adding new sites; or
- obtaining clinical materials or manufacturing sufficient quantities of FT218 for use in clinical trials.

We have limited experience as a commercial drug company targeting an orphan drug disease and the marketing and sale of FT218, if approved, may be unsuccessful or less successful than anticipated.

We have limited experience as a commercial drug company targeting an orphan disease and there is limited information about our ability to successfully overcome many of the risks and uncertainties encountered by companies commercializing drugs in the biopharmaceutical industry. To execute our business plan, in addition to successfully obtaining marketing approval and marketing and selling FT218, we will need to successfully:

- establish and maintain our relationships with healthcare providers who will be treating the patients who may receive our drug;
- obtain adequate pricing and reimbursement for FT218;
- develop and maintain successful strategic alliances; and
- manage our spending as costs and expenses increase due to marketing approvals and commercialization in multiple jurisdictions, if approved.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully commercialize FT218, raise capital, expand our business or continue our operations.

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of biotechnology and biopharmaceutical products. Arrangements with third-party payors and customers can expose biotechnology and biopharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, or AKS, and the federal False Claims Act, or 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 our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop. See the sections entitled, "*Business — Government Regulation — Coverage and Reimbursement*"
and "*Business — Government Regulation — Healthcare Laws*".

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 depends upon a number of factors.

In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

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

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved

products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

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

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union 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 any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

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

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, changes to our manufacturing arrangements; additions or modifications to product labeling; the recall or discontinuation of our products; or additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. See the section entitled, "*Business — Government Regulation — Healthcare Reform*".

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

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

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

FT218, if successfully developed and approved, may cause undesirable side effects that limit the commercial profile or result in other significant negative consequences for approved products; or delay or prevent further development or regulatory approval with respect to product candidates or new indications, or cause regulatory authorities to require labeling statements, such as boxed warnings.

Undesirable side effects caused by FT218, if successfully developed and approved, could limit the commercial profile of FT218 or result in significant negative consequences such as a more restrictive label or other limitations or restrictions. Undesirable side effects caused by FT218 could cause us or regulatory authorities to interrupt, delay or halt non-clinical studies and clinical trials or could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities.

Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, certain side effects of FT218 may only be uncovered with a significantly larger number of patients exposed to the drug, and those side effects could be serious or life-threatening. If we or others identify undesirable side effects caused by FT218 (or any other similar drugs), a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their marketing approval of such drugs;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or additions to an existing boxed warning, or a contraindication, including as a result of inclusion in a class of drugs for a particular disease;
- regulatory authorities may refuse to approve label expansions for additional indications for any approved drugs;
- we may be required to change the way such drugs are distributed or administered, conduct additional clinical trials or change the labeling of the drugs;
- regulatory authorities may require a modification of an existing REMS to mitigate risks;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove FT218 from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking FT218; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of FT218, if approved, and could substantially increase the costs of commercializing FT218 and significantly impact our ability to successfully commercialize FT218 and generate revenues.

We may incur significant liability if governmental authorities allege or determine that we are engaging in commercial activities or promoting FT218 in a way that violates applicable regulations.

Physicians have the discretion to prescribe drug products for uses that are not described in the product’s labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician’s choice of treatments, the FDA and other regulatory agencies regulate a manufacturer’s communications regarding off-label use and prohibit off-label promotion, as well as the dissemination of false or misleading labeling or promotional materials. Manufacturers may not promote drugs for off-label uses. Accordingly, if FT218 is approved, we may not promote FT218 in the U.S. for any indications other than its FDA-approved indication. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses, including promoting unapproved dosing regimens, may be subject to significant liability, which may include civil and administrative remedies as well as criminal sanctions.

Notwithstanding regulations related to product promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We currently, and intend to

increasingly, engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws and regulatory guidance.

Obtaining and maintaining regulatory approval of FT218 in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of FT218 in other jurisdictions.

Obtaining and maintaining regulatory approval of FT218 in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of FT218, comparable regulatory authorities in foreign jurisdictions must also approve FT218 in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of FT218 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 FT218 will be harmed.

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

As we seek to expand our operations outside of the U.S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act (FCPA) prohibits any U.S. individual or business from paying, offering, authorizing payment, or offering anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of such third party in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the 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 our product candidate to other available therapies. If we seek approval for our lead product candidate or future product candidates outside of the U.S. and reimbursement of our lead product

candidate or future product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

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

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

Risks Related to Our Financial Position and Capital Requirements

We incurred a net loss in 2021 and we will likely incur a net loss in 2022, and if we are not able to regain profitability in the future, the value of our shares may fall.

Although we reported a net income for the year ended December 31, 2020 due to the gain on the sale of our Hospital Products, we incurred a net loss of $77,329 for the year ended December 31, 2021. We do not expect to become profitable in the near future, and may never achieve profitability. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to recognize revenues from the commercialization of FT218, if approved. We have devoted significant financial resources to research and development, including our clinical development activities, and the pursuit of regulatory approval for FT218. If we obtain marketing approval, our future revenues will depend upon the size of any markets in which FT218 and any future products have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our product and any future products in those markets. In addition, we are in the process of building a sales organization and supporting commercial infrastructure and, accordingly, we will incur significant expenses as we continue to develop a sales organization and commercial infrastructure in advance of generating any commercial product sales. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

- the timely receipt of necessary approvals from the FDA for the commercialization of FT218;
- 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 FT218;
- the level of product and price competition for FT218;
- our ability to develop new partnerships and additional commercial applications for FT218 and any future product candidates;
- our ability to control our costs;
- the initiation of additional research, preclinical, clinical or other programs as we seek to identify and validate additional product candidates;
- our ability to acquire or in-license other product candidates and technologies;
- our ability to maintain, protect and expand our intellectual property portfolio;
- general economic conditions.

Even if the FDA approves our NDA for FT218, 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, which may not be available on favorable terms or at all, and which may result in dilution of the equity interest of the holders of ADSs.

We may require additional financing to fund the development and possible acquisition of new products and businesses. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize FT218, if approved. 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 financings, may result in dilution to the holders of ADSs. We could also be required to seek funds through arrangements with collaborative partners and we may be required to relinquish rights to some of our product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

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 $77,329 in 2021. We reported cash used in operating activities of $77,310. Cash and marketable securities as of December 31, 2021 totaled $157,221. Our business strategy is to primarily focus on the development and potential FDA approval of FT218 for the treatment of EDS or cataplexy in adults with narcolepsy. The successful pursuit of all components of our strategy will require substantial financial resources, and there can be no assurance that our existing cash and marketable securities assets and the cash generated by our operations will be adequate for these purposes. We will likely incur a net loss in 2022 and, if we use existing cash and marketable securities, there is no guarantee that we would be able to generate additional cash through our operations or through financing. Failure to implement any component of our strategy may prevent us from achieving profitability in the future or may otherwise have a material adverse effect on our financial condition and results of operation.

Risks Related to Regulation

The distribution and sale of FT218, if approved, will be subject to significant regulatory restrictions, including the requirements of a REMS and safety reporting requirements, and these regulatory requirements will subject us to risks and uncertainties, any of which could negatively impact sales of FT218, if approved.

The active pharmaceutical ingredient, or API, of FT218 is a form of gamma-hydroxybutyric acid, or GHB, a central nervous system depressant known to be associated with facilitated sexual assault as well as with respiratory depression and other serious side effects. As a result, the FDA requires that sponsors of sodium oxybate products, such as FT218, if approved, maintain a REMS to help ensure that the benefits of the drug in treatment of EDS or cataplexy in adults with narcolepsy outweigh the serious risks of the drug. A REMS imposed on FT218, if approved, may impose extensive controls and restrictions on the sales and marketing of FT218 that we will be responsible for implementing. Any failure to demonstrate our substantial compliance with any REMS obligations, including as a result of business or other interruptions resulting from the evolving effects of the COVID-19 pandemic, or a determination by the FDA that the REMS is not meeting its goals, could result in enforcement action by the FDA, lead to changes in our REMS obligations, negatively affect sales of FT218, 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 FT218, if approved. Any modifications approved, required or rejected by the FDA could change the safety profile of FT218, and have a significant negative impact in terms of product liability, public acceptance of FT218 for treatment of cataplexy or EDS in adults with narcolepsy, and prescribers' willingness to prescribe, and patients'

willingness to take, FT218, 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 FT218, make distribution easier for sodium oxybate competitors, disrupt continuity of care for FT218 patients or negatively affect sales of FT218.

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 FT218, if approved, must be regularly reported to the FDA and could result in the FDA requiring changes to FT218'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 FT218.

Any failure to demonstrate our substantial compliance with a REMS required for FT218, if approved, 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.

As of May 26, 2021, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical U.S. and non-U.S. inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to maintain its current pace and approval timelines could be extended due to the ongoing COVID-19 pandemic. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue, depending on the circumstances, or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. We cannot guarantee that the FDA, DEA and other agencies, as applicable, will be able to complete any required inspections or take other necessary actions in respect to our product candidate or future product candidates.

FT218, if approved by the FDA, may not obtain desired regulatory exclusivities, including orphan drug exclusivity.

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

population of 200,000 or more where there is no reasonable expectation that the cost of developing the drug for the rare disease or condition will be recovered from sales of the drug in the U.S. Generally, if a drug with orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease or condition for seven years, except in limited circumstances, such as if the FDA concludes that a subsequent same drug is clinically superior through greater safety, greater effectiveness, or a major contribution to patient care. In assessing whether a drug provides a "major contribution to patient care" over and above the currently approved drugs, which is evaluated by the FDA on a case-by-case basis, there is no one objective standard and the FDA may, in appropriate circumstances, consider such factors as convenience of treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses and potential for self-administration.

Although FT218 obtained orphan drug designation for the treatment of narcolepsy from the FDA in January 2018, there is no guarantee that we will obtain approval or orphan drug exclusivity for FT218. Orphan drug designation does not give a product candidate any advantage in, or shorten the timeline for, the FDA regulatory review and approval process. In addition, because FT218 would not be the first sodium oxybate product to be approved for the treatment of narcolepsy, we must demonstrate that FT218 is clinically superior to any previously approved same drug in order to obtain orphan drug exclusivity for FT218, and we may be required to demonstrate clinical superiority for the approval and exclusivity of other product candidates in the future. However, such a demonstration may be difficult to establish and there can be no assurance that we will be successful in these efforts. Even if we obtain orphan drug exclusivity for FT218, that exclusivity may not effectively protect FT218 from competition because different drugs can be approved for the same condition. In addition, the FDA could determine that unexpired orphan drug exclusivity for an approved product that is determined to be the same drug could delay the approval of FT218 unless we are able to demonstrate that FT218 is clinically superior to such approved product. Moreover, any orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantity of FT218 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 FT218, 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.

FT218 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 FT218, oxybate salts, are regulated by the DEA as Schedule I controlled substances, and FDA-approved products containing oxybate salts, including sodium oxybate, are currently Schedule III.

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

U.S. facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing of controlled substances must be registered (licensed) to perform these activities and must comply with the security, control, recordkeeping and reporting obligations under the CSA, DEA regulations and corresponding state requirements. DEA and state regulatory bodies conduct periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining

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

Because FT218 contains sodium oxybate, to conduct clinical trials with FT218 in the U.S. prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that allows those sites to handle and dispense FT218 and to obtain the product candidate. If the DEA delays or denies the grant of a researcher registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. In the event the product candidate would be made outside the U.S., the importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import.

We and our manufacturing partners in the U.S. are subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, even though FT218, if approved, will be classified as Schedule III, the active ingredient in the final dosage form, sodium oxybate, is a Schedule I controlled substance and will continue be subject to such quotas as long as it remains classified as Schedule I. The annual quota allocated to us or our U.S. manufacturing partners for sodium oxybate may not be sufficient to complete clinical trials or meet commercial demand of FT218, if approved. Consequently, any delay or refusal by the DEA in establishing our, or U.S. manufacturing partner's, procurement and/or production quota for controlled substances could delay or stop our clinical trials or commercial activities, if approved, which could have a material adverse effect on our business, financial position and results of operations.

If approved, FT218 will be classified as a Schedule III substance and an importer can 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 FT218 and have a material adverse effect on our business, results of operations and financial condition.

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

We will need to obtain FDA approval of any proposed product names, 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 regardless of whether we have secured a trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Related to our Reliance on Third-Parties

We rely, and intend to continue to rely on single source providers for the development, manufacture and supply of FT218, and if we experience problems with these suppliers, or they fail to comply with applicable regulatory requirements or to

supply sufficient quantities at acceptable quality levels or prices, or at all, our business would be materially and adversely affected.

Currently, we use single source providers for the development, supply of clinical materials and supply of commercial batches for our lead product candidate, FT218. We do not own or operate manufacturing facilities for clinical or commercial manufacture of FT218. We have limited personnel with experience in drug manufacturing and we lack the capabilities to manufacture FT218 clinical or commercial scale. There can be no assurance that our clinical development or commercial product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable quantities or prices to meet commercial demand, if FT218 is approved. If the supplies of these products or materials were interrupted for any reason, including but not limited to, natural disasters, labor or civil unrest, global health concerns or pandemics or acts of war or terrorism, delays at the manufacturer, delays related to quality control, delays related to the supply chain and the manufacturing and supply of certain products could be delayed. If the supplies of these products or materials were interrupted for any reason, our manufacturing, clinical development or commercial activities, if approved, of FT218 could be delayed. These delays could be extensive and expensive, especially in situations where a substitution was not readily available or required variations of existing regulatory approvals and certifications or additional regulatory approval For example, an alternative supplier may be required to pass an inspection by the FDA, EMA or the competent authorities of EU Member States for compliance with current cGMP requirements before supplying us with product or before we may incorporate that supplier's ingredients into the manufacturing of FT218 by our contract development and manufacturing organizations ("CDMOs").

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

We contract with third parties for the manufacture of FT218 for clinical testing and expect to continue to do so throughout commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidate or product or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of FT218 for clinical testing, as well as for the commercial manufacture of our product if FT218 receives marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidate or product or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

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

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

If any CDMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In such scenario, our clinical trials or commercial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidate or product, if approved, may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any

reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations, including those relating to controlled substances. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate or product according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop FT218 or commercialize our product, if approved, in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidate or product that such CDMO owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another CDMO manufacture our product candidate or product. In addition, in the case of CDMOs that supply our product candidate, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

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

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

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

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

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

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

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

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

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to

successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to obtain FDA approval for FT218 may make it more challenging to recruit and retain qualified personnel.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

We currently employ approximately 66 full-time employees. As we mature and commercialize FT218, if approved, we expect to expand our full-time employee base. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to recognize and/or grow revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize FT218 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 FT218 and future product candidates.

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

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

If we or our partners fail to comply with these laws and regulations, the FDA, or other foreign regulatory agencies, may take actions that could significantly restrict or prohibit commercial distribution of FT218. If the FDA or other foreign regulatory authorities determine that we are not in compliance with these laws and regulations, they could, among other things:

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

We may rely on collaborations with third parties to commercialize FT218 outside of the U.S., if approved, and certain of our future product candidates and such strategy involves risks that could impair our prospects for realizing profits from such products.

We expect that the commercialization of FT218 outside of the U.S., if approved, or future product candidates 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 approval by the FDA or comparable foreign regulatory authorities, the potential market for FT218 or future product candidates, the potential of competing products, the existence of uncertainty with respect to our ownership of our intellectual property, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for FT218. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

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

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of our product candidates for which we are seeking to collaborate, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop FT218 outside of the U.S., if approved, or future product candidates, or bring these products to market and generate product revenue.

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FT218 was submitted under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) NDA enables the applicant to

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

For 505(b)(2) NDAs, the patent certification and related provisions of the Hatch-Waxman Amendments apply. Accordingly, if the applicant relies for approval on the safety or effectiveness on information for a previously approved drug, referred to as a listed drug, the applicable is required to include patent certifications in our 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 our belief that the relevant patents are invalid or unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Otherwise, the 505(b)(2) NDA cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug. While we did not submit any Paragraph IV certifications in connection with our 505(b)(2) NDA for FT218, there can be no assurance that we will not be required to submit a Paragraph IV certification in respect of FT218 or any future product candidates for which we seek approval under Section 505(b)(2).

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

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

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

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

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

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

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

eliminated for non-compliance with these requirements.

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

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

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

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

Risks Related to Acceptance, Sales, Marketing and Competition

If we are unable to establish effective sales, marketing and distribution capabilities for FT218, if approved, or enter into agreements with third parties to market, sell and distribute our product candidate, if approved, or if we are unable to achieve market acceptance for FT218, our business, results of operations, financial condition and prospects will be materially adversely affected.

We are continuing to build the systems, processes, policies, relationships and materials necessary for the launch of FT218 in the U.S. for the treatment of cataplexy or EDS in adults with narcolepsy. If we receive regulatory approval to market or sell FT218, but are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition and prospects will be materially adversely affected. We may encounter issues, delays or other challenges in launching or commercializing FT218.

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 FT218 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 FT218 in any country or region, we will likely pursue collaborative arrangements regarding the sales and marketing of FT218. 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 FT218 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 FT218 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 FT218, if approved, or with respect to any other product candidate that may be approved in the future.

If the market opportunities for FT218 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.

FT218 is an investigational formulation of sodium oxybate designed to be taken once at bedtime for the treatment of EDS or cataplexy in adults with narcolepsy. Our estimates of the market opportunities for FT218 are based on the estimated market size for the twice-nightly administration of sodium oxybate, which is the current standard of care for EDS or cataplexy in patients with narcolepsy, and our expectations with regard to FT218's potential to take a significant share of this market. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The potential target population for FT218 may turn out to be lower or more difficult to identify than expected. Even if we obtain significant market share for FT218 in this indication, because the potential target population for FT218 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 FT218 and our ability to achieve and maintain profitability and, as a consequence, our business may suffer.

FT218, if approved, may not gain market acceptance.

FT218, if approved, may not gain market acceptance among physicians, patients, healthcare payor and medical communities. The degree of market acceptance of FT218, if approved, will depend on a number of factors, including, but not limited to:

- the clinical indications for which FT218 is approved and any restrictions placed upon the product in connection with its approval, such as a REMS or equivalent obligation by other regulatory authorities, patient registry requirements or labeling restrictions;
- the prevalence of the disease or condition for which FT218 is approved and its diagnosis;
- scheduling classification of sodium oxybate as a controlled substance regulated by the DEA;
- demonstration of the clinical safety and efficacy of the product or technology;
- the absence of evidence of undesirable side effects of the product or technology that delay or extend trials;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- availability of sufficient product inventory to meet demand;
- physicians' decisions relating to treatment practices based on availability;
- physician and patient assessment of the burdens associated with obtaining or maintaining the certifications required under the FT218 REMS, if approved;
- the lack of regulatory delays or other regulatory actions;
- its cost-effectiveness and related access to payor coverage;
- its potential advantage over alternative treatment methods;
- the availability of third-party reimbursement or other assistance for patients who are uninsured or underinsured; and
- the marketing and distribution support it receives.

If FT218, if approved, fails to achieve market acceptance, our ability to generate revenue will be limited, which would have a material adverse effect on our business.

FT218, if approved, will be subject to ongoing enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of FT218 from the market, if we fail to comply with all regulatory requirements. In addition, the terms of the marketing approval of FT218, if approved, and ongoing regulation of our product, may limit how we manufacture and market FT218 and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

If approved, FT218, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for FT218, will be subject to continual requirements of and review by the FDA and other applicable regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding drug distribution and the distribution of samples to physicians and recordkeeping.

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

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

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

In addition, we and our CDMOs will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, quality control and distribution. Under the DSCSA, for certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen, and intentionally adulterated products or other products that are otherwise unfit for distribution in the U.S. In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the PDMA, which regulations the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Prescription drug products must also meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. We, our CDMOs and other third parties upon whom we rely will be subject to applicable controlled substances laws, regulations and requirements. If FT218 is approved and we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for FT218 withdrawn by regulatory authorities and our ability to market FT218 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 or more effective than ours, or obtain regulatory approval and market such products before we do, our commercial opportunity will be diminished or eliminated.

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures and other pharmaceutical and biotechnology companies, including companies developing drug delivery technologies or niche brand or generic specialty pharmaceutical products. Some of these competitors may also be our business partners.

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

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

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

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

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

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

Risks Related to Our Business and Industry

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

The COVID-19 pandemic has spread globally. The continued spread of COVID-19 could adversely impact our operations, including our ability to fully enroll and complete RESTORE, our OLE/switch study of FT218, initiate and complete any future

clinical trials, manufacture sufficient supply of our FT218 at sufficient scale for commercialization, if approved. We submitted our 505(b)(2) NDA for FT218 in December 2020.

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

Since the beginning of the COVID-19 pandemic, three vaccines for COVID-19 have received Emergency Use Authorization by the FDA and two of those later received marketing approval. Additional vaccines may be authorized in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our OLE/switch clinical trial and future commercialization of FT218, if approved, which could lead to delays in these activities.

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

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

In February 2019, we announced a restructuring plan intended to achieve future cost savings through, among other actions, a reduction of our overall workforce by approximately 50 percent. Our management may determine we need to take further restructuring actions to achieve additional cost savings, to generate additional capital needed for our business strategy, or for other purposes. Certain restructuring scenarios that management consider could require obtaining the consent of third parties, such as holders of our Exchangeable Senior Notes due February 2023 (the “February 2023 Notes”). For example, the voluntary bankruptcy filing by Avadel Specialty Pharmaceuticals LLC (“Specialty Pharma”) required the consent of holders of a majority in principal amount of our February 2023 Notes in order to avoid a default under the Indenture governing such February 2023 Notes. While we were successful in obtaining that consent, there can be no assurance we will be successful in obtaining additional consents in the future from such holders or from other third parties whose consents may be required. Failure to obtain these third-party consents would prevent us from taking additional restructuring actions, which could have a material adverse effect on our cash flow, financial resources and ability to successfully pursue our business strategy.

Risks Related to Litigation and Legal Matters

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

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

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of Our Securities

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

The trading price of ADSs has been, and is likely to continue to be, highly volatile. The market value of an investment in ADSs may fall sharply at any time due to this volatility. During the year ended December 31, 2021, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged from $6.49 to $11.18. During the year ended December 31, 2020, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged from $4.06 to $11.75. The market prices for securities of drug delivery, specialty pharma, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our share price include, among others:

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

Risks Related to the 2023 Notes

Servicing our February 2023 Notes and our October 2023 Notes (as defined below) may require a significant amount of cash, and we may not have sufficient cash or the ability to raise the funds necessary to settle exchanges of the 2023 Notes in cash, repay the Notes at maturity, or repurchase the 2023 Notes as required following a fundamental change.

In February 2018, we issued $143,750 aggregate principal amount of our February 2023 Notes. Prior to February 2023, the February 2023 Notes are convertible at the option of the holders only under certain conditions or upon the occurrence of certain events. On March 16, 2022, we executed an agreement to exchange $117,375 of the February 2023 Notes for a new series of Exchangeable Senior Notes due October 2, 2023 (the "October 2023 Notes"). We refer to the February 2023 Notes and the October 2023 Notes as the "2023 Notes".

If holders of the 2023 Notes elect to exchange their 2023 Notes, unless we elect to deliver solely our ADSs to settle such exchanges, we will be required to make cash payments in respect of the 2023 Notes being exchanged. Holders of the 2023 Notes also have the right to require us to repurchase all or a portion of their 2023 Notes upon the occurrence of a fundamental change (as defined in the applicable indenture governing the 2023 Notes) at a repurchase price equal to 100% of the principal amount of the 2023 Notes to be repurchased, plus accrued and unpaid interest. If the 2023 Notes have not previously been exchanged or repurchased, we will be required to repay the 2023 Notes in cash at maturity. Our ability to make cash payments in connection with exchanges of the 2023 Notes, repurchase the 2023 Notes in the event of a fundamental change, or to repay or refinance the 2023 Notes at maturity will depend on market conditions and our future performance, which is subject to economic, financial, competitive, and other factors many of which are beyond our control. We had limited net income in 2020 and incurred a net loss in 2021. As a result, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase or repay the 2023 Notes or in the event we elect to pay cash with respect to 2023 Notes being exchanged.

The conditional exchange feature of the 2023 Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional exchange feature of the 2023 Notes is triggered, holders of 2023 Notes will be entitled to exchange the 2023 Notes at any time during specified periods at their option. If one or more holders elect to exchange their 2023 Notes, unless we elect to satisfy our exchange obligation by causing to be delivered solely ADSs (other than paying cash in lieu of any fractional ADSs), we would be required to settle a portion or all of our exchange obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to exchange their 2023 Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2023 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible and exchangeable debt securities that may be settled in cash, such as the 2023 Notes, could have a material effect on our reported financial results.

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

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

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

If any of the conditions to the convertibility of the 2023 Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the 2023 Notes as a current, rather than a long-term, liability. This reclassification could be required even if no noteholders convert their 2023 Notes and could materially reduce our reported working capital.

Exchanges of the 2023 Notes will dilute the ownership interest of our existing shareholders and holders of the ADSs, including holders who may exchange their 2023 Notes and receive ADSs upon exchange, to the extent our exchange obligation includes ADSs.

The exchange of some or all of the 2023 Notes will dilute the ownership interests of our existing shareholders and holders of the ADSs to the extent our exchange obligation includes ADSs. Any sales in the public market of the ADSs issuable upon such exchange of the 2023 Notes could adversely affect prevailing market prices of the ADSs and, in turn, the price of the 2023 Notes. In addition, the existence of the 2023 Notes may encourage short selling by market participants because the exchange of the 2023 Notes could depress the price of the ADSs.

The fundamental change repurchase feature of the 2023 Notes may delay or prevent an otherwise beneficial takeover attempt of Avadel.

The indenture governing the 2023 Notes will require us to repurchase the 2023 Notes for cash upon the occurrence of a fundamental change and, in certain circumstances, to increase the exchange rate for a holder that exchanges its 2023 Notes in connection with a make-whole fundamental change. A takeover of Avadel may trigger the requirement that we repurchase the 2023 Notes and/or increase the exchange rate, which could make it more costly for a potential acquirer to engage in a combinatory transaction with us. Such additional costs may have the effect of delaying or preventing a takeover of Avadel that would otherwise be beneficial to investors.

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

In certain circumstances, as an Irish tax resident company, we may be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to its shareholders. Shareholders that 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 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 withholding tax, which could adversely affect the price of ordinary shares and the value of their 2023 Notes.

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.

Holders of ADSs could have more difficulty protecting their interests than would the shareholders of a U.S. corporation. As an Irish 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.

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

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

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

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

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

Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands Court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

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

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

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

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

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

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

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

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

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

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

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

- the jurisdictions in which profits are determined to be earned and taxed;

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

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

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

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

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

As of December 31, 2021, we had $74,406 of net operating losses in the U.S. Of the $74,406 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 $64,041 are due to the losses at Avadel US Holdings, Inc. The portion due to the acquisition of FSC will expire in 2034 through 2035. The U.S. net operating losses acquired as part of the acquisition of FSC are subject to an annual limitation under Internal Revenue Code Section 382 and $1,473 of the $10,365 will not be fully utilized before they expire. The remaining $64,041 of net operating losses do not have an expiration date.

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

As of December 31, 2021, we had approximately $124,720 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, 2020 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 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 2021 taxable year, but that our non-U.S. subsidiaries were CFCs in the 2021 taxable year. We anticipate that our non-U.S. subsidiaries will remain CFCs in the 2021 taxable year, and it is possible that we may become a CFC in the 2022 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 have identified a material weakness in our internal control 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 additional material weaknesses.

As a public company in the United States organized, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the listing rules of the Nasdaq Stock Market ("Nasdaq"), and incur significant legal, accounting and other expenses to comply with applicable requirements. These rules impose various requirements on public companies, including requiring certain corporate governance practices. Our management and other

personnel devote a substantial amount of time to these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

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

During the Company's fiscal 2021 financial statement close process, management identified a deficiency in the design of internal control over financial reporting related to its February 2023 Notes indenture. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Specifically, management did not have a control to identify that we were in technical default of the February 2023 Notes and owed 0.50% of additional interest on the February 2023 Notes due to not removing a restrictive legend from the February 2023 Notes 365 days following the original issuance of the February 2023 Notes on February 16, 2018.

Once the material weakness was identified, we developed and implemented a remediation plan that includes the implementation of additional control procedures surrounding timely and period evaluation of all terms of our debt agreement and the associated calculation of interest expense in accordance with the terms of such debt agreement to ensure the completeness and accuracy of the calculation and timely payment of additional interest expense. Management is committed to maintaining a strong internal control environment and have fully implemented measures designed to help ensure that the control deficiency contributing to the material weakness is remediated. However, there cannot be any assurance that these remediation efforts will be successful or that our internal control over financial reporting will be effective as a result of these efforts. The material weakness will be fully remediated when, we have determined, through testing, these controls have operated effectively for a sufficient period of time.

In the future we may determine that we have additional material weaknesses. Our failure to remediate the material weaknesses or failure to identify and address any other material weaknesses or control deficiencies could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis, which could cause investors to lose confidence in our reported financial information, which may result in volatility in and a decline in the market price of our ADSs.

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

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

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.

Item 1B. Unresolved Staff Comments.

None.

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 15: 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 March 11, 2022, there were 59,032,237 ordinary shares outstanding, and our closing stock price was $7.22 per share.

The following table reports the high and low trading prices of the ADSs on the Nasdaq Global Market for the periods indicated:

	2021 Price Range		2020 Price Range	
	High	Low	High	Low
First quarter	$ 10.07	$ 6.61	$ 10.64	$ 4.06
Second quarter	9.05	6.73	11.75	7.25
Third quarter	9.91	6.49	8.98	5.02
Fourth quarter	11.18	7.34	7.95	5.03

Holders

As of March 11, 2022, there were 78 holders of record of our ordinary shares and 61 accounts registered with The Bank of New York Mellon, the Depositary of our ADS program, as holders of ADSs, one of which ADS accounts 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

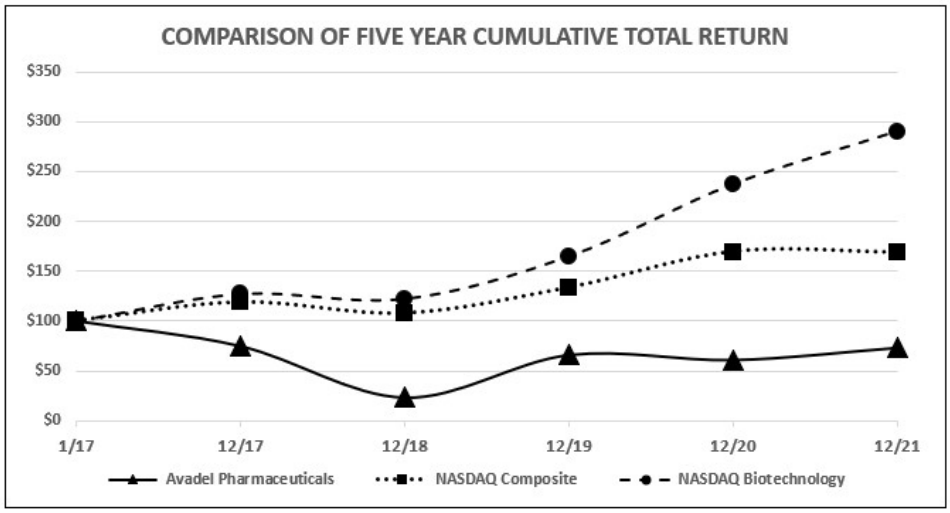
We did not repurchase any of our equity securities during the year ended December 31, 2021.

Recent Sales of Unregistered Securities

None.

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, 2017 and our relative performance is tracked through December 31, 2021. 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 of 1933 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 Content 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 2019 was included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, on pages 45 through 57, 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 9, 2021.

Overview

Nature of Operations

Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel," the "Company," "we," "our," or "us") is a biopharmaceutical company. Our lead product candidate, FT218, is an investigational once-nightly, extended-release formulation of sodium oxybate for the treatment of excessive daytime sleepiness ("EDS") or cataplexy in adults with narcolepsy. We are primarily focused on the development and potential United States ("U.S.") Food and Drug Administration ("FDA") approval of FT218. In December 2020, we submitted a New Drug Application ("NDA") to the FDA for FT218 to treat excessive daytime sleepiness or cataplexy in adults with narcolepsy. In February 2021, the NDA for FT218 was accepted by the FDA and was assigned a Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021. On October 15, 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this Annual Report, the FDA's review of our NDA for FT218 remains ongoing.

Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio. As of the date of this Annual Report, we do not have any approved or commercialized products in our portfolio.

FT218

FT218 is a once-nightly formulation of sodium oxybate that uses our Micropump controlled release drug-delivery technology for the treatment of EDS or cataplexy in adults suffering from narcolepsy. Sodium oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid. Immediate release sodium oxybate is approved in the U.S. for the treatment of EDS or cataplexy in patients with narcolepsy and is approved in Europe for the treatment of cataplexy in patients with narcolepsy. Since 2002, sodium oxybate has only been available as a formulation that must be taken twice nightly, first at bedtime, and then again 2.5 to 4 hours later.

On December 16, 2020, we announced the submission of our NDA to the FDA for FT218. On February 26, 2021, the FDA notified us of formal acceptance of the NDA and assigned a PDUFA target action date of October 15, 2021. On October 15, 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this Annual Report, the FDA's review of our NDA for FT218 remains ongoing.

We conducted a Phase 3 clinical trial of FT218, the REST-ON trial, which was a randomized, double-blind, placebo-controlled study that enrolled 212 patients who received at least one dose of FT218 or placebo, and was conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient, last visit was completed at the end of the first quarter of 2020, and positive top line data from the REST-ON trial was announced on April 27, 2020. Patients who received 9 g of once-nightly FT218, the highest dose administered in the trial, demonstrated statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test ("MWT"), clinical global impression-improvement ("CGI-I"), and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g also demonstrated statistically significant and clinically meaningful improvement on all three co-primary endpoints compared to placebo. We observed the 9 g dose of once-nightly FT218 to be generally well tolerated. Adverse reactions commonly associated with sodium oxybate were observed in a small number of patients (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3% and enuresis 9%), and 3.9% of the patients who received 9 g of FT218 discontinued the trial due to adverse reactions.

In January 2018, the FDA granted FT218 orphan drug designation for the treatment of narcolepsy, which makes FT218 potentially eligible for certain development and commercial incentives, including potential U.S. market exclusivity for up to seven years. Additionally, several FT218-related U.S. patents have been issued, and there are additional patent applications currently in development and/or pending at the U.S. Patent and Trademark Office ("USPTO"), as well as foreign patent offices.

In July 2020, we announced that the first patient was dosed in our open-label extension ("OLE")/switch study of FT218 as a potential treatment for EDS or cataplexy in patients with narcolepsy. The OLE/switch study is examining the long-term safety and maintenance of efficacy of FT218 in patients with narcolepsy who participated in the REST-ON study, as well as dosing and preference data for patients switching from twice-nightly sodium oxybate to once-nightly FT218, regardless of whether they participated in REST-ON. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study.

New secondary endpoints from the REST-ON trial were presented at the American Academy of Neurology, beginning April 17, 2021. The first poster described FT218 improvements in disturbed nocturnal sleep ("DNS"), defined in REST-ON as the

number of shifts from stages N1, N2, N3, and rapid eye movement (“REM”) sleep to wake and from stages N2, N3, and REM sleep to stage N1. FT218 also decreased the number of nocturnal arousals as measured on polysomnography. Improvements in DNS were further supported by post-hoc analyses demonstrating increased time in deep sleep (N3, also known as slow wave sleep), and less time in N1. A second poster described the statistically significant improvements in the Epworth Sleepiness Scale, both the quality of sleep and the refreshing nature of sleep, and a decrease in sleep paralysis. These clinically relevant improvements were observed for all doses, beginning at week 3, for the lowest 6 g dose, compared to placebo. FT218 did not demonstrate significant improvement for hypnagogic hallucinations compared to placebo.

Additional data supportive of the efficacy findings in REST-ON were presented at the 35th Annual Meeting of the Associated Professional Sleep Societies, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, also known as SLEEP 2021, beginning June 10, 2021. New data included post-hoc analyses demonstrating endpoints improvements, regardless of concomitant stimulant use, in both narcolepsy Type 1 or Type 2. Additionally, a post-hoc analysis showed that FT218 was associated with decreased body mass index compared to placebo, which may be relevant as people with narcolepsy often have co-morbid obesity. In August 2021, the primary results from the REST-ON trial were published by Kushida et al. in the journal SLEEP. New data was presented at the American College of Chest Physicians annual meeting, beginning October 17, 2021, including additional post-hoc analyses from the REST-ON trial, demonstrating a greater proportion of patients receiving FT218 experienced reductions in weekly cataplexy attacks and improvement in mean sleep latency compared to placebo, as well as the results of a discrete choice experiment, indicating that the overall driver of patient preference between sodium oxybate treatments is a once-nightly, versus twice-nightly, formulation.

We believe FT218 has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standards of care for EDS or cataplexy in patients with narcolepsy, which are twice-nightly oxybate formulations.

Micropump Drug-Delivery Technology

Our Micropump drug-delivery technology allows for the controlled delivery of small molecule drugs taken orally, which has the potential to improve dosing compliance, reduce toxicity and improve patient compliance. Beyond FT218, we believe there could be other product development opportunities for our Micropump drug-delivery technology, representing either life cycle opportunities, whereby additional intellectual property can be added to a pharmaceutical product to extend the commercial viability of a currently marketed product, or innovative formulation opportunities for new chemical entities.

Previously Approved FDA Products

On June 30, 2020 (“Closing Date”), we announced the sale of our portfolio of sterile injectable drugs used in the hospital setting (the “Hospital Products”), including our three FDA-approved commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, to Exela Sterile Medicines LLC (“Exela Buyer”).

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. As such, we expect to see generic competition for our products in the future.

- **Access to and Cost of Capital**: The process of raising capital and 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 the Company.

- **Continuing Net Loss from Operations**: We sold our Hospital Products on June 30, 2020 and no longer generate revenue. We expect to continue to incur operating losses for the foreseeable future to continue our preparations for the commercial launch of FT218, if approved.

Impact of COVID-19

Since early 2020, we have seen the profound impact that the ongoing coronavirus ("COVID-19") pandemic is having on human health, the global economy and society at large. We have continued to actively monitor the COVID-19 pandemic and have taken measures to mitigate the potential impacts to our employees and business, such as continuing to offer a work from home policy. We believe the ongoing impact of COVID-19 and measures to prevent its spread could impact our business in a number of ways, including: i) possibly delaying our ongoing RESTORE open-label extension/switch study, ii) disruptions to our supply chain and third parties; iii) requiring our employees to work from home for an extended period of time; and iv) hindering sales efforts for FT218, if approved. An extended period of global supply chain and economic disruption could materially affect our business, results of operations, access to sources of liquidity and financial condition. Despite progress in vaccination efforts, future developments and impact on our operations remain uncertain and cannot be predicted with confidence, including the duration of the COVID-19 pandemic, new variants of the virus, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that governments, or we, may direct, which may result in extending continued business disruptions.

Financial Highlights

Highlights of our consolidated results for the year ended December 31, 2021 are as follows:

- Revenue was $0 for the year ended December 31, 2021 compared to $22,334 in the same period last year. The year over year decrease was the result of the sale of the Hospital Products on June 30, 2020.

- Operating loss was $85,546 for the year ended December 31, 2021 compared to operating income of $5,815 for the year ended December 31, 2020. Operating income for the year ended December 31, 2020 was driven by the gain on sale of the Hospital Products on June 30, 2020 of $45,760. Selling, general & administrative expenses increased in the current year by $36,090, driven by the Company's continued commercial preparations and launch readiness activities for the potential approval of FT218.

- Net loss was $77,329 for the year ended December 31, 2021 compared to net income of $7,028 in the same period last year.

- Diluted net loss per share was $1.32 for the year ended December 31, 2021 compared to diluted net income per share of $0.13 in the same period last year.

- Cash and marketable securities decreased by $64,181 to $157,221 at December 31, 2021 from $221,402 at December 31, 2020. This decrease was largely driven by $77,310 of cash used in operations during the year ended December 31, 2021, partially offset by cash proceeds from the disposition of the Hospital Products of $16,500.

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.

Product Sales. Prior to June 30, 2020, revenue included sales of pharmaceutical products. We sold our products primarily through wholesalers and considered these wholesalers to be our customers. Revenue from product sales is recognized when the customer obtains control of our product, which occurs typically upon receipt by the customer. Our gross product sales were subject to a variety of price adjustments in arriving at reported net product sales.

The price adjustments contained estimates of product returns, chargebacks, payment discounts, rebates, and other sales allowances and were estimated based on analysis of historical data for the product or comparable products, future expectations for such products and other judgments and analysis. The estimates were reviewed monthly and any adjustments were recognized as adjustments to product sales in the period the adjustments were identified.

Any adjustments made were recognized as adjustments to product sales in the period that they were identified. We did not record any revenue from sales of pharmaceutical products in the year ended December 31, 2021 nor recognize any adjustments to product sales from prior periods.

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. Clinical studies and outside services 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.

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

When estimating R&D expense, we review open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed and some require advanced payments. We make estimates of our accrued expenses at each balance sheet date in our financial statements based on facts and circumstances known to us at that time.

If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid or accrued expenses accordingly. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Share-based Compensation. We account 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"). We recognize compensation cost, net of an estimated forfeiture rate, using the accelerated method over the requisite service period of the award.

As required by the Black-Scholes model, estimates are made of the underlying volatility of Avadel stock, a risk-free rate determined by reference to the U.S. Treasury yield curve, and an expected term of the option. We estimate the expected term using a simplified method, as we do not have enough historical exercise data for a majority of such options upon which to estimate an expected term.

Changes in the estimates used to determine the fair value of share-based equity compensation instruments could result in changes to our share-based compensation expense. We have not made any material changes to our assumptions and estimates related to our share-based compensation during the periods presented. Individual assumptions are not sensitive to change.

Income Taxes. Our income tax benefit, 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.

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 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, 2021, we had unremitted earnings of $3,916 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 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 test. We elected to perform a quantitative impairment assessment of goodwill in 2021 and 2020. Upon performing the quantitative 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. We have 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.

When performing the quantitative assessment of goodwill impairment, we estimate the fair value of our single reporting unit using the market approach, based on quoted market prices of our securities on the Nasdaq Global Market, adjusted for the effect of a control premium as contemplated by ASC 350. Based on the results of the annual quantitative evaluation for 2021, the fair value of our single reporting unit exceeded its respective carrying value and did not result in impairment for the reporting unit.

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 test is reasonable, different assumptions or changes in general industry, market and macro-economic conditions, including a more prolonged and/or severe COVID-19 pandemic, 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,		*Increase / (Decrease)* Change	
Comparative Statements of (Loss) Income:	**2021**	**2020**	**$**	**%**
Product sales	$ —	$ 22,334	$ (22,334)	(100.0)%
Operating expenses:				
Cost of products	—	5,742	(5,742)	(100.0)%
Research and development expenses	17,104	20,442	(3,338)	(16.3)%
Selling, general and administrative expenses	68,495	32,405	36,090	111.4 %
Intangible asset amortization	—	406	(406)	(100.0)%
Changes in fair value of contingent consideration	—	3,327	(3,327)	(100.0)%
Gain on sale of Hospital Products	—	(45,760)	45,760	100.0 %
Restructuring income	(53)	(43)	(10)	(23.3)%
Total operating expenses	85,546	16,519	69,027	417.9 %
Operating (loss) income	(85,546)	5,815	(91,361)	(1,571.1)%
Investment and other income (expense), net	2,126	(832)	2,958	355.5 %
Interest expense	(9,942)	(12,994)	3,052	23.5 %
Gain from release of certain liabilities	217	3,364	(3,147)	(93.5)%
Other expense - changes in fair value of contingent consideration payable	—	(435)	435	100.0 %
Loss before income taxes	(93,145)	(5,082)	(88,063)	(1,732.8)%
Income tax benefit	(15,816)	(12,110)	(3,706)	(30.6)%
Net (loss) income	$ (77,329)	$ 7,028	$ (84,357)	(1,200.3)%
Net (loss) income per share - diluted	$ (1.32)	$ 0.13	$ (1.45)	(1,115.4)%

On June 30, 2020, we announced the sale of the Hospital Products, including our three FDA-approved commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, to the Exela Buyer. As a result of the sale, the Company recorded a gain on the sale of the Hospital Products of $45,760 and no longer recorded revenue, cost of products, intangible amortization and changes to the fair value of the contingent consideration related to these products subsequent to the Closing Date.

	Years Ended December 31,		Change	
Research and Development Expenses	**2021**	**2020**	**$**	**%**
Research and development expenses	$ 17,104	$ 20,442	$ (3,338)	(16.3)%

Research and development (“R&D”) expenses decreased by $3,338 or 16.3% during the year ended December 31, 2021 as compared to the same period in 2020. This decrease was driven by lower clinical studies expense due to the completion of the FT218 clinical study during the year ended December 31, 2020, offset by higher pre-NDA approval activities and higher compensation expense.

Selling, General and Administrative Expenses	Years Ended December 31, 2021	2020	Change $	%
Selling, general and administrative expenses	$ 68,495	$ 32,405	$ 36,090	111.4 %

Selling, general and administrative ("SG&A") expenses increased by $36,090 or 111.4% during the year ended December 31, 2021 as compared to the prior year. This increase was driven primarily by the Company's continued commercial preparations and launch readiness activities for potential approval of FT218. These activities included an increase in marketing and market research costs of approximately $12,700 and an increase in other launch planning and preparation activities totaling $5,000. Compensation costs increased by approximately $11,000 due to an increase in headcount, primarily in commercial and medical affairs. Legal, technology and insurance costs increased by approximately $7,200.

Investment and Other Income (Expense), net	Years Ended December 31, 2021	2020	Change $	%
Investment and other income (expense), net	$ 2,126	$ (832)	$ 2,958	355.5 %

Investment and other income, net was $2,126 for the year ended December 31, 2021 as compared to investment and other expense, net of $832 for the year ended December 31, 2020. The increase in investment and other income (expense), net was driven by higher foreign currency gains of approximately $1,100, an $800 legal settlement related to a bankruptcy claim recognized in the prior period, higher interest income of approximately $600 and lower realized losses on our marketable securities of approximately $300.

Interest Expense	Years Ended December 31, 2021	2020	Change $	%
Interest expense	$ (9,942)	$ (12,994)	$ 3,052	23.5 %

Interest expense of $9,942 and $12,994 for the years ended December 31, 2021 and 2020, respectively, is related to interest on the February 2023 Notes. Included in these amounts are coupon interest expense of $6,469 for each period and the amortization of debt issuance costs of $1,248 and $998 for the year ended December 31, 2021 and 2020, respectively. Current period interest expense also included $2,225 of additional interest expense owed as a result of not removing a restrictive legend from the February 2023 Notes 365 days following original issuance of the February 2023 Notes on February 16, 2018. 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 for further details. Prior period interest expense also included amortization of a debt discount of $5,527, which is no longer recognized upon our adoption of ASU 2020-06. See *Note 11: 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 for further details.

Gain from release of certain liabilities	Years Ended December 31, 2021	2020	Change $	%
Gain from release of certain liabilities	$ 217	$ 3,364	$ (3,147)	(93.5)%

Subsequent to the finalization of the bankruptcy, we recognized non-cash gains of $217 and $3,364 for the years ended December 31, 2021 and 2020, respectively, from the release of certain liabilities that had been retained following the deconsolidation of Avadel Specialty Pharmaceuticals, LLC in February 2019.

Income Taxes	Years Ended December 31, 2021	2020	Change $	%
Income tax benefit	$ (15,816)	$ (12,110)	$ (3,706)	(30.6)%
Percentage of loss before income taxes	17.0 %	238.3 %		

In 2021, the income tax benefit increased by $3,706 when compared to the same period in 2020. The increase in the income tax benefit in 2021 was primarily driven by the additional tax benefit from an increase in the net operating losses in the U.S. in 2021, when compared to the same period in 2020. This was partially offset by the nonrecurring nature of tax benefits

recognized in 2020 from the sale of the Company's Hospital Products and passage of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") in the U.S.

Liquidity and Capital Resources

Overview of Sources and Uses of Cash

We have had no revenue from product sales since the sale of our Hospital Products on June 30, 2020. We expect to continue to incur operating losses for the foreseeable future to further the clinical development of and continue our preparations for the commercial launch of FT218, if approved. As a result, we may need to raise additional capital to support commercial launch of FT218, if approved, and the continued growth of Avadel. At December 31, 2021, we held cash and marketable securities of $157,221 that will be used satisfy any cash requirements that we will have during the twelve months ended December 31, 2022.

For the 12 month period ending December 31, 2022, we project that our fixed commitments will include (i) capital commitments, (ii) interest on our 2023 Notes, and (iii) lease payments. We project that our long-term fixed commitments will include (i) capital commitments, (ii) interest on and repayment of principal of our 2023 Notes, and (iii) lease payments.

Capital Commitments

At December 31, 2021, we have one commitment with our primary contract manufacturer related to facility upgrades and the purchase and validation of equipment to be used in the manufacture of FT218. The total cost of this commitment is estimated to be approximately $5,500 and is expected to be completed during the year ending December 31, 2022. We incurred approximately $3,348 of this commitment during the year ended December 31, 2021.

We also have a commitment with another contract manufacturer that commences in the first quarter of 2022 and will continue until FDA approval of the contract manufacturer. The commitment will be approximately $3,000 per year.

Debt Arrangements

For the twelve month period ending December 31, 2022, we will pay interest on our 2023 Notes of $8,694. For the twelve month period ending December 31, 2023, we will pay interest on our 2023 Notes of $3,234 and principal, upon maturity, of $143,750. On March 16, 2022, Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of the Company (the "Issuer"), executed an agreement to exchange $117,375 its 2023 Notes due February 1, 2023 for a new series of its Exchangeable Senior Notes due October 2, 2023 (the "October 2023 Notes") (the "Exchange"). The remaining $26,375 aggregate principal amount of the February 2023 Notes will maintain a maturity date of February 1, 2023. See *Note 11: Long-Term Debt* and *Note 23: Subsequent Events* to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for further details.

Operating Leases

At December 31, 2021, we have leases for office space and a production suite. We have a current obligation of $974 due within one year and a long-term obligation of $1,833 due between January 1, 2023 and December 31, 2025. See *Note 10: 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:

	Years Ended December 31,		Increase / (Decrease)	
Net Cash (Used In) Provided By	**2021**	**2020**	**$**	**%**
Operating activities	$ (77,310)	$ (48,734)	$ (28,576)	(58.6)%
Investing activities	56,929	(69,721)	126,650	181.7 %
Financing activities	263	179,683	(179,420)	(99.9)%

Operating Activities

Net cash used in operating activities of $77,310 for the year ended December 31, 2021 increased from net cash used in operating activities of $48,734 in the prior year. Net cash used in operating activities for the year ended December 31, 2021 was driven by net loss of $77,329 and unfavorable non-cash adjustments of $3,676, offset by favorable changes in working capital of $3,695. For the year ended December 31, 2020, net cash used in operating activities was driven by net income of $7,028 and favorable non-cash adjustments of $4,322, offset by the $45,760 gain recorded for the sale of the Hospital Products and a $14,324 unfavorable change in working capital. The year over year change in working capital is driven by an increase in accounts payable and accrued expenses in 2021 as a result of the Company's commercial preparations and launch readiness activities for potential approval of FT218.

Investing Activities

Cash provided by investing activities was $56,929 for the year ended December 31, 2021 compared to cash used in investing activities of $69,721 in the same prior year period. Net cash provided by investing activities for the year ended December 31, 2021 was driven by net proceeds from sales of marketable securities of $40,455 and proceeds of $16,500 received from the sale of the Hospital Products. Net cash used in investing activities for the year ended December 31, 2020 was driven by net purchases of marketable securities of $95,123, partially offset by proceeds from the disposition of the Hospital Products of $25,500.

Financing Activities

Cash provided by financing activities was $263 for the year ended December 31, 2021 compared to cash provided by financing activities of $179,683 for the same prior year period. Cash provided financing activities for the year ended December 31, 2021 related to proceeds from the issuance of ordinary shares related to employee equity awards. Cash provided by financing activities for the year ended December 31, 2020 was driven by the February private placement that resulted in net proceeds of $60,570, the May public offering that resulted in net proceeds of $116,924, and proceeds from the issuance of ordinary shares of $2,189 related to employee equity awards.

Risk Management

The adequacy of our cash resources depends on the outcome of certain business conditions including the cost of our FT218 clinical development and commercial launch plans, our cost structure, and other factors set forth in "Risk Factors" within Part I, Item 1A of this Annual Report on Form 10-K. To complete the FT218 clinical development and commercial launch plans we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business. Our assumptions concerning the outcome of certain business conditions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash and marketable securities balances which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business. Additionally, we are unable to estimate the near or long term impact of COVID-19, which may have a material adverse impact on our business.

If available to us, raising additional capital may be accomplished through one or more public or private debt or equity financings, royalty financings or collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders.

Cash, cash equivalent and marketable security balances as of December 31, 2021 and unused financing sources are expected to provide us with the flexibility to meet our liquidity needs in 2022, including operating requirements related to the commercial launch of FT218.

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, 2021 and December 31, 2020, 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 15: 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.

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. 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, 2021 would have had an immaterial impact on net loss for the year ended December 31, 2021.

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) income. As of December 31, 2021, 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, 2021.

Item 8. Financial Statements and Supplementary Data.

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

	Years ended December 31,		
	2021	**2020**	**2019**
Product sales	$ —	$ 22,334	$ 59,215
Operating expenses:			
Cost of products	—	5,742	12,125
Research and development expenses	17,104	20,442	32,917
Selling, general and administrative expenses	68,495	32,405	30,183
Intangible asset amortization	—	406	816
Changes in fair value of contingent consideration	—	3,327	845
Gain on sale of Hospital Products	—	(45,760)	—
Restructuring (income) costs	(53)	(43)	6,441
Total operating expenses	85,546	16,519	83,327
Operating (loss) income	(85,546)	5,815	(24,112)
Investment and other income (expense), net	2,126	(832)	1,069
Interest expense	(9,942)	(12,994)	(12,483)
Gain from release of certain liabilities	217	3,364	—
Loss on deconsolidation of subsidiary	—	—	(2,678)
Other expense - changes in fair value of contingent consideration payable	—	(435)	(378)
Loss before income taxes	(93,145)	(5,082)	(38,582)
Income tax benefit	(15,816)	(12,110)	(5,356)
Net (loss) income	$ (77,329)	$ 7,028	$ (33,226)
Net (loss) income per share - basic	$ (1.32)	$ 0.13	$ (0.89)
Net (loss) income per share - diluted	$ (1.32)	$ 0.13	$ (0.89)
Weighted average number of shares outstanding - basic	58,535	52,996	37,403
Weighted average number of shares outstanding - diluted	58,535	54,941	37,403

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2021	**2020**	**2019**
Net (loss) income	$ (77,329)	$ 7,028	$ (33,226)
Other comprehensive (loss) income, net of tax:			
Foreign currency translation (loss) gain	(1,228)	1,111	(117)
Net other comprehensive (loss) income, net of income tax benefit (expense) of $214, $(202), $(43), respectively	(1,661)	644	727
Total other comprehensive (loss) income, net of tax	(2,889)	1,755	610
Total comprehensive (loss) income	$ (80,218)	$ 8,783	$ (32,616)

See accompanying notes to consolidated financial statements.

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

	December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 50,708	$ 71,722
Marketable securities	106,513	149,680
Research and development tax credit receivable	2,443	3,326
Prepaid expenses and other current assets	32,826	38,726
Total current assets	192,490	263,454
Property and equipment, net	285	359
Operating lease right-of-use assets	2,652	2,604
Goodwill	16,836	16,836
Research and development tax credit receivable	1,225	3,445
Other non-current assets	33,777	24,939
Total assets	$ 247,265	$ 311,637
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of operating lease liability	$ 900	$ 474
Accounts payable	7,679	2,934
Accrued expenses	7,151	6,501
Other current liabilities	5,270	5,200
Total current liabilities	21,000	15,109
Long-term debt	142,397	128,210
Long-term operating lease liability	1,707	1,840
Other non-current liabilities	3,917	4,212
Total liabilities	169,021	149,371
Shareholders' equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at December 31, 2021 and 2020, respectively	5	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 58,620 and 58,396 issued and outstanding at December 31, 2021 and 2020, respectively	586	583
Additional paid-in capital	549,349	566,916
Accumulated deficit	(447,756)	(384,187)
Accumulated other comprehensive loss	(23,940)	(21,051)
Total shareholders' equity	78,244	162,266
Total liabilities and shareholders' equity	$ 247,265	$ 311,637

See accompanying notes to consolidated financial statements.

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

	Ordinary shares		Preferred shares		Additional	Accumulated	Accumulated other comprehensive	Treasury Shares		Total shareholders'
	Shares	Amount	Shares	Amount	paid-in capital	deficit	loss	Shares	Amount	equity
Balance, December 31, 2018	42,720	$ 427	—	$ —	$ 433,756	$ (357,989)	$ (23,416)	5,407	$ (49,998)	$ 2,780
Net loss	—	—	—	—	—	(33,226)	—	—	—	(33,226)
Other comprehensive income	—	—	—	—	—	—	610	—	—	610
Vesting of restricted shares	153	2	—	—	(2)	—	—	—	—	—
Employee share purchase plan share issuance	54	—	—	—	118	—	—	—	—	118
Share-based compensation expense	—	—	—	—	519	—	—	—	—	519
Balance, December 31, 2019	42,927	$ 429	$ —	$ —	$ 434,391	$ (391,215)	$ (22,806)	5,407	$ (49,998)	$ (29,199)
Net income	—	—	—	—	—	7,028	—	—	—	7,028
Other comprehensive income	—	—	—	—	—	—	1,755	—	—	1,755
Exercise of stock options	403	4	—	—	2,041	—	—	—	—	2,045
February 2020 private placement	8,680	87	488	5	60,478	—	—	—	—	60,570
May 2020 public offering	11,630	116	—	—	116,808	—	—	—	—	116,924
Vesting of restricted shares	114	1	—	—	(1)	—	—	—	—	—
Employee share purchase plan share issuance	49	—	—	—	144	—	—	—	—	144
Share-based compensation expense	—	—	—	—	2,999	—	—	—	—	2,999
Retirement of treasury shares	(5,407)	(54)	—	—	(49,944)	—	—	(5,407)	49,998	—
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

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities:			
Net (loss) income	$ (77,329)	$ 7,028	$ (33,226)
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Depreciation and amortization	815	1,690	2,486
Remeasurement of acquisition-related contingent consideration	—	3,327	845
Remeasurement of financing-related contingent consideration	—	435	378
Amortization of debt discount and debt issuance costs	1,248	6,524	5,995
Changes in deferred tax	(15,666)	(7,431)	(6,334)
Share-based compensation expense	8,872	2,999	519
Gain on the disposition of the Hospital Products	—	(45,760)	—
Loss on deconsolidation of subsidiary	—	—	1,750
Gain from the release of certain liabilities	(217)	(3,364)	—
Other adjustments	1,272	142	(254)
Net changes in assets and liabilities			
Accounts receivable	—	8,281	2,471
Inventories, net	—	(1,352)	1,155
Prepaid expenses and other current assets	(439)	1,863	(1,187)
Research and development tax credit receivable	2,796	2,213	(1,014)
Accounts payable & other current liabilities	4,232	(2,788)	4,641
Deferred revenue	—	—	(114)
Accrued expenses	895	(13,226)	357
Earn-out payments for contingent consideration in excess of acquisition-date fair value	—	(5,323)	(10,988)
Royalty payments for contingent consideration payable in excess of original fair value	—	(866)	(1,748)
Other assets and liabilities	(3,789)	(3,126)	(4,057)
Net cash used in operating activities	(77,310)	(48,734)	(38,325)
Cash flows from investing activities:			
Purchases of property and equipment	(26)	(98)	(29)
Proceeds from disposal of property and equipment	—	—	154
Proceeds from the disposition of the Hospital Products	16,500	25,500	—
Proceeds from sales of marketable securities	102,224	36,284	63,246
Purchases of marketable securities	(61,769)	(131,407)	(24,648)
Net cash provided by (used in) investing activities	56,929	(69,721)	38,723
Cash flows from financing activities:			
Proceeds from the February 2020 private placement	—	60,570	—
Proceeds from the May 2020 public offering	—	116,924	—
Proceeds from issuance of ordinary shares	263	2,189	118
Other financing activities, net	—	—	(145)
Net cash provided by (used in) financing activities	263	179,683	(27)
Effect of foreign currency exchange rate changes on cash and cash equivalents	(896)	720	78
Net change in cash and cash equivalents	(21,014)	61,948	449
Cash and cash equivalents at January 1	71,722	9,774	9,325
Cash and cash equivalents at December 31	$ 50,708	$ 71,722	$ 9,774
Supplemental disclosures of cash flow information:			
Income taxes paid (refund), net	$ 76	$ (1,701)	$ 140
Interest paid	6,469	6,469	6,469

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 St. Louis, Missouri, United States ("U.S").

The Company's lead product candidate, FT218, is an investigational once-nightly, extended-release formulation of sodium oxybate for the treatment of excessive daytime sleepiness ("EDS") or cataplexy in adults with narcolepsy. The Company is primarily focused on the development and potential United States ("U.S.") Food and Drug Administration ("FDA") approval of FT218. In December 2020, the Company submitted a New Drug Application ("NDA") to the FDA for FT218 to treat excessive daytime sleepiness or cataplexy in adults with narcolepsy. In February 2021, the NDA for FT218 was accepted by the FDA and was assigned a Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021. On October 15, 2021, the Company announced that the FDA informed us that the review of the Company's NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this Annual Report, the FDA's review of the Company's NDA for FT218 remains ongoing.

Outside of the Company's lead product candidate, the Company continues to evaluate opportunities to expand its product portfolio. As of the date of this Annual Report, the Company does not have any approved or commercialized products in its portfolio.

Basis of Presentation. These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and all subsidiaries. All intercompany accounts and transactions have been eliminated.

The Company's results of operations for the period January 1, 2019 through February 6, 2019 include the results of Avadel Specialty Pharmaceuticals, LLC ("Specialty Pharma") prior to its February 6, 2019 voluntary petition for reorganization under Chapter 11 of the U.S. Bankruptcy Code. See *Note 3: Subsidiary Bankruptcy and Deconsolidation*.

Reclassifications

Certain reclassifications are made to prior year amounts whenever necessary to conform with the current year presentation. Certain reclassifications have been made to the Consolidated Statements of Cash Flows for the fiscal year ended December 31, 2019 and balances within *Note 14: Other Assets and Liabilities* for the year ended December 31, 2020 to condense line items of the same nature into a single line. This change does not affect previously reported net cash flows used in operating activities in the Consolidated Statements of Cash Flows.

Out of Period Adjustments

In 2021, the Company determined that 0.50% of additional interest expense (the "Additional Interest"), as defined in the indenture dated as of February 16, 2018 among Avadel Finance Cayman Ltd, Avadel Pharmaceuticals PLC, and The Bank of New York Mellon as trustee (the "Indenture"), was owed on its long term 4.50% exchangeable unsecured senior notes due 2023 (the "2023 Notes") from a period of February 17, 2019 through December 31, 2021, totaling $817, $773, and $635 for the years ended December 31, 2021, 2020 and 2019, respectively. At December 31, 2020, the Company's accrued interest was understated by $1,408. The Additional Interest resulted from not removing a restrictive legend from the 2023 Notes 365 days following their original issuance on February 16, 2018. The restrictive legend was removed in March 2022 and the Additional Interest is no longer applicable following the date of removal of the restrictive legend. The Company identified and recorded an out of period adjustment for cumulative amount of the Additional Interest in 2021 of $1,408. Management assessed the materiality of the impact of the out of period adjustment on its financial statements, both quantitatively and qualitatively, and determined that it was not material for any quarterly or annual period.

The 2023 Notes were issued on February 16, 2018 (the "Original Issuance") with a restrictive legend which remained in place until March 14, 2022. Per the terms of the Indenture, if the restrictive legend on the 2023 Notes was not removed on the 365th day following the original issuance of the 2023 Notes, the Company owed Additional Interest, payable on each of the semi-annual interest payment dates of February 1 and August 1 beginning August 1, 2019 and each of the semi-annual payment dates thereafter until the restrictive legend was removed. The non-payment of the Additional Interest expense on the semi-annual

payment dates, which was first due beginning August 1, 2019, is defined as an “Event of Default” in the Indenture, causing the Company to be in technical default of its 2023 Notes until the default was cured. The Additional Interest was paid to the trustee on March 10, 2022, which under the terms of the indenture, management believes cured the Event of Default for all periods. Additionally, on March 14, 2022, the restrictive legend on the 2023 Notes was removed and the Company is not subject to the Additional Interest after that date. Had the Company identified and been unable to cure the technical default prior to the issuance of its financial statements for fiscal years 2020 and 2019, it could have resulted in the reclassification of the long-term principal balance of 2023 Notes reported in those periods. As a result of curing the technical default, the Company classified the 2023 Notes as long-term at December 31, 2021 and 2020. The Indenture is included as Exhibit 4.2 to this Annual Report on Form 10-K.

Revenue. Prior to June 30, 2020, revenue included sales of pharmaceutical products, licensing fees, and, if any, milestone payments for research and development (“R&D”) achievements.

To determine the appropriate revenue recognition, the Company performs 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. 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

Prior to June 30, 2020, the Company sold products primarily through wholesalers and considered these wholesalers to be the Company’s customers. Revenue from product sales is recognized when the customer obtains control of the Company’s product, which occurs typically upon receipt by the customer. The Company’s gross product sales were subject to a variety of price adjustments in arriving at reported net product sales. These adjustments included estimates of product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated based on analysis of historical data for the product or comparable products, future expectations for such products and other judgments and analysis.

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 $0, $312 and $372 for the years ended December 31, 2021, 2020 and 2019, 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.

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) income. 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) income ("AOCI") in shareholders' equity, with the exception of unrealized gains and losses on equity instruments and allowances for expected credit losses, if any, which are reported in earnings in the current period. The cost of securities sold is based upon the specific identification method.

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.

Allowance for Credit Losses. Amounts owed to the Company are presented net of an allowance that includes as assessment of expected credit losses. An allowance for credit losses is established based on expected losses. Expected losses are estimated by reviewing individual accounts, considering aging, financial condition of the debtor, payment history, current and forecast economic conditions and other relevant factors. To the extent that the 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

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	5-10 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, 2021 and 2020.

Long-Lived Assets. Long-lived assets include fixed assets and intangible assets. Prior to the sale of the Company's portfolio of sterile injectable drugs used in the hospital setting ("Hospital Products") on June 30, 2020, intangible assets consisted primarily of purchased licenses and intangible assets recognized as part of the Éclat Pharmaceuticals acquisition. Acquired in-process research and development ("IPR&D") had an indefinite life and was not amortized until completion and development of the project, at which time the IPR&D became an amortizable asset, for which amortization of such intangible assets was computed using the straight-line method over the estimated useful life of the assets.

Long-lived assets are reviewed for impairment whenever conditions indicate that the carrying value of the assets may not be fully recoverable. Such impairment tests are based on a comparison of the pretax undiscounted cash flows expected to be generated by the asset to the recorded value of the asset or other market-based value approaches. If impairment is indicated, the asset value is written down to its market value if readily determinable or its estimated fair value based on discounted cash flows. Any significant changes in business or market conditions that vary from current expectations could have an impact on the fair value of these assets and any potential associated impairment. On June 30, 2020, the Company transferred its remaining intangible asset to Exela Sterile Medicines LLC ("Exela Buyer") as part of the disposition of the Hospital Products.

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) income 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) income.

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 and liabilities, including marketable securities and contingent liabilities at the date of the consolidated financial statements and the reported amounts of sales and expenses during the periods presented. These estimates and assumptions are based on the best information available to management at the balance sheet dates and depending on the nature of the estimate can require significant judgments. Changes to these estimates and judgments can have and have had a material impact on the Company's consolidated statements of (loss) income and balance sheets. Actual results could differ from those estimates under different assumptions or conditions.

NOTE 2: Newly Issued Accounting Standards

Recently Adopted Accounting Guidance

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. The FASB's amendments primarily impact ASC 740, Income Taxes, and may impact both interim and annual reporting periods. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years and early adoption is 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 reduce the number of accounting models for convertible instruments and expand the existing disclosure requirements over earnings per share as it relates to convertible instruments. Convertible debt will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The update also requires the if-converted method to be used for convertible instruments and the effect of potential share settlement be included in the diluted earnings per share calculation when an instrument may be settled in cash or shares. This ASU will be effective for the Company's fiscal year beginning January 1, 2022 and interim periods therein. Early adoption is 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 (the "2023 Notes") are a convertible instrument with a cash-conversion feature that is 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.

NOTE 3: Subsidiary Bankruptcy and Deconsolidation

On February 6, 2019, the Company deconsolidated Specialty Pharma effective with the filing of the Chapter 11 bankruptcy and recorded a non-cash charge of approximately $2,678 for the year ended December 31, 2019.

The Company recognized a non-cash gain of $217 and $3,364 from the release of certain liabilities that had been retained following the deconsolidation of Specialty Pharma. These gains are included in "Gain from release of certain liabilities" within non-operating (loss) income for the years ended December 31, 2021 and 2020.

On October 26, 2021, the U.S. Bankruptcy Court for the District of Delaware issued the Final Decree and Order, dismissing the bankruptcy case and dissolving Specialty Pharma.

NOTE 4: Disposition of the Hospital Products

On June 30, 2020 (the "Closing Date"), the Company announced the sale of its Hospital Products, which included its three FDA-approved commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, to the Exela Buyer pursuant to an Asset Purchase Agreement (the "Transaction").

Pursuant to the Transaction, the Exela Buyer agreed to pay a total aggregate consideration amount of $42,000, of which $14,500 was paid on the Closing Date and an additional $27,500 was paid in ten equal monthly installments following the Closing Date. During the year ended December 31, 2020, the Company collected four installment payments, totaling $11,000. The Company collected the remaining six installment payments, totaling $16,500 during 2021. In connection with the sale of the Hospital Products, the parties also agreed to cause the dismissal of the pending civil litigation related to Nouress in the District Court for the District of Delaware.

The Company was party to a Membership Interest Purchase Agreement, dated March 13, 2012, by and among the Company, Avadel Legacy, Breaking Stick Holdings, LLC, Deerfield Private Design International II, L.P. ("Deerfield International"), Deerfield Private Design Fund II, L.P. ("Deerfield Fund") and Horizon Santé FLML, Sarl ("Horizon") (the "Deerfield MIPA") and a Royalty Agreement, dated February 4, 2013, by and among the Company, Avadel Legacy, the Deerfield Fund and Horizon (the "Deerfield Royalty Agreement"). In connection with the closing of the sale of the Hospital Products, the Deerfield MIPA (with respect to certain sections thereof) and the Royalty Agreement were assigned to the Exela Buyer. Pursuant to the Purchase Agreement, the Exela Buyer assumed and will pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy under the Deerfield Royalty Agreement for obligations that arise after the Closing Date.

The Company was also party to a Royalty Agreement, dated December 3, 2013, by and between the Company, Avadel Legacy and Broadfin Healthcare Master Fund, Ltd. (the "Broadfin Royalty Agreement"). In connection with the closing of the sale of the Hospital Products, the Broadfin Royalty Agreement was assigned to the Exela Buyer and the Exela Buyer assumed and shall pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy under the Broadfin Royalty Agreement for obligations that arise after the Closing Date.

The Company recorded a net gain on the sale of the Hospital Products of $45,760 during the year ended December 31, 2020 which has been recorded on the consolidated statements of (loss) income. The $45,760 gain represents the aggregate consideration of $42,000, less transaction fees of $2,928, plus the assets and liabilities either transferred to the Exela Buyer or eliminated by the Company due to the sale of the Hospital Products, which are listed below.

	June 30, 2020
Prepaid expenses and other current assets	$ (134)
Inventories	(4,922)
Goodwill	(1,654)
Intangible assets, net	(407)
Other non-current assets	(1,095)
Total long-term contingent consideration payable	14,900
Net liabilities disposed of	6,688
Aggregate consideration	42,000
Less transaction fees	(2,928)
Net gain on the sale of the Hospital Products	$ 45,760

Subsequent to the disposition of the Hospital Products, the Company entered into a separate and distinct agreement with the Exela Buyer, whereby the Exela Buyer assumed all future returns of the Hospital Products in exchange for cash consideration paid by the Company. The Company recorded a $518 gain from this transaction, which is recorded in "Selling, general and administrative expenses" for the year ended December 31, 2020.

The Company evaluated various qualitative and quantitative factors related to the disposition of the Hospital Products and determined that it did not meet the criteria for presentation as a discontinued operation.

The unaudited pro forma condensed combined statements of (loss) income for the years ended December 31, 2020 and 2019 included below is being provided for information purposes only and are not necessarily indicative of the results of operations that would have resulted if the Transaction had actually occurred on the date indicated. The pro forma adjustments are based on available information and assumptions that the Company believes are attributable to the sale.

	Unaudited Pro Forma Condensed Combined Statement of (Loss) Income			
	Year Ended December 31, 2020			
	As Reported	Pro Forma Adjustments	Notes	Pro Forma
Product sales	$ 22,334	$ (22,175)	(a)	$ 159
Total operating expense	16,519	(8,392)	(b)	8,127
Operating income (loss)	5,815	(13,783)		(7,968)
Loss before income taxes	$ (5,082)	$ (13,348)	(c)	$ (18,430)

	Unaudited Pro Forma Condensed Combined Statement of (Loss) Income			
	Year Ended December 31, 2019			
	As Reported	Pro Forma Adjustments	Notes	Pro Forma
Product sales	$ 59,215	$ (59,273)	(a)	$ (58)
Total operating expense	83,327	(16,092)	(d)	67,235
Operating loss	(24,112)	(43,181)		(67,293)
Loss before income taxes	$ (38,582)	$ (42,803)	(e)	$ (81,385)

Adjustments to the pro forma unaudited condensed combined statements of (loss) income

(a) This adjustment reflects Product sales attributable to the Hospital Products.

(b) This adjustment reflects the following estimated expenses attributable to the Hospital Products:

- Cost of products of $3,540.
- R&D expenses of $322.
- Selling, general and administrative expenses of $797.
- Intangible asset amortization on acquired development technology for Vazculep of $406.

- Changes in fair value of related party contingent consideration of $3,327. The Company will no longer be responsible for these payments.

(c) This amount reflects the adjustments noted in (a) and (b) above, as well as estimated Changes in fair value of related party payable of $435 attributable to the Hospital Products. The Company will no longer be responsible for these payments.

(d) This adjustment reflects the following estimated expenses attributable to the Hospital Products:

- Cost of products of $11,368.
- R&D expenses of $1,960.
- Selling, general and administrative expenses of $1,102.
- Intangible asset amortization on acquired development technology for Vazculep of $816.
- Changes in fair value of related party contingent consideration of $845. The Company will no longer be responsible for these payments.

(e) This amount reflects the adjustments noted in (a) and (d) above, as well as the reversal of estimated Changes in fair value of related party payable of $378 attributable to the Hospital Products. The Company will no longer be responsible for these payments.

NOTE 5: Revenue Recognition

Prior to June 30, 2020, the Company generated revenue primarily from the sale of pharmaceutical products to customers. On June 30, 2020, the Company sold the Hospital Products. See *Note 4: Disposition of the Hospital Products*.

Product Sales and Services

Prior to June 30, 2020, the Company sold products primarily through wholesalers and considered these wholesalers to be its customers. Revenue from product sales was recognized when the customer obtained control of the Company's product and its performance obligations were met, which occurred typically upon receipt of delivery to the customer. As is customary in the pharmaceutical industry, the Company's gross product sales were subject to a variety of price adjustments in arriving at reported net product sales. These adjustments included estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated when the product is delivered based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

Reserves to reduce Gross Revenues to Net Revenues

Revenues from product sales were recorded at the net selling price, which included estimated reserves to reduce gross product sales to net product sales resulting from product returns, chargebacks, payment discounts, rebates, and other sales allowances that are offered within contracts between the Company and its customers and end users. These reserves were based on the amounts earned or to be claimed on the related sales and were classified as reductions of accounts receivable if the amount was payable to the customer, except in the case of the estimated reserve for future expired product returns, which were classified as a liability. The reserves were classified as a liability if the amount is payable to a party other than a customer. Where appropriate, these estimated reserves took into consideration relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflected the Company's best estimates to reduce gross selling price to net selling price to which it expected to be entitled based on the terms of its contracts. The actual selling price ultimately received may differ from the Company's estimates.

Product Returns

Consistent with industry practice, the Company maintained a returns policy that generally offered customers a right of return for product that has been purchased from the Company. The Company estimated the amount of product returns and records this estimate as a reduction of revenue in the period the related product revenue was recognized. The Company estimated product return liabilities based on analysis of historical data for the product or comparable products, as well as future expectations for such products and other judgments and analysis.

Chargebacks, Discounts and Rebates

Chargebacks, discounts and rebates represent the estimated obligations resulting from contractual commitments to sell products to its customers or end users at prices lower than the list prices charged to the Company's wholesale customers. Customers charged the Company for the difference between the gross selling price they pay for the product and the ultimate contractual price agreed to between the Company and these end users. These reserves were established in the same period that the related revenue was recognized, resulting in a reduction of product revenue and accounts receivable. Chargebacks, discounts and rebates were estimated at the time of sale to the customer.

Disaggregation of revenue

The Company's primary source of revenue was from the sale of pharmaceutical products, which are equally affected by the same economic factors as it relates to the nature, amount, timing, and uncertainty of revenue and cash flows. For further detail about the Company's revenues by product, see *Note 21: Company Operations by Product, Customer and Geography.*

Contract Balances

The Company does not recognize revenue in advance of invoicing its customers and therefore has no related contract assets.

A receivable is recognized in the period the Company sells its products and when the Company's right to consideration is unconditional.

There were no material deferred contract costs at December 31, 2021 and 2020.

Transaction Price Allocated to the Remaining Performance Obligation

For product sales, the Company generally satisfies its performance obligations within the same period the product is delivered. Product sales recognized in 2020 and 2019 from performance obligations satisfied (or partially satisfied) in previous periods were immaterial. No product sales were recognized in 2021.

The Company has elected certain of the practical expedients from the disclosure requirement for remaining performance obligations for specific situations in which an entity need not estimate variable consideration to recognize revenue. Accordingly, the Company applies the practical expedient in ASC 606 to its stand-alone contracts and does not disclose information about variable consideration from remaining performance obligations for which it recognizes revenue.

NOTE 6: 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, 2021			As of December 31, 2020		
Fair Value Measurements:	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Marketable securities (see *Note 7)*						
Mutual and money market funds	$ 78,098	$ —	$ —	$ 104,672	$ —	$ —
Corporate bonds	—	16,479	—	—	22,155	—
Government securities - U.S.	—	9,471	—	—	18,999	—
Other fixed-income securities	—	2,465	—	—	3,854	—
Total assets	$ 78,098	$ 28,415	$ —	$ 104,672	$ 45,008	$ —

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 fiscal year ended December 31, 2021, there were no transfers in and out of Level 1, 2, or 3. During the twelve months ended December 31, 2021, 2020 and 2019, the Company did not recognize any allowances for credit losses.

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

Debt

The Company estimates the fair value of its $143,750 aggregate principal amount of the 2023 Notes based on interest rates that would be currently available to the Company for issuance of similar types of debt instruments with similar terms and remaining maturities or recent trading prices obtained from brokers (a Level 2 input). The estimated fair value of the 2023 Notes at December 31, 2021 is $153,273. See *Note 11: Long-Term Debt* for additional information regarding the Company's debt obligations.

NOTE 7: 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, net of income tax effects. As of December 31, 2021, 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, 2021 and 2020, respectively:

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

	2020			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Mutual and money market funds	$ 103,404	$ 1,288	$ (20)	$ 104,672
Corporate bonds	21,811	350	(6)	22,155
Government securities - U.S.	18,849	155	(5)	18,999
Other fixed-income securities	3,839	22	(7)	3,854
Total	$ 147,903	$ 1,815	$ (38)	$ 149,680

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 in the accompanying consolidated statements of (loss) income.

The Company recognized gross realized gains of $174, $474 and $483 for the twelve months ended December 31, 2021, 2020 and 2019, respectively. These realized gains were offset by realized losses of $275, $912 and $151 for the twelve-months ended December 31, 2021, 2020 and 2019, respectively.

The following table summarizes the estimated fair value of the Company's investments in marketable debt securities, accounted for as available-for-sale securities and classified by the contractual maturity date of the securities as of December 31, 2021:

	Maturities				
Marketable Debt Securities:	**Less than 1 Year**	**1-5 Years**	**5-10 Years**	**Greater than 10 Years**	**Total**
Corporate bonds	$ 5,288	$ 10,873	$ 318	$ —	$ 16,479
Government securities - U.S.	1,531	5,938	807	1,195	9,471
Other fixed-income securities	—	1,860	605	—	2,465
Total	$ 6,819	$ 18,671	$ 1,730	$ 1,195	$ 28,415

The Company has classified its investment in available-for-sale marketable 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.

Total gross unrealized losses of the Company's available-for-sale debt securities at December 31, 2021 were immaterial and have been in an unrealized loss position for less than one year. The unrealized losses are driven by factors other than credit risk. The Company does not intend to sell the investments and it is not more likely than not that it will be required to sell the investments before recovery of their amortized cost bases.

NOTE 8: Property and Equipment, net

The principal categories of property and equipment, net at December 31, 2021 and 2020, respectively, are as follows:

Property and Equipment, net:	**2021**	**2020**
Software, office and computer equipment	$ 448	$ 1,443
Furniture, fixtures and fittings	302	300
Less - accumulated depreciation	(465)	(1,384)
Total	$ 285	$ 359

Depreciation expense for the years ended December 31, 2021, 2020 and 2019 was $97, $287 and $459, respectively.

NOTE 9: Goodwill and Intangible Assets

The Company's goodwill is $16,836 at December 31, 2021 and 2020.

The Company recorded amortization expense related to an amortizable intangible asset that was assumed by the Exela Buyer as part of the disposition of the Hospital Products on June 30, 2020 of $406 and $816 for the years ended December 31, 2020 and 2019, respectively. Refer to *Note 4: Disposition of the Hospital Products*. There was no amortization expense recorded during the year ended December 31, 2021.

No impairment loss related to goodwill or intangible assets was recognized during the years ended December 31, 2021 or 2020.

NOTE 10: Leases

The Company leases office space and a production suite. All leased facilities are classified as operating leases with remaining lease terms between two and four 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) income of years ended December 31, 2021, 2020 and 2019 were as follows:

Lease cost:	**2021**	**2020**	**2019**
Operating lease costs [(1)]	$ 821	$ 1,133	$ 1,515
Sublease income [(2)]	(110)	(336)	(276)
Total lease cost	$ 711	$ 797	$ 1,239

[(1)] Variable lease costs were immaterial for the years ended December 31, 2021, 2020 and 2019.
[(2)] Represents sublease income received for office subleases.

During the years ended December 31, 2021 and 2020, the Company reduced its operating lease liabilities by $578 and $769 for cash paid. During the year ended December 31, 2021, the Company remeasured its production suite lease liability. During the year ended December 31, 2021, the Company did not enter into any new operating or finance leases.

As of December 31, 2021, the Company's operating leases have a weighted-average remaining lease term of 2.9 years and a weighted-average discount rate of 4.9%. 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**
2022	$ 974
2023	1,013
2024	614
2025	206
2026	—
Thereafter	—
Total lease payments	2,807
Less: interest	200
Present value of lease liabilities	$ 2,607

NOTE 11: Long-Term Debt

Long-term debt is summarized as follows:

	December 31, 2021	December 31, 2020
Principal amount of 4.50% exchangeable senior notes due 2023	$ 143,750	$ 143,750
Less: unamortized debt discount and issuance costs, net	(1,353)	(15,540)
Net carrying amount of liability component	142,397	128,210
Less: current maturities	—	—
Long-term debt	$ 142,397	$ 128,210
Equity component:		
Equity component of exchangeable notes, net of issuance costs	$ —	$ (26,699)

For the years ended December 31, 2021, 2020 and 2019, the total interest expense was $9,942, $12,994 and $12,464, respectively, with coupon interest expense of $6,469 for each period and the amortization of debt issuance costs and debt discount of $1,248, $6,525 and $5,995, respectively. Current period interest expense also included $2,225 of additional interest expense owed as a result of not removing a restrictive legend from the 2023 Notes 365 days following original issuance of the 2023 Notes on February 16, 2018. See *Note 1: Background and Basis of Presentation* for further details.

As described in *Note 2: Newly Issued Accounting Standards*, the Company elected to early adopt ASU 2020-06 as of January 1, 2021 using a modified retrospective method. The adoption resulted in a $12,939 increase in long-term debt and a $26,699 decrease in the equity component of the 2023 Notes.

2023 Notes

On February 16, 2018, Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of the Company (the "Issuer"), issued $125,000 aggregate principal amount of 4.50% exchangeable senior notes due 2023 (the "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 2023 Notes a 30-day option to purchase up to an additional $18,750 aggregate principal amount of the 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 2023 Notes are the Company's senior unsecured obligations and rank 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.

The 2023 Notes will be exchangeable at the option of the holders at an initial exchange rate of 92.6956 ADSs per $1 principal amount of 2023 Notes, which is equivalent to an initial exchange price of approximately $10.79 per ADS. Such initial exchange price represents a premium of approximately 20% to the $8.99 per ADS closing price on The Nasdaq Global Market on February 13, 2018. Upon the exchange of any 2023 Notes, the Issuer will pay or cause to be delivered, as the case may be, cash, ADSs or a combination of cash and ADSs, at the Issuer's election. Holders of the 2023 Notes may convert their 2023 Notes, at their option, only under the following circumstances prior to the close of business on the business day immediately preceding August 1, 2022, under the circumstances and during the periods set forth below and regardless of the conditions described below, on or after August 1, 2022 and prior to the close of business on the business day immediately preceding the maturity date:

- Prior to the close of business on the business day immediately preceding August 1, 2022, a holder of the 2023 Notes may surrender all or any portion of its 2023 Notes for exchange at any time during the five business day period immediately after any five consecutive trading day period (the "Measurement Period") in which the trading price per $1 principal amount of 2023 Notes, as determined following a request by a holder of the 2023 Notes, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the ADSs and the exchange rate on each such trading day.

- If a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs prior to the close of business on the business day immediately preceding August 1, 2022, regardless of whether a holder of the 2023 Notes has the right to require the Company to repurchase the 2023 Notes, or if Avadel is a party to a merger

event that occurs prior to the close of business on the business day immediately preceding August 1, 2022, all or any portion of a the holder's 2023 Notes may be surrendered for exchange at any time from or after the date that is 95 scheduled trading days prior to the anticipated effective date of the transaction (or, if later, the earlier of (x) the business day after the Company gives notice of such transaction and (y) the actual effective date of such transaction) until 35 trading days after the actual effective date of such transaction or, if such transaction also constitutes a fundamental change, until the related fundamental change repurchase date.

- Prior to the close of business on the business day immediately preceding August 1, 2022, a holder of the 2023 Notes may surrender all or any portion of its 2023 Notes for exchange at any time during any calendar quarter commencing after the calendar quarter ending on June 30, 2018 (and only during such calendar quarter), if the last reported sale price of the ADSs for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the exchange price on each applicable trading day.

- If the Company calls the 2023 Notes for redemption pursuant to Article 16 to the Indenture prior to the close of business on the business day immediately preceding August 1, 2022, then a holder of the 2023 Notes may surrender all or any portion of its 2023 Notes for exchange at any time prior to the close of business on the second business day prior to the redemption date, even if the 2023 Notes are not otherwise exchangeable at such time. After that time, the right to exchange shall expire, unless the Company defaults in the payment of the redemption price, in which case a holder of the 2023 Notes may exchange its 2023 Notes until the redemption price has been paid or duly provided for.

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

NOTE 12: Contingent Consideration Payable

Prior to the sale of the Hospital Products on June 30, 2020, the Company computed the fair value of the contingent consideration using several significant assumptions and when those assumptions changed, due to underlying market conditions, the fair value of these liabilities changed as well. Prior to the sale of the Hospital Products, these changes had a material impact on the Company's consolidated statements of (loss) income and balance sheets. As part of the sale of the Hospital Products on June 30, 2020, the Exela Buyer assumed and will pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy and the Company under the Deerfield Royalty Agreement and the Broadfin Royalty Agreement. As of December 31, 2021 and 2020, the balance of the contingent consideration payable is $0.

The following table summarizes changes to the contingent consideration payables, a recurring Level 3 measurement, for the twelve-month periods ended December 31, 2020 and 2019:

Contingent Consideration Payable:	**Balance**
Balance at December 31, 2018	$ 28,840
Payments of related party payable	(12,736)
Fair value adjustments [(1)]	1,223
Balance at December 31, 2019	17,327
Payments of contingent consideration payable	(6,189)
Fair value adjustments [(1)]	3,762
Disposition of the Hospital Products	(14,900)
Balance at December 31, 2020	$ —

[(1)] Fair value adjustments are reported as changes in fair value of contingent consideration and other expense - changes in fair value of contingent consideration payable in the consolidated statements of (loss) income.

NOTE 13: Income Taxes

The components of loss before income taxes for the years ended twelve months ended December 31, are as follows:

Loss Before Income Taxes:	2021	2020	2019
Ireland	$ (36,631)	$ (27,205)	$ (50,134)
U.S.	(56,687)	22,335	10,401
France	173	(212)	1,151
Total loss before income taxes	$ (93,145)	$ (5,082)	$ (38,582)

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

Income Tax Benefit:	2021	2020	2019
Current:			
U.S. - Federal	$ —	$ (12,810)	$ —
U.S. - State	60	20	97
Total current	60	(12,790)	97
Deferred:			
Ireland	—	—	(1,256)
U.S. - Federal	(15,876)	680	(4,093)
U.S. - State	—	—	(104)
Total deferred	(15,876)	680	(5,453)
Income tax benefit	$ (15,816)	$ (12,110)	$ (5,356)

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

Reconciliation to Effective Income Tax Rate:	2021	2020	2019
Income tax benefit - at statutory tax rate	$ (11,642)	$ (636)	$ (4,823)
Differences in international tax rates	(8,950)	1,755	(1,218)
Nondeductible changes in fair value of contingent consideration	—	988	121
Intercompany asset transfer	—	—	(8,190)
Change in valuation allowances	4,296	4,231	7,379
Nondeductible share-based compensation	645	1,060	1,039
Hospital Products sale	—	(9,328)	—
Unrealized tax benefits	239	(274)	(261)
State and local taxes (net of federal)	60	20	(7)
Change in U.S. tax law	—	(9,124)	—
Nondeductible interest expense	2,173	1,728	982
Orphan drug and R&D tax credit	(1,524)	(2,793)	—
Other	(1,113)	263	(378)
Income tax benefit - at effective income tax rate	$ (15,816)	$ (12,110)	$ (5,356)

In 2021, the income tax benefit increased by $3,706 when compared to the same period in 2020. The increase in the income tax benefit in 2021 was primarily driven by the additional tax benefit from an increase in the net operating losses in the U.S. in 2021, when compared to the same period in 2020. This was partially offset by the nonrecurring nature of tax benefits recognized in 2020 from the sale of the Company's Hospital Products and passage of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") in the U.S.

In 2020, the income tax benefit increased by $6,754 when compared to the same period in 2019. The increase in the income tax benefit in 2020 was primarily driven by the tax benefits from the sale of the Company's Hospital Products and passage of the CARES Act in the U.S. The Company recorded additional tax benefit in 2020 from the Orphan Drug and R&D tax credit in the U.S. Tax benefit from the intercompany asset transfer recorded in 2019 did not recur, resulting in a partial offset of tax benefits described above.

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 2017. During 2020, the Company completed the 2015 through 2017 U.S. Federal Tax Audit. Completion of the audit resulted in an assessment of $1,937 for the 2015 through 2017 U.S. Federal Tax Returns compared to the IRS Claims of $50,695 made on July 2, 2019 and the updated IRS Claims of $9,302 on October 2, 2019 made as part of the Specialty Pharma bankruptcy proceedings, which at this time does not include interest and penalties.

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	**2021**	**2020**	**2019**
Balance at January 1:	$ 3,143	$ 6,465	$ 5,315
Increases for tax positions of prior years	—	—	2,416
Statute of limitations expiration	—	—	(1,266)
Settlements	—	(3,322)	—
Balance at December 31:	$ 3,143	$ 3,143	$ 6,465

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, 2021, 2020 and 2019, there are $2,483, $2,483 and $3,806 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 expense. During the years ended December 31, 2021, 2020 and 2019, the Company recognized approximately $239, $203 and $555 in interest and penalties. The Company had approximately $1,777 and $1,475 for the payment of interest and penalties accrued at December 31, 2021 and 2020, 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, 2021 and 2020 resulted from the following temporary differences:

Net Deferred Tax Assets and Liabilities:	**2021**	**2020**
Deferred tax assets:		
Net operating loss carryforwards	$ 35,990	$ 31,302
Orphan drug and R&D tax credit	4,964	2,793
Share-based compensation	4,108	2,626
Amortization	3,429	3,701
Other	662	423
Gross deferred tax assets	49,153	40,845
Deferred tax liabilities:		
Other	(925)	(890)
Prepaid expenses	(75)	(75)
Gross deferred tax liabilities	(1,000)	(965)
Less: valuation allowances	(24,025)	(21,624)
Net deferred tax assets	$ 24,128	$ 18,256

At December 31, 2021, the Company had $124,720 of net operating losses in Ireland that do not have an expiration date and $74,406 of net operating losses in the U.S. Of the $74,406 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 $64,041 are due to the losses at US Holdings. The portion due to the acquisition of FSC will expire in 2034 through 2035. A valuation allowance is recorded if, based on the weight of available evidence, it is more likely than not that a deferred tax asset will not be realized. This assessment is based on an evaluation of the level of historical taxable income and projections for future taxable income. For the year ended December 31, 2021, the Company recorded $4,045 of valuation allowances related to Irish net operating losses. The U.S. net operating losses are subject to an annual limitation as a result of the FSC acquisition under Internal Revenue Code Section 382 and will not be fully utilized before they expire.

The Company recorded a valuation allowance against all of its net operating losses in Ireland and France as of December 31, 2021 and 2020. The Company intends to continue maintaining a full valuation allowance on the Irish net operating losses until there is sufficient evidence to support the reversal of all or some portion of these allowances.

While the Company believes it is more likely than not that it will be able to realize the deferred tax assets in the U.S., the Company continues to monitor any unfavorable changes that could ultimately impact its assessment of the realizability of the Company’s U.S. deferred tax assets. If the Company experiences an ownership change under Internal Revenue Code Section 382, the U.S. net operating losses could also be limited in their utilization.

At December 31, 2021, the Company has unremitted earnings of $3,916 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, 2021, the Company’s net research tax credit receivable amounts to $3,668 and represents a French gross research

tax credit of $3,139 and an Irish gross research tax credit of $529. As of December 31, 2020, the Company's net research tax credit receivable amounts to $6,771 and represents a French gross research tax credit of $6,396 and an Irish gross research tax credit of $375.

2020 CARES Act

The CARES Act, enacted on March 27, 2020, includes significant business tax provisions. In particular, the CARES Act modified the rules associated with net operating losses. Under the temporary provisions of the CARES Act, net operating loss carryforwards and carrybacks may offset 100% of taxable income for taxable years beginning before 2021. In addition, net operating losses arising in 2018, 2019 and 2020 taxable years may be carried back to each of the preceding five years to generate a refund. During the twelve months ended December 31, 2020, the income tax benefit includes a discrete tax benefit of $9,124 as a result of the Company's ability under the CARES Act to carry back net operating losses incurred to periods when the statutory U.S. Federal tax rate was 35% versus the Company's current U.S. Federal tax rate of 21%. During the twelve months ended December 31, 2020, the Company received $3,351 in cash tax refunds from carryback claims related to the CARES Act from the carryback of 2018 tax losses. The Company filed refund claims for $18,753 associated with the carryback of 2019 tax losses and a $10,273 refund claim associated with the carryback of 2020 tax losses.

NOTE 14: 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:	**2021**	**2020**
Income tax receivable (see *Note 13*)	$ 29,097	$ 18,615
Prepaid and other expenses	3,179	1,018
Guarantee from Armistice	279	318
Other	271	798
Receivable from Exela (see *Note 4*)	—	16,500
Short-term deposit	—	1,477
Total	$ 32,826	$ 38,726

Other Non-Current Assets:	**2021**	**2020**
Deferred tax assets (see *Note 13*)	$ 24,128	$ 18,256
Right of use assets at contract manufacturing organizations	8,549	5,201
Guarantee from Armistice	771	1,050
Other	329	432
Total	$ 33,777	$ 24,939

Accrued Expenses:	**2021**	**2020**
Accrued compensation	$ 3,167	$ 1,697
Accrued professional fees	2,678	2,781
Accrued outsourced contract costs	1,048	473
Customer allowances	217	1,030
Accrued restructuring (see *Note 16*)	41	520
Total	$ 7,151	$ 6,501

Other Current Liabilities:	2021	2020
Accrued interest	$ 4,920	$ 2,695
Guarantee to Deerfield	280	319
Other	70	160
Due to Exela	—	2,026
Total	$ 5,270	$ 5,200

Other Non-Current Liabilities:	2021	2020
Tax liabilities and other	$ 3,143	$ 3,159
Guarantee to Deerfield	774	1,053
Total	$ 3,917	$ 4,212

NOTE 15: 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, 2021, there were no contingent liabilities with respect to any litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Company's consolidated financial position, results of operations, cash flows or liquidity.

First 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 will infringe at least one claim of US Patent No. 8731963, 10758488, 10813885, 10959956 and/or 10966931 (collectively, the "patents-in-suit"). The First Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses.

On 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'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.

Second 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 Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 11077079. The Second Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses.

On 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.

Third 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 Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 11147782. The Third Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses. This case will proceed on the same schedule as the cases associated with the First and Second Complaints above.

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

On 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.

Material Commitments

At December 31, 2021, the Company has one commitment with its primary contract manufacturer related to facility upgrades and the purchase and validation of equipment to be used in the manufacture of FT218. The total cost of this commitment is estimated to be approximately $5,500 and is expected to be completed during the year ending December 31, 2022. The Company has incurred approximately $3,348 of this commitment during the year ended December 31, 2021.

The Company also has a commitment with another contract manufacturer that commences in the first quarter of 2022 and will continue until FDA approval of the contract manufacturer. The commitment will be approximately $3,000 per year.

Guarantees

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 $1,054 at December 31, 2021. 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 $1,050 at December 31, 2021. This asset is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

The fair values of the Company's guarantee to Deerfield and the guarantee received by the Company from Armistice largely offset and when combined are not material.

NOTE 16: Restructuring Costs

2019 French Restructuring

During the second quarter of 2019, the Company initiated a plan to discontinue all French R&D activities, which resulted in the redundancy and reduction of its entire workforce at its Vénissieux, France site ("2019 French Restructuring"). This reduction was part of an effort to align the Company's cost structure with its ongoing and future planned projects. The discontinuation of R&D activities and elimination of the workforce in France was completed during the year ended December 31, 2020. Restructuring charges associated with this plan recognized during the years ended December 31, 2021 and 2020 were immaterial. Restructuring charges associated with this plan of $4,855 of were recognized during the year ended December 31, 2019. Included in the 2019 French Restructuring charges of $4,855 were charges for employee severance, benefits and other costs of $4,339, charges related to fixed asset impairment of $629, charges related to the early termination penalty related to the office and copier lease terminations of $887, partially offset by a benefit of $1,000 related to the reversal of the French retirement indemnity obligation. At December 31, 2021, there are no future expected retirement indemnity benefits to be paid. The Company does not expect to incur any additional expenses related to the 2019 French Restructuring. The following table sets forth activities for the Company's cost reduction plan obligations for the years ended December 31, 2021 and 2020:

2019 French Restructuring Obligation:	**2021**	**2020**
Balance of restructuring accrual at January 1,	$ 248	$ 1,922
(Benefit) charges for employee severance, benefits and other costs	(122)	172
Payments	(77)	(1,813)
Foreign currency impact	(8)	(33)
Balance of restructuring accrual at December 31,	$ 41	$ 248

The 2019 French Restructuring liability of $41 is included in the consolidated balance sheet in accrued expenses at December 31, 2021.

2019 Corporate Restructuring

During the first quarter of 2019, the Company announced a plan to reduce its corporate workforce by more than 50% (the "2019 Corporate Restructuring"). The reduction in workforce is primarily a result of the exit of Noctiva during the first quarter of 2019 (see *Note 3: Subsidiary Bankruptcy and Deconsolidation*), as well as an effort to better align the Company's remaining cost structure at its U.S. and Ireland locations with its ongoing and future planned projects. The reduction in workforce was completed during the year ended December 31, 2020. Restructuring income associated with this plan for the years ended December 31, 2021 and 2020 were immaterial. Restructuring charges associated with this plan of $1,755 were recognized during the year ended December 31, 2019. Included in the 2019 Corporate Restructuring charges of $1,755 for the year ended December 31, 2019 were charges for employee severance, benefit and other costs of $3,406, charges related to the early termination penalty related to the office lease termination of $288, the write-off of $125 of property, plant and equipment, net, partially offset by a benefit of $2,064 related to share based compensation forfeitures related to the employees affected by the global reduction in workforce. The Company does not expect to incur any additional expenses related to the 2019 Corporate Restructuring.

During the years ended December 31, 2021, 2020 and 2019, the Company paid $272, $1,014, and $2,326 respectively, and has no remaining obligation for the 2019 Corporate Restructuring plan as of December 31, 2021.

NOTE 17: 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, 2021, the Company had 58,620 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 488 are currently issued and outstanding as of December 31, 2021.

Shelf Registration Statement on Form S-3

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

a. up to $250,000 in aggregate of ordinary shares, nominal value US$0.01 per share (the “Ordinary Shares”), each of which may be represented by American Depositary Shares (“ADSs”), preferred shares, nominal value US$0.01 per share (the “Preferred Shares”), debt securities (the “Debt Securities”), warrants to purchase Ordinary Shares, ADSs, Preferred Shares and/or Debt Securities (the “Warrants”), and/or units consisting of Ordinary Shares, ADSs, Preferred Shares, one or more Debt Securities or Warrants in one or more series, in any combination, pursuant to the terms of the 2020 Shelf Registration Statement, the base prospectus contained in the 2020 Shelf Registration Statement (the “Base Prospectus”), and any amendments or supplements thereto (together, the “Securities”); 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 on February 4, 2020 (the “Sales Agreement”), the 2020 Shelf Registration Statement, the Base Prospectus and the terms of the sales agreement prospectus contained in the 2020 Shelf Registration Statement.

The transactions costs associated with the 2020 Shelf Registration Statement totaled $428 of which $214 was charged against additional paid-in capital during the twelve months ended December 31, 2020 as a result of the May 2020 Public Offering, discussed below. The remaining costs of $214 are recorded as a prepaid asset at December 31, 2021.

February 2020 Private Placement

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

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

Issuance costs of $4,430 have been recorded as a reduction of additional paid-in capital.

May 2020 Public Offering

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

Retirement of Treasury Shares

In August 2020, the Company retired all of its 5,407 treasury shares, or $49,998 previously repurchased ordinary shares. As a result, the Company reduced additional paid-in capital by $49,944 and ordinary shares by $54 during the twelve months ended December 31, 2020. The portion allocated to additional paid-in capital is determined pro rata by applying a percentage, determined by dividing the number of shares to be retired by the number of shares issued and outstanding as of the retirement date, to the balance of additional paid-in capital as of the retirement date. Based on this calculation, the entirety of the excess of repurchase price over par of $49,944 was allocated to additional paid-in capital.

NOTE 18: Share-Based Compensation

Compensation expense included in the Company's consolidated statements of (loss) income for all share-based compensation arrangements was as follows for the periods ended December 31, 2021, 2020 and 2019, respectively:

Share-based Compensation Expense:	**2021**	**2020**	**2019**
Research and development	$ 758	$ 139	$ 429
Selling, general and administrative	8,114	3,281	2,154
Restructuring costs	—	(421)	(2,064)
Total share-based compensation expense	$ 8,872	$ 2,999	$ 519

As of December 31, 2021, the Company expects $18,429 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 3.2 years.

The excess tax benefit related to share-based compensation recorded by the Company was not material for the years ended December 31, 2021, 2020 and 2019.

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, 2021, there were 1,336 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, 2021, the Company had not issued any shares under this Inducement Plan.

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. 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. 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, 2021, 2020 and 2019, are as follows:

Stock Option Assumptions:	2021	2020	2019
Stock option grants:			
Expected term (years)	6.20	6.08	6.25
Expected volatility	73.91 %	75.76 %	56.48 %
Risk-free interest rate	1.10 %	0.72 %	2.52 %
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, 2021 is as follows:

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

The aggregate intrinsic value of options exercisable at December 31, 2021, 2020 and 2019 was $6,291, $1,841, and $572, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2021, 2020 and 2019 was $5.36, $4.63 and $1.24 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 from 2017-2020 vest over a three-year period; two-thirds (2/3) vesting on the second anniversary of the grant date and the remaining one-third (1/3) vesting on the third anniversary of the grant date. In 2021, restricted share awards granted to employees vest over a four-year period; one-fourth (1/4) on each anniversary of the grant date. In 2018, the Company issued restricted share awards to its Board of Directors vesting over a three-year period; one-third (1/3) vesting on each of the three anniversaries of the grant date. Compensation expense for such awards granted during and after 2017 is recognized over the applicable vesting period.

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

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

The weighted average grant date fair value of restricted share awards granted during the years ended December 31, 2021, 2020 and 2019 was $8.22, $7.69 and $2.47, respectively.

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 various 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 2020, the Company granted performance share awards, of which 50% vest upon the achievement of certain regulatory milestones related to FT218 and the other 50% vest one year following achievement of those milestones ("2020 PSU awards"). The Company has not yet recognized any share-based compensation expense related to the 2020 PSU awards as the regulatory milestones have not yet been met; however, in the event the performance conditions are met before a certain date, approximately 100% of the outstanding shares, or $1,786 of compensation expense will be recognized by the Company for the 2020 PSU awards outstanding as of December 31, 2021.

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 Company has not yet recognized any share-based compensation expense related to the 2021 PSU awards as the objectives have not yet been met; however, in the event the performance conditions are met and exceeded, approximately 150% of the outstanding shares, or $3,509 of compensation expense will be recognized by the Company for the 2021 PSU awards outstanding as of December 31, 2021.

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

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

The weighted average grant date fair value of performance share awards granted during the years ended December 31, 2021 and 2020 was $8.20 and $7.09 per share, respectively. There were no performance share awards granted during the year ended December 31, 2019.

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, 2021 and 2020, the Company issued 17 and 49 ordinary shares to employees, respectively. Expense related to the ESPP for the years ended December 31, 2021, 2020 and 2019 was immaterial.

NOTE 19: Net (Loss) Income Per Share

Basic net (loss) income per share is calculated by dividing net (loss) income by the weighted average number of shares outstanding during each period. Diluted net (loss) income per share is calculated by dividing net (loss) income - diluted by the diluted number of shares outstanding during each period. Except where the result would be anti-dilutive to net (loss) income, diluted net (loss) income per share would be calculated assuming the impact of the conversion of 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 has a choice to settle the conversion obligation under the 2023 Notes in cash, shares or any combination of the two. The Company utilizes the if-converted method to reflect the impact of the conversion of the 2023 Notes, unless the result is anti-dilutive. This method assumes the conversion of the 2023 Notes into shares of the Company's ordinary shares and reflects the elimination of the interest expense related to the 2023 Notes.

The dilutive effect of the stock options, restricted stock units, preferred shares and ordinary shares expected to be issued under the Company's ESPP has been calculated using the treasury stock method. The dilutive effect of the PSUs will be calculated using the treasury stock method, if and when the contingent vesting condition is achieved.

A reconciliation of basic and diluted net (loss) income per share, together with the related shares outstanding in thousands for the years ended December 31, 2021, 2020 and 2019, is as follows:

Net (Loss) Income Per Share:	**2021**	**2020**	**2019**
Net (loss) income	$ (77,329)	$ 7,028	$ (33,226)
Weighted average shares:			
Basic shares	58,535	52,996	37,403
Effect of dilutive securities—employee and director equity awards outstanding	—	1,945	—
Diluted shares	58,535	54,941	37,403
Net (loss) income per share - basic	$ (1.32)	$ 0.13	$ (0.89)
Net (loss) income per share - diluted	$ (1.32)	$ 0.13	$ (0.89)

Potential ordinary shares of 15,327, 14,915, and 16,740 were excluded from the calculation of weighted average shares for the years ended December 31, 2021, 2020 and 2019, 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, 2021 and 2019, the effects of dilutive securities were entirely excluded from the calculation of net (loss) income per share as a net loss was reported in these periods.

NOTE 20: 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:	2021	2020	2019
Foreign currency translation adjustment:			
Beginning balance	$ (22,627)	$ (23,738)	$ (23,621)
Net other comprehensive (loss) income	(1,228)	1,111	(117)
Balance at December 31,	$ (23,855)	$ (22,627)	$ (23,738)
Unrealized (loss) gain on marketable securities, net			
Beginning balance	$ 1,576	$ 932	$ 205
Net other comprehensive (loss) income, net of income tax benefit (expense) of $214, $(202), $(43), respectively	(1,661)	644	727
Balance at December 31,	$ (85)	$ 1,576	$ 932
Accumulated other comprehensive loss at December 31,	$ (23,940)	$ (21,051)	$ (22,806)

NOTE 21: Company Operations by Product, Customer and Geographic Area

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 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.

On June 30, 2020, the Company sold the Hospital Products. See *Note 4: Disposition of the Hospital Products*. The Company had no revenue during the twelve months ended December 31, 2021.

The following table presents a summary of total revenues by product for the twelve months ended December 31, 2020 and 2019:

Revenue by Product:	2020	2019
Bloxiverz	$ 2,201	$ 7,479
Vazculep	10,429	33,152
Akovaz	9,545	18,642
Other	159	(58)
Product sales	$ 22,334	$ 59,215

The following table presents a summary of total revenues by significant customer for the twelve months ended December 31, 2020 and 2019:

Revenue by Significant Customer:	2020	2019
McKesson Corporation	$ 5,758	$ 14,900
Cardinal Health	5,155	15,088
AmerisourceBergen	3,155	12,059
QuVa Pharma	3,117	3,252
Others	5,149	13,916
Product sales	$ 22,334	$ 59,215

All revenue earned during the years ended December 31, 2020 and 2019 was generated in the U.S.

Concentration of credit risk with respect to accounts receivable was limited due to the high credit quality comprising a significant portion of the Company's customers. Management periodically monitors the creditworthiness of the Company's customers and believes that it has adequately provided for any exposure to potential credit loss.

Currently, the Company is working with contract manufacturing organizations for the manufacture of FT218. Additionally, the Company purchases raw materials used in FT218 from a limited number of suppliers, including a single supplier for certain key ingredients.

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, 2021, 2020, and 2019:

Long-lived Assets by Geographic Region:	**2021**	**2020**	**2019**
U.S.	$ 19,605	$ 20,424	$ 22,254
France	—	11	196
Ireland	9,817	6,047	7,244
Total	$ 29,422	$ 26,482	$ 29,694

NOTE 22: Related Party Transactions

As noted in *Note 4: Disposition of the Hospital Products*, prior to June 30, 2020, the Company was party to a Membership Interest Purchase Agreement by and among the Company, Avadel Legacy, Breaking Stick Holdings, LLC, Deerfield Private Design International II, L.P. ("Deerfield International"), Deerfield Private Design Fund II, L.P. ("Deerfield Fund") and Horizon Santé FLML, Sarl ("Horizon") (the "Deerfield MIPA") and a Royalty Agreement by and among the Company, Avadel Legacy, the Deerfield Fund and Horizon (the "Deerfield Royalty Agreement"). In connection with the closing of the sale of the Hospital Products, the Deerfield MIPA (with respect to certain sections thereof) and the Royalty Agreement were assigned to the Exela Buyer. Pursuant to the Purchase Agreement, the Exela Buyer assumed and will pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy under the Deerfield Royalty Agreement for obligations that arise after the Closing Date.

Prior to June 30, 2020, the Company was also party to a Royalty Agreement by and between itself, Avadel Legacy and Broadfin Healthcare Master Fund, Ltd. (the "Broadfin Royalty Agreement"). In connection with the closing of the sale of the Hospital Products, the Broadfin Royalty Agreement was assigned to the Exela Buyer and the Exela Buyer assumed and shall pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy under the Broadfin Royalty Agreement for obligations that arise after the Closing Date.

Refer to *Note 12: Contingent Consideration Payable* for a summary of payments made for and changes to the fair value of the related party payable for the year ended December 31, 2019. Deerfield and Broadfin disposed of their 2023 Notes and ordinary shares in the Company during the year ended December 31, 2020 and are no longer considered related parties for the years ended December 31, 2021 and 2020.

NOTE 23: Subsequent Events

On March 16, 2022, Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of the Company (the "Issuer"), executed an agreement to exchange $117,375 of its 2023 Notes due February 1, 2023 (the "February 2023 Notes") for a new series of its Exchangeable Senior Notes due October 2, 2023 (the "October 2023 Notes") (the "Exchange"). The remaining $26,375 aggregate principal amount of the February 2023 Notes will maintain a maturity date of February 1, 2023. Taking into consideration the Exchange and the maturity date of the October 2023 Notes and based on the Company's current plans, the Company has sufficient cash on hand and available liquidity to satisfy its obligations and fund working capital needs for at least twelve months following the date of issuance of the Consolidated Financial Statements. The Company has a recent history of generating losses from operations including during 2021 and expects to continue generating losses over the next twelve months. Similar to other businesses in the Company's industry and at its stage of development, the Company will continue in the medium term to rely on external sources of capital to fund its business.

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, 2021 and 2020, the related consolidated statements of (loss) income, comprehensive (loss) income, shareholders' equity, and cash flows, for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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 March 16, 2022 expressed an adverse 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 Matters

Critical audit matters are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Deloitte and Touche LLP
St. Louis, Missouri
March 16, 2022

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, 2021, 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, because of the effect of the material weakness identified below on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2021, 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, 2021, of the Company and our report dated March 16, 2022, 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.

Material Weakness

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material weakness of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment: Management did not have a control to identify that they were in technical default of its 2023 convertible notes and owed 0.50% of additional interest due to the failure to remove a restrictive legend from the 2023 convertible notes. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements as of and for the year ended December 31, 2021, of the Company, and this report does not affect our report on such financial statements.

/s/ Deloitte and Touche LLP
St. Louis, Missouri
March 16, 2022

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

As required by Rule 15d -15(b) of the Exchange Act, our management has evaluated, under the supervision and with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Based on that evaluation, our principal executive officer and principal financial officer concluded that as of the end of the period covered by this Annual Report our disclosure controls and procedures were not effective due to the material weakness in our internal control over financial reporting described below.

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, 2021. 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, 2021, the Company's internal control over financial reporting was not effective.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

Material Weakness in Internal Control Over Financial Reporting

During the Company's fiscal 2021 financial statement close process, management identified a deficiency in the design of internal control over financial reporting related to its February 2023 Notes indenture. Specifically, management did not have a control to identify that we were in technical default of the February 2023 Notes and owed 0.50% of additional interest on the February 2023 Notes due to not removing a restrictive legend from the February 2023 Notes 365 days following the original issuance of the February 2023 Notes on February 16, 2018. The Company cured the default through payment of the additional interest in March 2022.

The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report included in this Annual Report. This report contains an adverse opinion on the effectiveness of our internal control over financial reporting.

Remediation of Material Weakness

Once the material weakness was identified, we developed and implemented a remediation plan that includes the implementation of additional control procedures surrounding timely and periodic evaluation of all terms of our debt agreement and the associated calculation of interest expense in accordance with the terms of such debt agreement to ensure the completeness and accuracy of the calculation and timely payment of interest expense, classification of debt and compliance with terms of the debt agreement.

We are committed to maintaining a strong internal control environment and have fully implemented measures designed to help ensure that the control deficiency contributing to the material weakness is remediated. However, there cannot be any assurance that these remediation efforts will be successful or that our internal control over financial reporting will be effective as a result of these efforts. The material weakness will be fully remediated when, we have determined, through testing, these controls have operated effectively for a sufficient period of time.

Other Changes in Internal Control Over Financial Reporting

Except as noted above, there have been no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

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 2022 annual general meeting of shareholders pursuant to Regulation 14A of the Securities Exchange Act of 1934 (our "Definitive 2022 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 2022 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 2022 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2021.

Item 11. Executive Compensation.

Information regarding Executive Compensation is hereby incorporated by reference to our Definitive 2022 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2021.

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 2022 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2021.

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 2022 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2021.

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 2022 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2021.

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
2021	$ 21,624	$ 4,235	$ (51)	$ (1,783)	$ 24,025
2020	$ 17,037	$ 2,805	$ —	$ 1,782	$ 21,624
2019	$ 21,199	$ 6,496	$ (4,762)	$ (5,896)	$ 17,037

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

The Company has elected not to include summary information.

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)

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	Indenture, dated as of February 16, 2018, by and between Avadel Finance Cayman Limited, Avadel Pharmaceuticals plc, and The Bank of New York Mellon, as Trustee (including an as exhibit the Form of 4.50% Exchangeable Senior Note due 2023) (incorporated by reference to Exhibit 4.1 to the registrant's current report on Form 8-K, filed on February 16, 2018)
4.3	First Supplemental Indenture, dated as of February 6, 2019, by and among Avadel Finance Cayman Limited, Avadel Pharmaceuticals plc, and The Bank of New York Mellon, as Trustee (incorporated by reference to Exhibit 4.1 to the registrant's current report on Form 8-K, filed on February 7, 2019)
4.4	Description of Securities (incorporated by reference to Exhibit 4.6 to the registrants annual report on Form 10-K, filed on March 16, 2020)
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‡	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)

10.11*	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)
10.12*	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)
10.13*	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)
10.14#	Securities Purchase Agreement, dated February 20, 2020, by and among Avadel Pharmaceuticals plc and the Investors named therein (incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K, filed on February 24, 2020)
10.15	Registration Rights Agreement, dated February 25, 2020, by and among Avadel Pharmaceuticals plc and the Investors named therein incorporated by reference to Exhibit 10.40 to the registrant's annual report on Form 10-K, filed on March 16, 2020)
10.16*#	Asset Purchase Agreement, dated as of June 30, 2020, by and between Avadel Seller, Seller Parent, Exela Buyer and Buyer Parent (incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K, filed on July 2, 2020)
10.17‡	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)
10.18‡	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)
10.19‡	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	Avadel Pharmaceuticals plc 2021 Inducement Plan and related equity award agreements (filed herewith)
10.21‡	Employment Agreement dated as of February 14, 2022 between Avadel Management Corporation and Douglas Williamson (filed herewith)
10.22	Form of Exchange Agreement between Avadel Finance Cayman Limited, Avadel Pharmaceuticals plc and certain holders of its February 2023 Notes (filed herewith)
14.1	Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2020, filed on March 9, 2021)
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)
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.

(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: March 16, 2022 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	March 16, 2022
/s/ Thomas S. McHugh Thomas S. McHugh	Chief Financial Officer and Principal Financial and Accounting Officer	March 16, 2022
/s/ Geoffrey M. Glass Geoffrey M. Glass	Non-Executive Chairman of the Board and Director	March 16, 2022
/s/ Dr. Eric J. Ende Dr. Eric J. Ende	Director	March 16, 2022
/s/ Mark A. McCamish, MD, Ph.D. Mark A. McCamish, MD, Ph.D.	Director	March 16, 2022
/s/ Linda S. Palczuk Linda S. Palczuk	Director	March 16, 2022
/s/ Peter J. Thornton Peter J. Thornton	Director	March 16, 2022

AVADEL PHARMACEUTICALS PLC

2021 INDUCEMENT PLAN

SECTION 1. GENERAL PURPOSE OF THE PLAN; DEFINITIONS

The name of the plan is the Avadel Pharmaceuticals plc 2021 Inducement Plan (the "Plan"). The purpose of the Plan is to enable Avadel Pharmaceuticals plc, an Irish public limited company (the "Company") to grant equity awards to induce highly-qualified prospective officers and employees who are not currently employed by the Company and its Affiliates to accept employment and provide them with a proprietary interest in the Company. It is anticipated that providing such persons with a direct stake in the Company's welfare will assure a closer identification of their interests with those of the Company and its shareholders, thereby stimulating their efforts on the Company's behalf and strengthening their desire to remain with the Company. The Company intends that the Plan be reserved for persons to whom the Company may issue securities without shareholder approval as an inducement pursuant to Rule 5635(c)(4) of the Marketplace Rules of NASDAQ Stock Market, Inc.

The following terms shall be defined as set forth below:

"Act" means the United States Securities Act of 1933, as amended, and the rules and regulations thereunder.

"Administrator" means either the Board or the compensation committee of the Board or a similar committee of the Board performing the functions of the compensation committee and which is comprised of not less than two Non-Employee Directors who are independent.

"ADS" means an American Depositary Share representing one Ordinary Share, registered with the SEC and listed for trading on the Nasdaq Global Market under the trading symbol "AVDL"; an ADS may be represented by a physical certificate referred to as an American Depositary Receipt, or "ADR."

"*Affiliate*" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 of the Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

"Award" or *"Awards,"* except where referring to a particular category of grant under the Plan, shall include Non-Qualified Options, Share Appreciation Rights, Restricted Share Units, Restricted Share Awards, Unrestricted Share Awards, and Dividend Equivalent Rights.

"Award Certificate" means a written or electronic document setting forth the terms and provisions applicable to an Award granted under the Plan. Each Award Certificate is subject to the terms and conditions of the Plan.

"Board" means the Board of Directors of the Company.

"Code" means the United States Internal Revenue Code of 1986, as amended, and any successor Code, and related rules, regulations and interpretations.

"Companies Act" means the Companies Act 2014 of Ireland (as amended).

"*Consultant*" means a consultant or adviser who provides *bona fide* services to the Company or an Affiliate as an independent contractor and who qualifies as a consultant or advisor under Instruction A.1.(a)(1) of Form S-8 under the Act.

"*Dividend Equivalent Right*" means an Award entitling the grantee to receive credits based on cash dividends that would have been paid on the Shares specified in the Dividend Equivalent Right (or other award to which it relates) if such shares had been issued to and held by the grantee.

"*Effective Date*" means the date on which the Plan becomes effective as set forth in Section 18.

"*Exchange Act*" means the United States Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder.

"*Fair Market Value*" of a Share (represented by ADSs) on any given date means the fair market value of a Share determined in good faith by the Administrator; provided, however, that if the Shares or ADSs are listed on the NASDAQ, The NASDAQ Global Market, The NASDAQ Global Select Market, The New York Stock Exchange or another securities exchange or traded on any established market, the determination shall be made by reference to market quotations. If there are no market quotations for such date, the determination shall be made by reference to the last date preceding such date for which there are market quotations.

"*Non-Employee Director*" means a member of the Board who is not also an employee of the Company or any Subsidiary.

"*Non-Qualified Option*" means any Option that is not an "incentive stock option" under Section 422 of the Code.

"*Option*" means any option to purchase Shares granted pursuant to Section 5.

"*Ordinary Share*" means an ordinary share, par value $0.01, in the capital of the Company.

"*Restricted Shares*" means the Shares underlying a Restricted Share Award that remain subject to a risk of forfeiture or the Company's right of repurchase.

"*Restricted Share Award*" means an Award of Restricted Shares subject to such restrictions and conditions as the Administrator may determine at the time of grant.

"*Restricted Share Units*" means an Award of share units subject to such restrictions and conditions as the Administrator may determine at the time of grant.

"*Sale Event*" means (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) the following individuals cease for any reason to constitute a majority of the number of directors then serving on the Board: individuals who, on the Effective Date, constitute the Board and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including, but not limited to, a consent solicitation relating to the election of directors of the Company) whose appointment or election by the Board or nomination for election by the Company's shareholders was approved or recommended by a vote of at least a majority of the directors then still in office who either were members of the Board on the Effective Date or whose appointment, election or nomination for election was previously so approved (the "Incumbent Directors"); (iii) a merger, reorganization or consolidation with any other

corporation or other entity, other than (A) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding Shares immediately prior to such transaction continue to own a majority of the outstanding voting power and outstanding Shares or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction and (B) the Incumbent Directors continuing immediately thereafter to represent at least a majority of the board of directors of the resulting or successor entity (or its ultimate parent, if applicable), (iv) the sale of all of the Shares of the Company to an unrelated person, entity or group thereof acting in concert, or (v) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company. For the avoidance of doubt, any one or more of the above events may be effective pursuant to (a) a compromise or arrangement sanctioned by the court under Chapter 1 of Part 9 of the Companies Act, (b) an acquisition pursuant to Chapter 2 of Part 9 of the Companies Act, or (c) a merger pursuant to the European Communities (Cross-Border Mergers) Regulations 2008. Notwithstanding the foregoing, in the case of any Award that constitutes deferred compensation within the meaning of Section 409A of the Code, there shall not be a Sale Event unless there is a change in the ownership or effective control of the Company, or in a substantial portion of the assets of the Company, within the meaning of Section 409A of the Code where necessary for such Award to comply with Section 409A of the Code.

"*Sale Price*" means the value as determined by the Administrator of the consideration payable, or otherwise to be received by shareholders, per Share pursuant to a Sale Event.

"*Section 409A*" means Section 409A of the Code and the regulations and other guidance promulgated thereunder.

"*Service Relationship*" means any relationship as an employee, director or Consultant of the Company or any Affiliate (e.g., a Service Relationship shall be deemed to continue without interruption in the event an individual's status changes from full-time employee to part-time employee or Consultant).

"*Share*" means an Ordinary Share, subject to adjustment pursuant to Section 3; unless the context otherwise requires, references herein to "Shares" shall include references to ADSs.

"*Share Appreciation Right*" means an Award entitling the recipient to receive Shares (or cash, to the extent explicitly provided for in the applicable Award Certificate) having a value equal to the excess of the Fair Market Value of the Share on the date of exercise over the exercise price of the Share Appreciation Right multiplied by the number of Shares with respect to which the Share Appreciation Right shall have been exercised.

"*Subsidiary*" means any corporation or other entity (other than the Company) in which the Company has at least a 50 percent interest, either directly or indirectly.

"*Unrestricted Share Award*" means an Award of Shares free of any restrictions.

SECTION 2. ADMINISTRATION OF PLAN; ADMINISTRATOR AUTHORITY TO SELECT GRANTEES AND DETERMINE AWARDS

(a) Administration of Plan. The Plan shall be administered by the Administrator.

(b) Powers of Administrator. The Administrator shall have the power and authority to grant Awards consistent with the terms of the Plan, including the power and authority:

(i) to select the individuals to whom Awards may from time to time be granted;

(ii) to determine the time or times of grant, and the extent, if any, of Non-Qualified Options, Share Appreciation Rights, Restricted Share Awards, Restricted Share Units, Unrestricted Share Awards, and Dividend Equivalent Rights, or any combination of the foregoing, granted to any one or more grantees;

(iii) to determine the number of Shares to be covered by any Award and to determine whether any Award shall pertain to Shares or ADSs;

(iv) to determine and modify from time to time the terms and conditions, including restrictions, not inconsistent with the terms of the Plan, of any Award, which terms and conditions may differ among individual Awards and grantees, and to approve the forms of Award Certificates;

(v) to accelerate at any time the exercisability or vesting of all or any portion of any Award;

(vi) subject to the provisions of Section 5(c), to extend at any time the period in which Options may be exercised; and

(vii) at any time to adopt, alter and repeal such rules, guidelines and practices for administration of the Plan and for its own acts and proceedings as it shall deem advisable; to interpret the terms and provisions of the Plan and any Award (including related written instruments); to make all determinations it deems advisable for the administration of the Plan; to decide all disputes arising in connection with the Plan; and to otherwise supervise the administration of the Plan.

All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and Plan grantees.

(c) Award Certificate. Awards under the Plan shall be evidenced by Award Certificates that set forth the terms, conditions and limitations for each Award which may include, without limitation, the term of an Award and the provisions applicable in the event employment or service terminates.

(d) Reserved.

(e) Indemnification. Neither the Board nor the Administrator, nor any member of either or any delegate thereof, shall be liable for any act, omission, interpretation, construction or determination made in good faith in connection with the Plan, and the members of the Board and the Administrator (and any delegate thereof) shall be entitled in all cases to indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including, without limitation, reasonable attorneys' fees) arising or resulting therefrom to the fullest extent permitted by law and/or under the Company's constitution or any directors' and officers' liability insurance coverage which may be in effect from time to time and/or any indemnification agreement between such individual and the Company.

(f) Non-U.S. Award Recipients. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws of countries other than the U.S. in which the Company and its Subsidiaries operate or have employees or other individuals eligible for Awards, the Administrator, in its sole discretion, shall have the power and authority to: (i) determine which Subsidiaries shall be covered by the Plan; (ii) determine which individuals outside the United

States are eligible to participate in the Plan; (iii) modify the terms and conditions of any Award granted to individuals outside the United States to comply with applicable foreign laws; (iv) establish subplans and modify exercise procedures and other terms and procedures, to the extent the Administrator determines such actions to be necessary or advisable (and such subplans and/or modifications shall be attached to this Plan as appendices); provided, however, that no such subplans and/or modifications shall increase the share limitations contained in Section 3(a) hereof; and (v) take any action, before or after an Award is made, that the Administrator determines to be necessary or advisable to obtain approval or comply with any local governmental regulatory exemptions or approvals. Notwithstanding the foregoing, the Administrator may not take any actions hereunder, and no Awards shall be granted, that would violate the Exchange Act or any other applicable United States securities law, the Code, any other applicable United States governing statute or law, or any applicable Irish law.

SECTION 3. STOCK ISSUABLE UNDER THE PLAN; MERGERS; SUBSTITUTION

(a) Stock Issuable. The maximum number of Shares reserved and available for issuance under the Plan shall be 1,500,000 Shares, subject to adjustment as provided in this Section 3. For purposes of this limitation, the Shares underlying any awards under the Plan that are forfeited, canceled or otherwise terminated (other than by exercise) shall be added back to the Shares available for issuance under the Plan. Notwithstanding the foregoing, the following Shares shall not be added to the Shares authorized for grant under the Plan: (i) Shares tendered or held back upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding, and (ii) Shares subject to a Share Appreciation Right that are not issued in connection with the share settlement of the Share Appreciation Right upon exercise thereof. In the event the Company repurchases Shares on the open market, such Shares shall not be added to the Shares available for issuance under the Plan. Subject to such overall limitations, Shares may be issued up to such maximum number pursuant to any type or types of Award. The Shares available for issuance under the Plan may be authorized but unissued Shares or Shares reacquired by the Company.

(b) Changes in Shares. Subject to Section 3(c) hereof, if, as a result of any reorganization, recapitalization, reclassification, share dividend, share split, reverse share split or other similar change in the Company's capital, the outstanding Shares are increased or decreased or are exchanged for a different number or kind of shares or other securities of the Company, or additional shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such Shares or other securities, or, if, as a result of any Sale Event, or sale of all or substantially all of the assets of the Company, the outstanding Shares are converted into or exchanged for securities of the Company or any successor entity (or a parent or subsidiary thereof), the Administrator shall make an appropriate or proportionate adjustment in (i) the maximum number of Shares reserved for issuance under the Plan, (ii) the number and kind of Shares or other securities subject to any then outstanding Awards under the Plan, (iii) the repurchase price, if any, per Share subject to each outstanding Restricted Share Award, and (iv) the exercise price for each Share subject to any then outstanding Options and Share Appreciation Rights under the Plan, without changing the aggregate exercise price (i.e., the exercise price multiplied by the number of shares subject to Options and Share Appreciation Rights) as to which such Options and Share Appreciation Rights remain exercisable. The Administrator shall also make equitable or proportionate adjustments in the number of shares subject to outstanding Awards and the exercise price and the terms of outstanding Awards to take into consideration cash dividends paid other than in the ordinary course or any other extraordinary corporate event. The adjustment by the Administrator shall be final, binding and conclusive. No fractional Shares shall be issued under the Plan resulting from any such adjustment, but the Administrator in its discretion may make a cash payment in lieu of fractional Shares.

(c) Sale Events. In the case of and subject to the consummation of a Sale Event, the parties thereto may cause the assumption or continuation of Awards theretofore granted by the successor entity, or the substitution of such Awards with new Awards of the successor entity or parent thereof, with appropriate adjustment as to the number and kind of shares and, if appropriate, the per share exercise prices, as such parties shall agree. To the extent the parties to such Sale Event do not provide for the assumption, continuation or substitution of Awards, upon the effective time of the Sale Event, the Plan and all outstanding Awards granted hereunder shall terminate. In the event of such termination, (i) the Company shall have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the grantees holding Options and Share Appreciation Rights, in exchange for the cancellation thereof, in an amount equal to the difference between (A) the Sale Price multiplied by the number of Shares subject to outstanding Options and Share Appreciation Rights (to the extent then vested and exercisable at prices not in excess of the Sale Price) and (B) the aggregate exercise price of all such outstanding Options and Share Appreciation Rights (provided that, in the case of an Option or Share Appreciation Right with an exercise price equal to or greater than the Sale Price, such Option or Share Appreciation Right shall be cancelled for no consideration); or (ii) each grantee shall be permitted, within a specified period of time prior to the consummation of the Sale Event as determined by the Administrator, to exercise all outstanding Options and Share Appreciation Rights (to the extent then vested and exercisable) held by such grantee. The Company shall also have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the grantees holding other Awards in an amount equal to the Sale Price multiplied by the number of vested Shares under such Awards.

SECTION 4. ELIGIBILITY

Grantees under the Plan will be such employees of the Company and its Affiliates as to whom the Company may issue securities without shareholder approval in accordance with Rule 5635(c)(4) of the Marketplace Rules of NASDAQ Stock Market, Inc. as selected from time to time by the Administrator in its sole discretion; provided that Awards may not be granted to employees who are providing services only to any "parent" of the Company, as such term is defined in Rule 405 of the Act, unless (i) the stock underlying the Awards is treated as "service recipient stock" under Section 409A or (ii) the Company has determined that such Awards are exempt from or otherwise comply with Section 409A.

SECTION 5. OPTIONS

(a) Award of Options. The Administrator may grant Options under the Plan. Any Option granted under the Plan shall be a Non-Qualified Option, and shall be in such form as the Administrator may from time to time approve.

Options granted pursuant to this Section 5 shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Administrator shall deem desirable. .

(b) Exercise Price. The exercise price per Share covered by an Option granted pursuant to this Section 5 shall be determined by the Administrator at the time of grant but shall not be less than 100 percent of the Fair Market Value on the date of grant. Notwithstanding the foregoing, Options may be granted with an exercise price per Share that is less than 100 percent of the Fair Market Value on the date of grant (i) to individuals who are not subject to U.S. income tax on the date of grant or (ii) if the Option is otherwise compliant with Section 409A.

(c) Option Term. The term of each Option shall be fixed by the Administrator, but no Option shall be exercisable more than ten years after the date the Option is granted. Where an Option is granted with an exercise price per share that is less than 100 percent of the Fair Market

Value on the date of grant to an individual who is tax resident in Ireland, the Option shall lapse if not exercised within 7 years of the date of grant.

(d) Exercisability; Rights of a Shareholder. Options shall become exercisable at such time or times, whether or not in installments, as shall be determined by the Administrator at or after the grant date. The Administrator may at any time accelerate the exercisability of all or any portion of any Option. An optionee shall have the rights of a shareholder only as to Shares acquired upon the exercise of an Option and not as to unexercised Options.

(e) Method of Exercise. Options may be exercised in whole or in part, by giving written or electronic notice of exercise to the Company, specifying the number of Shares to be purchased. Payment of the purchase price may be made by one or more of the following methods except to the extent otherwise provided in the Award Certificate:

(i) In cash, by certified or bank check or other instrument acceptable to the Administrator;

(ii) Through the delivery (or attestation to the ownership following such procedures as the Company may prescribe) of Shares that are not then subject to restrictions under any Company plan. Such surrendered Shares shall be valued at Fair Market Value on the exercise date;

(iii) By the optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company for the purchase price; provided that in the event the optionee chooses to pay the purchase price as so provided, the optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Company shall prescribe as a condition of such payment procedure; or

(iv) By a “net exercise” arrangement pursuant to which the Company will reduce the number of Shares issuable upon exercise by the largest whole number of Shares with a Fair Market Value that does not exceed the aggregate exercise price. Where newly issued Shares are to be delivered in this way, the Affiliate which employs the grantee, if so agreed with the Company, shall pay to the Company such price as is at least equal to the aggregate nominal value of the Shares issued.

Payment instruments will be received subject to collection. The transfer to the optionee on the records of the Company or of the transfer agent of the Shares to be purchased pursuant to the exercise of an Option will be contingent upon receipt from the optionee (or a purchaser acting in his or her stead in accordance with the provisions of the Option) by the Company of the full purchase price for such shares and the fulfillment of any other requirements contained in the Award Certificate or applicable provisions of laws (including the satisfaction of any withholding taxes that the Company is obligated to withhold with respect to the optionee). In the event an optionee chooses to pay the purchase price by previously-owned Shares through the attestation method, the number of Shares transferred to the optionee upon the exercise of the Option shall be net of the number of attested Shares. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the exercise of Options, such as a system using an internet website or interactive voice response, then the paperless exercise of Options may be permitted through the use of such an automated system.

SECTION 6. SHARE APPRECIATION RIGHTS

(a) Award of Share Appreciation Rights. The Administrator may grant Share Appreciation Rights under the Plan. A Share Appreciation Right is an Award entitling the

recipient to receive Shares (or cash, to the extent explicitly provided for in the applicable Award Certificate) having a value equal to the excess of the Fair Market Value of a Share on the date of exercise over the exercise price of the Share Appreciation Right multiplied by the number of Shares with respect to which the Share Appreciation Right shall have been exercised.

(b) Exercise Price of Share Appreciation Rights. The exercise price of a Share Appreciation Right shall not be less than 100 percent of the Fair Market Value of a Share on the date of grant.

(c) Grant and Exercise of Share Appreciation Rights. Share Appreciation Rights may be granted by the Administrator independently of any Option granted pursuant to Section 5 of the Plan.

(d) Terms and Conditions of Share Appreciation Rights. Share Appreciation Rights shall be subject to such terms and conditions as shall be determined on the date of grant by the Administrator. The term of a Share Appreciation Right may not exceed ten years. The terms and conditions of each such Award shall be determined by the Administrator, and such terms and conditions may differ among individual Awards and grantees.

SECTION 7. RESTRICTED SHARE AWARDS

(a) Nature of Restricted Share Awards. The Administrator may grant Restricted Share Awards under the Plan. A Restricted Share Award is any Award of Restricted Shares subject to such restrictions and conditions as the Administrator may determine at the time of grant. Conditions may be based on continuing employment (or other Service Relationship) and/or achievement of pre-established performance goals and objectives.

(b) Rights as a Shareholder. Upon the grant of the Restricted Share Award and payment of any applicable purchase price, a grantee shall have the rights of a shareholder with respect to the voting of the Restricted Shares and receipt of dividends; provided that any dividends paid by the Company during the vesting period shall accrue and shall not be paid to the grantee until and to the extent the Restricted Shares vest. Unless the Administrator shall otherwise determine, (i) uncertificated Restricted Shares shall be accompanied by a notation on the records of the Company or the transfer agent to the effect that they are subject to forfeiture until such Restricted Shares are vested as provided in Section 7(d) below, and (ii) certificated Restricted Shares shall remain in the possession of the Company until such Restricted Shares are vested as provided in Section 7(d) below, and the grantee shall be required, as a condition of the grant, to deliver to the Company such instruments of transfer as the Administrator may prescribe.

(c) Restrictions. Restricted Shares may not be sold, assigned, transferred, pledged or otherwise encumbered or disposed of except as specifically provided herein or in the Restricted Share Award Certificate. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 15 below, in writing after the Award is issued, if a grantee's employment (or other Service Relationship) with the Company and its Subsidiaries terminates for any reason, any Restricted Shares that have not vested at the time of termination shall automatically and without any requirement of notice to such grantee from or other action by or on behalf of, the Company be deemed to have been reacquired by the Company at its original purchase price (if any) from such grantee or such grantee's legal representative simultaneously with such termination of employment (or other Service Relationship), and thereafter shall cease to represent any ownership of the Company by the grantee or rights of the grantee as a shareholder. Following such deemed reacquisition of Restricted Shares that are represented by physical certificates, a grantee shall surrender such certificates to the Company upon request without consideration.

(d) Vesting and payment of Restricted Shares. The Administrator at the time of grant shall specify the date or dates and/or the attainment of pre-established performance goals, objectives and other conditions on which the non-transferability of the Restricted Shares and the Company's right of repurchase or forfeiture shall lapse. Subsequent to such date or dates and/or the attainment of such pre-established performance goals, objectives and other conditions, the Shares on which all restrictions have lapsed shall no longer be Restricted Shares and shall be deemed "vested." Where newly issued Shares are to be delivered on the vesting of a Restricted Share Award, the Affiliate which employs the grantee, if so agreed with the Company, shall pay to the Company such price as is at least equal to the aggregate nominal value of the Shares the subject of the Restricted Share Award.

SECTION 8. RESTRICTED SHARE UNITS

(a) Nature of Restricted Share Units. The Administrator may grant Restricted Share Units under the Plan. A Restricted Share Unit is an Award of stock units that may be settled in Shares (or cash, to the extent explicitly provided for in the Award Certificate) upon the satisfaction of such restrictions and conditions at the time of grant. Conditions may be based on continuing employment (or other Service Relationship) and/or achievement of pre-established performance goals and objectives. The terms and conditions of each such Award shall be determined by the Administrator, and such terms and conditions may differ among individual Awards and grantees. Except in the case of Restricted Share Units with a deferred settlement date that complies with Section 409A, at the end of the vesting period, the Restricted Share Units, to the extent vested, shall be settled in the form of Shares. Restricted Share Units with deferred settlement dates are subject to Section 409A and shall contain such additional terms and conditions as the Administrator shall determine in its sole discretion in order to comply with the requirements of Section 409A.

(b) Rights as a Shareholder. A grantee shall have the rights as a shareholder only as to Shares acquired by the grantee upon settlement of Restricted Share Units; provided, however, that the grantee may be credited with Dividend Equivalent Rights with respect to the stock units underlying his or her Restricted Share Units, subject to the provisions of Section 10 and such terms and conditions as the Administrator may determine. Where newly issued Shares are to be delivered on the vesting of a Restricted Share Unit, the Affiliate which employs the grantee, if so agreed with the Company, shall pay to the Company such price as is at least equal to the aggregate nominal value of the Shares the subject of the Restricted Share Unit.

(c) Termination. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 15 below, in writing after the Award is issued, a grantee's right in all Restricted Share Units that have not vested shall automatically terminate upon the grantee's termination of employment (or cessation of Service Relationship) with the Company and its Subsidiaries for any reason.

SECTION 9. UNRESTRICTED SHARE AWARDS

Grant or Sale of Unrestricted Shares. The Administrator may grant (or sell at par value or such higher purchase price determined by the Administrator) an Unrestricted Share Award under the Plan. An Unrestricted Share Award is an Award pursuant to which the grantee may receive Shares free of any restrictions under the Plan. Unrestricted Share Awards may be granted in respect of past services or other valid consideration, or in lieu of cash compensation due to such grantee.

SECTION 10. DIVIDEND EQUIVALENT RIGHTS

(a) Dividend Equivalent Rights. The Administrator may grant Dividend Equivalent Rights under the Plan. A Dividend Equivalent Right is an Award entitling the grantee to receive credits based on cash dividends that would have been paid on the Shares specified in the Dividend Equivalent Right (or other Award to which it relates) if such shares had been issued to the grantee. A Dividend Equivalent Right may be granted hereunder to any grantee as a component of an award of Restricted Share Units or as a freestanding award. The terms and conditions of Dividend Equivalent Rights shall be specified in the Award Certificate. Dividend equivalents credited to the holder of a Dividend Equivalent Right may be paid currently or may be deemed to be reinvested in additional Shares, which may thereafter accrue additional equivalents. Any such reinvestment shall be at Fair Market Value on the date of reinvestment or such other price as may then apply under a dividend reinvestment plan sponsored by the Company, if any. Dividend Equivalent Rights may be settled in cash or Shares or a combination thereof, in a single installment or installments. A Dividend Equivalent Right granted as a component of an Award of Restricted Share Units shall provide that such Dividend Equivalent Right shall be settled only upon settlement or payment of, or lapse of restrictions on, such other Award, and that such Dividend Equivalent Right shall expire or be forfeited or annulled under the same conditions as such other Award.

(b) Termination. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 15 below, in writing after the Award is issued, a grantee's rights in all Dividend Equivalent Rights shall automatically terminate upon the grantee's termination of employment (or cessation of Service Relationship) with the Company and its Subsidiaries for any reason.

SECTION 11. TRANSFERABILITY OF AWARDS

(a) Transferability. Except as provided in Section 11(b) below, during a grantee's lifetime, his or her Awards shall be exercisable only by the grantee, or by the grantee's legal representative or guardian in the event of the grantee's incapacity. No Awards shall be sold, assigned, transferred or otherwise encumbered or disposed of by a grantee other than by will or by the laws of descent and distribution or pursuant to a domestic relations order. No Awards shall be subject, in whole or in part, to attachment, execution, or levy of any kind, and any purported transfer in violation hereof shall be null and void.

(b) Administrator Action. Notwithstanding Section 11(a), the Administrator, in its discretion, may provide either in the Award Certificate regarding a given Award or by subsequent written approval that the grantee (who is an employee or director) may transfer his or her Non-Qualified Options to his or her immediate family members, to trusts for the benefit of such family members, or to partnerships in which such family members are the only partners, provided that the transferee agrees in writing with the Company to be bound by all of the terms and conditions of this Plan and the applicable Award. In no event may an Award be transferred by a grantee for value.

(c) Family Member. For purposes of Section 11(b), "family member" shall mean a grantee's child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, any person sharing the grantee's household (other than a tenant of the grantee), a trust in which these persons (or the grantee) have more than 50 percent of the beneficial interest, a foundation in which these persons (or the grantee) control the management of assets, and any other entity in which these persons (or the grantee) own more than 50 percent of the voting interests.

(d) Designation of Beneficiary. To the extent permitted by the Company, each grantee to whom an Award has been made under the Plan may designate a beneficiary or beneficiaries to exercise any Award or receive any payment under any Award payable on or after the grantee's death. Any such designation shall be on a form provided for that purpose by the Administrator and shall not be effective until received by the Administrator. If no beneficiary has been designated by a deceased grantee, or if the designated beneficiaries have predeceased the grantee, the beneficiary shall be the grantee's estate.

SECTION 12. TAX WITHHOLDING

(a) Payment by Grantee. Each grantee shall, no later than the date as of which the value of an Award or of any Share or other amount received thereunder first becomes includable in the gross income of the grantee for income tax purposes, pay to the Company, or make arrangements satisfactory to the Administrator regarding payment of, any Federal, state, or local taxes of any kind required by law to be withheld by the Company with respect to such income. The Company and its Subsidiaries shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the grantee. The Company's obligation to deliver evidence of book entry (or stock certificates) to any grantee is subject to and conditioned on tax withholding obligations being satisfied by the grantee.

(b) Payment in Stock. The Administrator may require the Company's tax withholding obligation to be satisfied, in whole or in part, by the Company withholding from Shares to be issued pursuant to any Award a number of Shares with an aggregate Fair Market Value (as of the date the withholding is effected) that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid liability accounting treatment. For purposes of share withholding, the Fair Market Value of withheld shares shall be determined in the same manner as the value of Shares includible in income of the grantees. The Administrator may also require the Company's tax withholding obligation to be satisfied, in whole or in part, by an arrangement whereby a certain number of Shares issued pursuant to any Award are immediately sold and proceeds from such sale are remitted to the Company in an amount that would satisfy the withholding amount due.

SECTION 13. SECTION 409A AWARDS

Awards are intended to be exempt from Section 409A to the greatest extent possible and to otherwise comply with Section 409A. The Plan and all Awards shall be interpreted in accordance with such intent. To the extent that any Award is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A (a "409A Award"), the Award shall be subject to such additional rules and requirements as specified by the Administrator from time to time in order to comply with Section 409A. In this regard, if any amount under a 409A Award is payable upon a "separation from service" (within the meaning of Section 409A) to a grantee who is then considered a "specified employee" (within the meaning of Section 409A), then no such payment shall be made prior to the date that is the earlier of (i) six months and one day after the grantee's separation from service, or (ii) the grantee's death, but only to the extent such delay is necessary to prevent such payment from being subject to interest, penalties and/or additional tax imposed pursuant to Section 409A. Further, the settlement of any 409A Award may not be accelerated except to the extent permitted by Section 409A.

SECTION 14. TERMINATION OF SERVICE RELATIONSHIP, TRANSFER, LEAVE OF ABSENCE, ETC.

(a) Termination of Service Relationship. If the grantee's Service Relationship is with an Affiliate and such Affiliate ceases to be an Affiliate, the grantee shall be deemed to have terminated his or her Service Relationship for purposes of the Plan.

(b) For purposes of the Plan, the following events shall not be deemed a termination of a Service Relationship:

(i) a transfer to the employment of the Company from an Affiliate or from the Company to an Affiliate, or from one Affiliate to another; or

(ii) an approved leave of absence for military service or sickness, or for any other purpose approved by the Company, if the employee's right to re-employment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise so provides in writing.

SECTION 15. AMENDMENTS AND TERMINATION

The Board may, at any time, amend or discontinue the Plan and the Administrator may, at any time, amend or cancel any outstanding Award for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall materially and adversely affect rights under any outstanding Award without the holder's consent. Except as provided in Section 3(b) or 3(c), without prior shareholder approval, in no event may the Administrator exercise its discretion to reduce the exercise price of outstanding Options or Share Appreciation Rights or effect repricing through cancellation and re-grants or cancellation of Options or Share Appreciation Rights in exchange for cash or other Awards. Nothing in this Section 15 shall limit the Administrator's authority to take any action permitted pursuant to Section 3(b) or 3(c).

SECTION 16. STATUS OF PLAN

With respect to the portion of any Award that has not been exercised and any payments in cash, Shares or other consideration not received by a grantee, a grantee shall have no rights greater than those of a general creditor of the Company unless the Administrator shall otherwise expressly determine in connection with any Award or Awards. In its sole discretion, the Administrator may authorize the creation of trusts or other arrangements to meet the Company's obligations to deliver Shares or make payments with respect to Awards hereunder, provided that the existence of such trusts or other arrangements is consistent with the foregoing sentence.

SECTION 17. GENERAL PROVISIONS

(a) No Distribution. The Administrator may require each person acquiring Shares pursuant to an Award to represent to and agree with the Company in writing that such person is acquiring the shares without a view to distribution thereof.

(b) Issuance of Stock. To the extent certificated, stock certificates to grantees under this Plan shall be deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have mailed such certificates, addressed to the grantee, at the grantee's last known address on file with the Company. Uncertificated Shares shall be deemed delivered for all purposes when the Company or a Share transfer agent of the Company shall have given to the grantee by electronic mail (with proof of receipt) or by United States mail, addressed to the grantee, at the grantee's last known address on file with the Company, notice of issuance and recorded the issuance in its records (which may include electronic "book entry" records).

Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any evidence of book entry or certificates evidencing Shares pursuant to the exercise or settlement of any Award, unless and until the Administrator has determined, with advice of counsel (to the extent the Administrator deems such advice necessary or advisable), that the issuance and delivery is in compliance with all applicable laws, regulations of governmental authorities and, if applicable, the requirements of any exchange on which the Shares are listed, quoted or traded. Any Shares issued pursuant to the Plan shall be subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with Federal, state or foreign jurisdiction, securities or other laws, rules and quotation system on which the Shares are listed, quoted or traded. The Administrator may place legends on any Share certificate or notations on any book entry to reference restrictions applicable to the Shares. In addition to the terms and conditions provided herein, the Administrator may require that an individual make such reasonable covenants, agreements, and representations as the Administrator, in its discretion, deems necessary or advisable in order to comply with any such laws, regulations, or requirements. The Administrator shall have the right to require any individual to comply with any timing or other restrictions with respect to the settlement or exercise of any Award, including a window-period limitation, as may be imposed in the discretion of the Administrator.

(c) Shareholder Rights. Until Shares are deemed delivered in accordance with Section 17(b), no right to vote or receive dividends or any other rights of a shareholder will exist with respect to Shares to be issued in connection with an Award, notwithstanding the exercise of an Option or any other action by the grantee with respect to an Award.

(d) Other Compensation Arrangements; No Employment Rights. Nothing contained in this Plan shall prevent the Board from adopting other or additional compensation arrangements, including trusts, and such arrangements may be either generally applicable or applicable only in specific cases. The adoption of this Plan and the grant of Awards do not confer upon any employee any right to continued employment with the Company or any Subsidiary.

(e) Payment of Nominal Value. Notwithstanding any other provision of this Plan, no Shares in the authorized but unissued share capital of the Company shall be issued in settlement of an Award unless they are paid-up, on issuance, to at least their nominal value. If the Board determines that an Award is to be settled by the issuance of authorized but unissued Shares, the Board may decide that the Shares so issued will be: (1) paid-up from the exercise price (if any); (2) otherwise paid-up by the grantee; (3) subject to applicable law, paid-up by the Company from distributable profits or other reserves which may be applied for that purpose; or (4) subject to applicable law, paid-up by a subsidiary of the Company or by another person.

(f) Trading Policy Restrictions. Option exercises and other Awards under the Plan shall be subject to the Company's insider trading policies and procedures, as in effect from time to time.

(g) Clawback Policy. Awards under the Plan shall be subject to the Company's clawback policy, as in effect from time to time.

(h) Concert-Party Restrictions under the Irish Takeover Rules. In the event that any individual who is eligible to receive an Award is, or is presumed to be, a "person acting in concert" for the purposes of the Irish Takeover Rules, and the grant, exercise, vesting, settlement or any other action in relation to an Award to such individual may, in the reasonable opinion of the Administrator, result in the individual and/or any person acting, or presumed to be acting, in concert with such individual ("Participant") becoming obliged under the Irish Takeover Rules to make an offer for the Company under Rule 9 of the Irish Takeover Rules ("a Concert-Party

Offer"), the Administrator may decide that either (i) such grant, exercise, vesting, settlement or other action in relation to such individual or Participant shall not take effect unless the Company is in receipt of a confirmation, direction or ruling from the Irish Takeover Panel that satisfies the Board that such grant, exercise, vesting, settlement or other action would not result in an obligation to make a Concert-Party Offer; or the Shares which are to be delivered on the vesting or settlement of the relevant Award shall not have any voting rights. If the Administrator determines that the exercise or settlement of any such Award by way of the issuance of Shares is not possible or desirable, it may determine that such Award shall be settled in cash, on such conditions as the Administrator may determine.

SECTION 18. EFFECTIVE DATE OF PLAN

This Plan shall become effective immediately upon approval by the Board.

SECTION 19. GOVERNING LAW

This Plan and all Awards and actions taken thereunder shall be governed by, and construed in accordance with, the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by and construed in accordance with the internal laws of the State of Delaware, applied without regard to conflict of law principles.

DATE APPROVED BY BOARD OF DIRECTORS: November 23, 2021

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of the 14th day of February 2022 by and among Douglas Williamson, currently residing at 6 N Michigan Ave., Unit 1303, Chicago, Illinois 60602 (the "Executive"), and Avadel Management Corporation, a Delaware corporation with a principal office located at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005 (the "Company"). The Company is an indirect wholly owned subsidiary of Avadel Pharmaceuticals plc, an Irish public limited company with a principal office located at Ten Earlsfort Terrace, Dublin 2, D02 T380 Ireland ("Avadel plc").

WITNESSETH

WHEREAS, the Executive will begin his employment with the Company as of February 14, 2022 (the "Effective Date"), and the Executive and the Company wish to set forth in this Agreement the terms of such employment.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. EMPLOYMENT TERMS

1.1 Position.

(a) Positions. The Executive shall serve as the Chief Medical Officer of Avadel plc and will be employed by the Company as the Chief Medical Officer, and shall carry out such work as may be reasonably required by the Company in connection with the business of Avadel plc and the Company consistent with such positions and the terms and conditions of this Agreement. The Executive will devote substantially all of the Executive's business time, attention and efforts to Avadel plc and the Company and during such time the Executive will make the best use of his energy, knowledge and training for the purpose of advancing the interests of Avadel plc and the Company. Except as may be otherwise expressly authorized in writing by the Chief Executive Officer of Avadel plc, during his employment with the Company the Executive will accept no other employment nor serve as an officer, director or principal of any other company or organization (other than a member of the Avadel Group of Companies (as hereinafter defined). Notwithstanding the foregoing, the Executive may engage in religious, charitable or other community activities (which may include service as a board member of a religious, charitable or other not-for-profit organization) as long as such activities do not interfere with the Executive's performance of his duties to or with respect to Avadel plc and each of its direct or indirect subsidiaries including the Company (collectively, the "Avadel Group of Companies"). The Executive will comply with all written policies of the Avadel Group of Companies to the extent applicable to the Executive.

(b) Reporting. Executive shall report directly to the Company's Chief Executive Officer, currently Gregory J. Divis.

1.2 Duration. The duration of the Executive's employment commenced as of the Effective Date and shall continue under the terms and condition of this Agreement, for one (1) year following the Effective Date, with this Agreement automatically renewing thereafter for successive periods of one (1) year unless the Executive or the Company provides written notice to the other of his or its intention not to renew the Agreement at least thirty (30) days prior to the next upcoming expiration date. Notwithstanding the foregoing, this Agreement and the Executive's at-will employment hereunder may be terminated at any time pursuant to Section 3.1 hereof. At the termination of this Agreement, the Executive's employment with the Company shall terminate simultaneously.

2. COMPENSATION; BENEFITS

2.1 Base Salary. The Company shall pay to the Executive a gross annual base salary of four hundred and fifty thousand dollars ($450,000) per year, paid on a semi-monthly basis and subject to ordinary and lawful deductions. The Company will review the Executive's base salary on or about the first of every calendar year, and, in the Company's sole discretion, make any increases that the Company deems warranted. If the Executive's base salary is increased, the new increased base salary will be the base salary for purposes of this Agreement.

2.2 Bonus. The Executive shall be eligible for a potential annual bonus with a target payout of no less than forty-five percent (45%) of the Executive's base salary based upon the Executive's achievement of certain business and individual performance objectives as well as the performance of Avadel plc against its objectives as determined by the Company. Subject to the requirement that the Executive shall be employed by a member of the Avadel Group of Companies on the date that the bonus is deemed earned by the Compensation Committee of the Board of Directors of Avadel plc (the "Board"), any bonus payments due hereunder shall be paid to the Executive no later than March 15 of the calendar year following the applicable year to which the annual bonus relates, subject to ordinary and lawful deductions. For the calendar year 2022, any bonus shall be pro-rated based on the date you begin employment with the Company.

2.3 Stock Options and Additional Equity Grants. In connection with the commencement of his employment, and subject to Board approval, the Executive will be awarded 275,000 stock options that will vest pursuant to the terms of the applicable stock option agreement and the Avadel plc 2021 Inducement Plan (together, the "Equity Documents"). The Executive will also be eligible to participate in future equity awards which may be granted to executive management, based upon Company and individual performance, at the sole discretion of the Board.

2.4 Insurance and Benefits.

(a) Plan Participation. The Company shall facilitate the participation by the Executive and his family in medical, health, vision, dental, hospitalization, term life, and workers compensation insurance, long-term disability, short-term disability, and 401k savings plan programs of the Company, to the extent now existing or hereafter established, that are generally made available to executives or employees of the Company, in each case according to the terms and conditions (including eligibility requirements) of such plans or programs. The Executive acknowledges that the current insurance plans and Company policies are subject to changes at the business discretion of the Company.

(b) Vacation and Paid Time Off. The Executive shall be eligible for vacation of twenty (20) days per year which shall be accrued or earned each month. The Executive shall also be entitled to the Company's usual and customary holidays, including two (2) floating holidays per year and corporate holidays (of which there are thirteen (13) scheduled during 2022) to be taken in accordance with the normal Company paid vacation and time-off policies. The Company also grants the Executive five (5) sick days annually.

(c) Indemnification; General Liability.

(i) To the fullest extent permitted by applicable law, the Company, its receiver, or its trustee shall indemnify, defend, and hold the Executive harmless from and against any expense, loss, damage, or liability incurred or connected with any claim, suit, demand, loss, judgment, liability, cost, or expense (including reasonable attorneys' fees) arising from or related to the services performed by him under the terms of this Agreement and amounts paid in settlement of any of the foregoing; provided that the same were not the result of the Executive's fraud, gross negligence, or reckless or intentional misconduct. The Company may advance to the Executive the costs of defending any claim, suit, or action against him if he undertakes to repay the funds advanced, with interest, should it later be determined that he is not entitled to indemnification under this Section 2.4(c); provided, however, and notwithstanding the foregoing, this sentence shall not apply to the defense of any claim that may be brought by the Company or any of the Avadel Group of Companies against the Executive.

(ii) The Company shall provide coverage to the Executive for his general liability, director and officer liability, and professional liability insurance at the same levels and on the same terms as provided to its other executive officers.

2.5 Reimbursement of Expenses. The Company shall reimburse the Executive, subject to presentation of adequate substantiation, including receipts, for the reasonable travel, entertainment, lodging and other business expenses incurred by the Executive in accordance with the Company's expense reimbursement policy in effect at the time such expenses are incurred. In no event will such reimbursements, if any, be made

later than the last day of the year following the year in which the Executive incurs the expense.

3. TERMINATION AND SEVERANCE

3.1 Termination.

(a) Nothing in this Agreement shall prevent the Company from terminating the Executive's employment with the Company and this Agreement at any time, with or without "Cause." "Cause" means: (i) conviction of the Executive of, or the Executive's plea of nolo contendere to, a felony or crime involving moral turpitude; (ii) fraud, theft, or misappropriation by the Executive of any asset or property of any member of the Avadel Group of Companies, including, without limitation, any theft or embezzlement or any diversion of any corporate opportunity; (iii) breach by the Executive of any of the material obligations contained in this Agreement; (iv) conduct by the Executive materially contrary to the material policies of any member of the Avadel Group of Companies; (v) material failure by the Executive to meet the goals and objectives established by any member of the Avadel Group of Companies; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such failure; or (vi) conduct by the Executive that results in a material detriment to any member of the Avadel Group of Companies, or its program, or goals or that is inimical to its reputation and interest; provided that the Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such conduct. Any reoccurrence of such acts constituting Cause within one (1) year of the original occurrence will require no such pre-termination right of the Executive to cure.

(b) The Executive may terminate the Executive's employment with the Company and this Agreement for or other than for "Good Reason". "Good Reason" means, without the Executive's consent, any of the following: (i) the Company's diminution in the Executive's authority, duties or responsibilities with respect to Avadel plc or the Company in any material respect or the Company's assignment to the Executive of duties or responsibilities that are materially inconsistent with the Executive's position with Avadel plc or the Company as stated in this Agreement; (ii) a change in the location of the Executive's employment which increases the Executive's one-way commute by more than sixty (60) miles; or (iii) a material breach by the Company of this Agreement.

(c) In the event that the Executive desires to resign from the Company, he shall promptly give the Company written notice of the date that such resignation will be effective, provided that the notice period shall be no less than thirty (30) days; provided further, that the Company may unilaterally accelerate the date of termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement. In the event that the Executive desires to resign from the Company for Good Reason, he shall provide the Company with written notice setting forth the acts constituting Good Reason within ninety (90) days of the initial occurrence of the Good Reason condition and providing that the Company may cure such acts within thirty (30) days of receipt of such notice. If such condition is not remedied within such thirty- (30-)

day cure period, any termination of employment by the Executive for "Good Reason" must occur within ninety (90) days after the period for remedying such condition has expired.

(d) In the event that the Company desires to terminate the Executive's employment, with or without Cause, the Company shall give the Executive written notice thereof, and the termination shall be effective as of the date specified in the written notice.

(e) The Executive's employment and this Agreement shall terminate automatically upon the Executive's death. If the Company determines that the Executive is subject to an Incapacity (as hereinafter defined), the Company may terminate the Executive's employment and this Agreement effective upon the Executive's Incapacity. "Incapacity" shall mean the inability of the Executive to perform the essential functions of the Executive's job, with or without reasonable accommodation, for a period of 90 days in the aggregate in any 180-day period.

(f) If the Executive's employment is terminated for any reason, the Company shall pay to the Executive (or, after the Executive's death, his estate) any accrued or awarded but unpaid annual bonus and accrued but unused vacation pay, expense reimbursement and other benefits due to the Executive under any Company-provided benefit plans, policies and arrangements, with such accrued but unpaid annual bonus and vacation pay and expense reimbursements payable no later than thirty (30) days after the date of termination of employment (sooner to the extent required by applicable law or to the extent the bonus is payable prior to such time) and any other benefits payable in accordance with the applicable terms of the benefit plans, policies and arrangements. The payments in this Section 3.1(f) are collectively referred to as the "Accrued Obligations."

3.2 Severance. If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company without Cause or by non-renewal of this Agreement by the Company, the Company shall pay severance to the Executive as follows:

(i) severance pay in an amount equal to 1.0 times the Executive's then-current annual base salary, such amount to be paid in a one-time installment; and

(ii) if the Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company each month will pay for the Executive's COBRA premiums for such coverage (at coverage levels in effect immediately prior to the Executive's termination) until the earlier of: (A) the expiration of a period of twelve (12) months from the date of termination or (B) the date upon which the Executive becomes covered under similar plans of any subsequent employer or is otherwise ineligible for COBRA; provided, however, if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law

(including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Executive for the time period specified above. Such payments shall be subject to applicable tax-related deductions and withholdings and paid on the Company's regular payroll dates.

All payments and benefits set forth in the foregoing items (i) and (ii) hereof are defined as the "Severance Pay and Benefits." The Executive's receipt of the foregoing Severance Pay and Benefits is conditioned upon his execution and delivery to the Company of a separation and release agreement acceptable to the Company governing the termination of the employment relationship between the Executive and the Company and the Executive's release of all claims against all members of the Avadel Group of Companies and their employees, officers, directors, contractors and other related persons (the "Separation and Release Agreement"), and allowing the applicable revocation period required by law to expire without revoking or causing revocation of same, within the time period set forth in the Separation and Release Agreement and in no event more than sixty (60) days following the date of termination of the Executive's employment. The amounts payable under this Section 3.2, to the extent taxable, shall be paid or commence to be paid within 60 days after the Executive's date of termination; provided, however, that if the 60-day period spans more than one calendar year, any payments that the Executive is entitled to receive during such period shall be accumulated and paid in a lump sum only in the subsequent calendar year.

3.3 Change of Control.

(a) If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company without Cause or by non-renewal of this Agreement by the Company, and such termination occurs during a Change of Control Period (as hereinafter defined), then, in addition to the Executive being eligible for the Severance Pay and Benefits, subject to the terms of Section 3.2 above, and notwithstanding any other provision in any applicable equity compensation plan and/or individual stock option plan or agreement, the Executive's outstanding and vested stock options as of the Executive's termination of employment date will remain exercisable until the eighteen (18) month anniversary of the termination of employment date; provided, however, that the post-termination exercise period for any individual stock option right will not extend beyond its original maximum term as of the original date of the grant (the "Extended Exercise Period").

(b) The Executive's receipt of the foregoing Extended Exercise Period is conditioned upon his execution and delivery to the Company of the Separation and Release Agreement within the time period set forth in the Separation and Release Agreement and in no event more than sixty (60) days following the date of termination of the Executive's employment.

3.4 Change of Control Definitions. For purposes of Section 3.3 above, the following definitions shall apply:

(a) "Change of Control" means the occurrence of any of the following events:

(i) a change in the ownership of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company that, together with the other equity interests held by such Person, constitute more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable); provided, however, that for purposes of this subsection, the acquisition of additional equity interests by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the equity interests of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) will not be considered a Change or Control; or

(ii) a change in the effective control of Avadel plc, Avadel US Holdings, Inc. or the Company which occurs on the date that a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of Directors of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable), the acquisition of additional control of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) by the same Person will not be considered a Change of Control; or

(iii) a change in the ownership of a substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair

market value of all of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) immediately prior to such acquisition or acquisitions.

Notwithstanding the foregoing, the Change in Control must constitute a change in ownership, effective control or substantial portion of the assets of Avadel plc, Avadel US Holdings, Inc. or the Company (as applicable) within the meaning of Section 409A of the Code.

(b) "Change of Control Period" means the period ending eighteen (18) months following a Change of Control.

3.5 Other Termination. If the Executive terminates this Agreement and his employment with the Company other than for Good Reason or by non-renewal of this Agreement by the Executive, or if the Executive's employment with the Company is terminated by the Company for Cause or as the result of the Executive's Incapacity, or the Executive dies while employed by the Company, the Company shall pay to the Executive the Accrued Obligations, but the Executive shall not be entitled to any further compensation from the Company pursuant to this Agreement or otherwise.

3.6 Resignations. Notwithstanding any other provision of this Agreement, the Executive agrees to resign, as soon as administratively practicable, from any and all positions held with all members of the Avadel Group of Companies, at the time of termination of the Executive's employment with any member of the Avadel Group of Companies.

4. RESTRICTIVE COVENANTS

4.1 Confidentiality.

(a) Restriction. To the fullest extent permitted under applicable law, at all times during the Executive's employment by the Company and for a period of five (5) years after termination of the Executive's employment with the Company, the Executive (i) shall hold in strictest confidence all Restricted Information (as hereinafter defined), (ii) shall not directly or indirectly use, copy, disclose or otherwise distribute any Restricted Information, except for the benefit of a member of the Avadel Group of Companies to the extent necessary to perform his obligations to Avadel plc and the Company under this Agreement, and (iii) shall not disclose any Restricted Information to any person, firm, corporation or other entity without written authorization of the Chief Executive Officer or Board of Directors of Avadel plc. Any breach of any provision of this Section 4.1(a) shall be considered a material breach of this Agreement.

(b) Definitions. As used in this Section 4, the following terms shall have the meanings set forth below:

(i) "Restricted Information" means any Confidential Information (as hereinafter defined) and any Trade Secrets (as hereinafter defined).

(ii) "Confidential Information" means any information of or about any member of the Avadel Group of Companies, and any of the employees, customers and/or suppliers of any member of the Avadel Group of Companies, which is not generally known outside of the Avadel Group of Companies, which the Executive obtains (whether before, on or after the date of this Agreement) in connection with the Executive's employment with the Company, and which may be useful to any competitor of the Avadel Group of Companies or the disclosure of which would be damaging to any member of the Avadel Group of Companies. Confidential Information includes, but is not limited to, any and all of the following information about any member of the Avadel Group of Companies: (A) information about products, product candidates, and research and development plans, activities and results (including information about planned and in-process clinical trials); (B) information about business and employment policies, marketing methods and the targets of those methods, finances, business plans, promotional materials and price lists; (C) the manner or terms upon which products or services are obtained from suppliers or on which products or services are provided to customers; (D) without duplication of item (A) above, the nature, origin, composition, performance and development of any products or services; (E) information about finances, financial condition, results of operations and prospects; and (F) information about employees, consultants or customers or suppliers. For the avoidance of doubt, Confidential Information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by the Executive in violation of the provisions hereof; or (3) was already in the possession of the Executive without an obligation of confidentiality prior to the date his employment with the Company began.

(iii) "Trade Secret" means any Confidential Information to the extent such information constitutes a trade secret under applicable law.

(c) Certain Permitted Disclosures. Notwithstanding the foregoing, the Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a Trade Secret that (i) is made (A) in confidence to a Federal, State or local government official, either directly or indirectly, or to an attorney, and (B) solely for purposes of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding filed in a lawsuit or other proceeding, if such filing is made under seal. If the Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, the Executive may disclose the Trade Secret to the Executive's attorney and use the Trade Secret in the court proceeding, if

the Executive (i) files any document containing the Trade Secret under seal and (ii) does not disclose the Trade Secret, except pursuant to court order.

4.2 Invention Assignment.

(a) The Executive will make full and prompt disclosure to the Company of all inventions, discoveries, designs, developments, methods, modifications, improvements, processes, algorithms, databases, computer programs, formulae, techniques, trade secrets, graphics or images, and audio or visual works and other works of authorship (collectively "Developments"), whether or not patentable or copyrightable, that are created, made, conceived or reduced to practice by the Executive (alone or jointly with others) or under the Executive's direction during the period of the Executive's employment. The Executive acknowledges that all work performed by him is on a "work for hire" basis, and the Executive hereby does assign and transfer and, to the extent any such assignment cannot be made at present, will assign and transfer, to the Company and its successors and assigns all his right, title and interest in all Developments that (a) relate to the business of the Company or any customer of or supplier to the Company or any of the products or services being researched, developed, manufactured or sold by the Avadel Group of Companies or which may be used with such products or services; or (b) result from tasks assigned to him by the Avadel Group of Companies; or (c) result from the use of premises or personal property (whether tangible or intangible) owned, leased or contracted for by the Avadel Group of Companies ("Company-Related Developments"), and all related patents, patent applications, trademarks and trademark applications, copyrights and copyright applications, and other intellectual property rights in all countries and territories worldwide and under any international conventions ("Intellectual Property Rights"). For the avoidance of doubt, this Section 4.2 applies to the Executive's entire service relationship with the Company.

(b) To preclude any possible uncertainty, the Executive has set forth on Exhibit A attached hereto a complete list of Developments that the Executive has, alone or jointly with others, conceived, developed or reduced to practice prior to the commencement of his employment with the Company that he considers to be his property or the property of third parties and that he wishes to have excluded from the scope of this Agreement ("Prior Inventions"). If disclosure of any such Prior Invention would cause the Executive to violate any prior confidentiality agreement, the Executive understands that he is not to list such Prior Inventions in Exhibit A but is only to disclose a cursory name for each such invention, a listing of the party(ies) to whom it belongs and the fact that full disclosure as to such inventions has not been made for that reason. The Executive has also listed on Exhibit A all patents and patent applications in which he is named as an inventor, other than those which have been assigned to the Company ("Other Patent Rights"). If no such disclosure is attached, the Executive represents that there are no Prior Inventions or Other Patent Rights. If, in the course of the Executive's employment with the Company, he incorporates a Prior Invention into a Company product, process or machine or other work done for the Avadel Group of

Companies, the Executive hereby grants to the Company a nonexclusive, royalty-free, paid-up, irrevocable, worldwide license (with the full right to sublicense) to make, have made, modify, use, sell, offer for sale and import such Prior Invention. Notwithstanding the foregoing, the Executive will not incorporate, or permit to be incorporated, Prior Inventions in any Company-Related Development without the Company's prior written consent.

(c) This Agreement does not obligate the Executive to assign to the Company any Development which, in the sole judgment of the Company, reasonably exercised, is developed entirely on the Executive's own time and does not relate to the business efforts or research and development efforts in which, during the period of his employment, the Avadel Group of Companies actually is engaged or reasonably would be engaged, and does not result from the use of premises or equipment owned or leased by the Avadel Group of Companies. However, the Executive will also promptly disclose to the Company any such Developments for the purpose of determining whether they qualify for such exclusion. The Executive understands that to the extent this Agreement is required to be construed in accordance with the laws of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this Section 4.2 will be interpreted not to apply to any invention that a court rules and/or the Company agrees falls within such classes. The Executive also hereby waives all claims to any moral rights or other special rights which the Executive may have or accrue in any Company-Related Developments.

4.3 Non-Competition. In order to protect Confidential Information and goodwill, during the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company for any reason (the "Restricted Period"), the Executive shall not, directly or indirectly, whether as owner, partner, shareholder, director, manager, consultant, agent, employee, co-venturer or otherwise, anywhere in the United States or in any other country in which the Avadel Group of Companies does business, engage or otherwise participate in any business that develops, manufactures or markets any products, or performs any services, that are competitive with the products or services of the Avadel Group of Companies, or products or services that the Avadel Group of Companies or its affiliates, has under development or that are the subject of active planning at any time during the Executive's employment.

4.4 Non-Solicitation of Employees and Contractors. During the Restricted Period, the Executive shall not, directly or indirectly, solicit or attempt to solicit any employee, consultant or other contractor of or service provider to any member of the Avadel Group of Companies with whom the Executive had Material Contact to perform services for the Executive or for any other business or entity, whether as an executive, consultant, partner or participant in any such business or entity, or to terminate or lessen any such employee's, consultant's or other contractor's service with any member of the Avadel Group of Companies. "Material Contact" means contact in person, by telephone, or by paper or electronic correspondence in furtherance of the business of any member of the

Avadel Group of Companies. This Section 4.4 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.5 Non-Solicitation of Customers and Suppliers. During the Restricted Period, the Executive shall not, directly or indirectly, solicit any actual or prospective customers or suppliers of any member of the Avadel Group of Companies with whom the Executive had Material Contact, for the purpose of selling any products or services which compete with the business of any member of the Avadel Group of Companies. This Section 4.5 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.6 Relief. The Executive agrees that it would be difficult to measure any damages caused to the Company that might result from any breach by the Executive of any portion of Sections 4.1 through 4.5, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, the Executive agrees that if the Executive breaches, or proposes to breach, any portion of Section 4.1 through 4.5, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company and without the posting of a bond.

4.7 Protected Rights. Notwithstanding any other provision of this Agreement, the Company and the Executive hereby acknowledge and agree that:

(i) Nothing in this Agreement shall prohibit the Executive from reporting possible violations of Federal, State or other law or regulations to, or filing a charge or other complaint with, any governmental agency or entity, including but not limited to the Department of Justice, the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, Congress, and any Inspector General, or making any other disclosures that are protected under any whistleblower provisions of Federal, State or other law or regulation or assisting in any such investigation or proceeding.

(ii) Nothing herein limits the Executive's ability to communicate with any such governmental agency or entity or otherwise participate in any such investigation or proceeding that may be conducted by any such governmental agency or entity, including providing documents or other information, without notice to the Company.

(iii) The Executive does not need the prior authorization of the Company to make any such reports or disclosures, and the Executive is

not required to notify the Company that the Executive made any such reports or disclosures or is assisting in any such investigation.

(iv) The Executive (A) does not waive any rights to any individual monetary recovery or other awards in connection with reporting any such information to any such governmental agency or entity, (B) does not breach any confidentiality or other provision hereunder in connection with any such reporting or disclosures, and (C) will not be prohibited from receiving any amounts hereunder as the result of making any such reports or disclosures or assisting with any such investigation or proceeding.

5. MISCELLANEOUS

5.1 Entire Agreement. This Agreement (including any exhibits hereto) supersedes any and all other understandings and agreements, either oral or in writing, among the parties (including affiliates of the Company) with respect to the subject matter, and constitutes the sole agreement among the parties with respect to the subject matter hereof.

5.2 Severability. If any term or provision of this Agreement or any application of this Agreement shall be declared or held invalid, illegal, or unenforceable, in whole or in part, whether generally or in any particular jurisdiction, such provision shall be deemed amended to the extent, but only to the extent, necessary to cure such invalidity, illegality, or unenforceability, and the validity, legality, and enforceability of the remaining provisions, both generally and in every other jurisdiction, shall not in any way be affected or impaired thereby.

5.3 Survival. Notwithstanding any expiration or termination of this Agreement, Section 2.4(c) hereof, Section 4 hereof and this Section 5 shall survive such expiration or termination to the extent necessary to effectuate the terms contained herein.

5.4 Interpretation of Agreement.

(a) Unless otherwise indicated to the contrary herein by the context or use thereof: (i) the words, "herein," "hereto," "hereof," and words of similar import refer to this Agreement as a whole and not to any particular Article, Section, subsection, or paragraph hereof; (ii) words importing the masculine gender shall include the feminine and neuter genders and vice versa; and (iii) words importing the singular shall include the plural, and vice versa.

(b) All parties to this Agreement have participated in the drafting and negotiation of this Agreement. This Agreement has been prepared by all parties equally, and is to be interpreted according to its terms. No inference shall be drawn that the Agreement was prepared by or is the product of any particular party or parties.

5.5 Taxes.

(a) The parties hereto acknowledge that the requirements of Section 409A of the Internal Revenue Code ("Section 409A") are still being developed and interpreted by government agencies and that the parties hereto have made a good faith effort to comply with current guidance under Section 409A. Notwithstanding anything in this Agreement to the contrary, in the event that amendments to this Agreement are necessary in order to continue to comply with future guidance or interpretations under Section 409A, including amendments necessary to ensure that compensation will not be subject to tax under Section 409A (which may require deferral of severance or other compensation), the Company and the Executive agree to negotiate in good faith the applicable terms of such amendments and to implement such negotiated amendments, on a prospective and/or retroactive basis as needed. Further, to the extent any amount or benefit under this Agreement is subject to the requirements of Section 409A, then, with respect to such amount or benefit, this Agreement will be interpreted in a manner to comply with the requirements of Section 409A.

(b) Further, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or as a result of a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination", "termination of employment", "Termination Date", or the like shall mean "separation from service".

(c) For purposes of this Agreement, all rights to payments and benefits hereunder shall be treated as rights to receive a series of separate payments and benefits to the fullest extent allowed by Section 409A of the Code.

(d) If the Executive is a key employee (as defined in Section 416(i) of the Code without regard to paragraph (5) thereof) and any of Avadel's securities are publicly traded on an established securities market or otherwise, then payment of any amount or provision of any benefit under this Agreement which is considered deferred compensation subject to Section 409A of the Code shall be deferred for six (6) months after termination of Executive's employment or, if earlier, Executive's death, if and as required by Section 409A(a)(2)(B)(i) of the Code (the "409A Deferral Period"). In the event such payments are otherwise due to be made in installments or periodically during the 409A Deferral Period, the payments which would otherwise have been made in the 409A Deferral Period shall be accumulated and paid in a lump sum as soon as the 409A Deferral Period ends, and the balance of the payments shall be made as otherwise scheduled. In the event benefits are required to be deferred, any such benefit may be provided during the 409A Deferral Period at the Executive's expense, with the Executive having a right to reimbursement from the Company once the 409A Deferral Period ends, and the balance of the benefits shall be provided as otherwise scheduled.

(e) To the extent that some portion of the payments under this Agreement may be bifurcated and treated as exempt from Code Section 409A under the "short-term deferral" or "separation pay" exemptions, then such amounts shall be so treated as exempt from Code Section 409A (and in particular, the earliest amounts to be paid under Section 3

of the Agreement will be first treated as exempt from Code Section 409A under the short-term deferral exemption and then the separation pay exemption to the extent available).

(f) Any reimbursements, in-kind benefits or offset provided under this Agreement that constitutes deferred compensation under Code Section 409A shall be made or provided in accordance with the requirement of Code Section 409A, including, where applicable, the requirement that (i) any reimbursement is for expense incurred during the period of time specified in this Agreement, (ii) the amount of expense eligible for reimbursement, or in-kind benefits, provided during a calendar year may not affect the expense eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year, (iii) the reimbursement of an eligible expense will be made no later than the last day of the calendar year following the calendar in which the expense is incurred, and (iv) the right to reimbursement or in-kind benefits is not subject to liquidation of exchange for another benefit.

(g) The Company makes no warranty regarding the tax treatment to the Executive of payments provided for under this Agreement, including the tax treatment of such payments that may be subject to Section 409A. The Executive will be responsible for paying all federal, state, and local income and employment taxes that may be due on such payment, provided that the Company will be responsible for any withholding obligations under applicable law. The Company will not be liable to the Executive if any payment or benefit which is to be provided pursuant to this Agreement and which is considered deferred compensation subject to Code Section 409A otherwise fails to comply with, or be exempt from, the requirements of Code Section 409A.

5.6 Mandatory Reduction of Payments in Certain Events. Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment or distribution by the Company to or for the benefit of Executive (whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise) (a "Payment") would be subject to the excise tax (the "Excise Tax") imposed by Section 4999 of the Code, then, prior to the making of any Payment to Executive, a calculation shall be made comparing (i) the net benefit to Executive of the Payment after payment of the Excise Tax to (ii) the net benefit to Executive if the Payment had been limited to the extent necessary to avoid being subject to the Excise Tax. If the amount calculated under (i) above is less than the amount calculated under (ii) above, then the Payment shall be limited to the extent necessary to avoid being subject to the Excise Tax (the "Reduced Amount"). In that event, cash payments shall be modified or reduced first from the latest amounts to be paid and then any other benefits. The determination of whether an Excise Tax would be imposed, the amount of such Excise Tax, and the calculation of the amounts referred to in clauses (i) and (ii) of the foregoing sentence shall be made by an independent accounting firm selected by Company and reasonably acceptable to the Executive, at the Company's expense (the "Accounting Firm"), and the Accounting Firm shall provide detailed supporting calculations. Any determination by the Accounting Firm shall be binding upon the Company and the Executive. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Payments which Executive was entitled to, but did not receive pursuant to this Section 5.6 could have been

made without the imposition of the Excise Tax ("Underpayment"). In such event, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive.

5.7 Governing Law. Notwithstanding the place where this Agreement may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be construed in accordance with and governed by the laws of the State of Missouri, or, to the extent applicable the laws of the United States of America, in each case without giving effect to the principles of choice or conflicts of laws thereof. Each of the parties hereto consents and agrees to the exclusive personal jurisdiction of any state or federal court sitting in the State of Missouri, and waives any objection based on venue or *forum non conveniens* with respect to any action instituted therein, and agrees that any dispute concerning the conduct of any party in connection with this Agreement shall be heard only in the courts described above.

5.8 Binding Arbitration.

(a) All disputes arising under this Agreement or arising out of or relating to the Executive's employment relationship with the Company shall be submitted to final and binding arbitration. Arbitration of such matters shall proceed consistent with the Employment Arbitration Rules and Mediation Procedures as established by the American Arbitration Association ("AAA"). Venue for any arbitration shall be St. Louis, Missouri or any other location mutually agreed upon by the Executive and the Company.

(b) The arbitration shall be conducted using the Expedited Procedures of the AAA Rules, regardless of the amount in dispute.

(c) The disputing parties shall agree on an arbitrator qualified to conduct AAA arbitration. If the disputing parties cannot agree on the choice of arbitrator, then each party shall choose one independent arbitrator. The two arbitrators so chosen shall jointly select a third arbitrator, who shall conduct the arbitration.

(d) All disputes relating to this Agreement shall be governed by the laws of the State of Missouri, and the arbitrator shall apply such law without regard to the principles of choice or conflicts of laws thereof.

(e) All aspects of the arbitration shall be treated as confidential.

(f) The Company and the Executive shall each pay 50% of the arbitrator's fees and costs. Each party shall pay its own deposition, witness, expert, and attorneys' fees and other expenses to the same extent as if the matter were being heard in court. However, if any party prevails on a statutory claim that affords the prevailing party attorneys' fees and costs, or if there is a written agreement providing for attorneys' fees and costs to be awarded to the prevailing party, the arbitrator may award reasonable attorneys' fees in accordance with the applicable statute or written agreement. The arbitrator shall resolve any dispute as to the reasonableness of any fees or costs awarded under this paragraph.

(g) The decision of the arbitrator shall be final, and the parties agree to entry of such decision as judgments in all courts of appropriate jurisdiction.

(h) Notwithstanding the foregoing, this Section 5.8 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate, including, without limitation, relief sought under Section 4 of this Agreement; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 5.8.

5.9 Amendments. This Agreement shall not be modified or amended except by a writing signed by all of the parties.

5.10 Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the successors and assigns of each party hereto.

5.11 Assignment.

(a) This Agreement and all of the Executive's rights and obligations hereunder are personal to the Executive and may not be transferred or assigned by him at any time, except that any assets accruing to the Executive in connection with this Agreement shall accrue to the benefit of the Executive's heirs, executors, administrators, successors, permitted assigns, trustees, and legal representatives.

(b) The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with a merger, consolidation or sale or transfer of all or substantially all of the Company's assets to such entity; provided further, that the Company will require any successor to the Company in the case of a merger, consolidation or sale or transfer of all or substantially all of the assets of Avadel plc or the Company to assume this Agreement.

5.12 Waiver. Any of the terms or conditions of this Agreement may be waived at any time by the party or parties entitled to the benefit thereof, but only by a writing signed by the party or parties waiving such terms or conditions. No waiver of any provision of this Agreement or of any right or benefit arising hereunder shall be deemed to constitute or shall constitute a waiver of any other provision of this Agreement (whether or not similar), nor shall any such waiver constitute a continuing waiver, unless otherwise expressly so provided in writing.

5.13 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Agreement may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Employment Agreement as of the date and year first above written.

THE COMPANY

AVADEL MANAGEMENT CORPORATION

By: _____
Name: Gregory J. Divis
Title: President

THE EXECUTIVE

_____
Name: Douglas Williamson

March 16, 2022

Avadel Finance Cayman Limited
c/o Avadel Pharmaceuticals plc
10 Earlsfort Terrace
Dublin 2, Ireland
D02 T380
Attention: General Counsel

Re: Exchange for Avadel Finance Cayman Limited Exchangeable Senior Notes due 2023

Ladies and Gentlemen:

Avadel Finance Cayman Limited, a Cayman Islands exempted company limited by shares (the "**Company**"), is offering a new series of its Exchangeable Senior Notes due 2023 (the "**New Notes**"). The New Notes will be fully and unconditionally guaranteed on a senior unsecured basis (the "**Guarantee**") by Avadel Pharmaceuticals plc, a public limited company incorporated under the laws of Ireland and the parent company of the Company ("**Parent**"). The New Notes will be exchangeable into cash, American Depositary Shares ("**ADSs**"), each representing, as of the date hereof, one ordinary share of Parent, nominal value $0.01 per share (the "**Ordinary Shares**" and such ADSs into which the New Notes are exchangeable, the "**Underlying ADSs**"), or a combination of cash and Underlying ADSs, at the Company's election. Any ADSs to be issued upon conversion of the New Notes are to be issued pursuant to, and in accordance with the applicable procedures of, the Deposit Agreement, dated as of January 3, 2017, among Parent, The Bank of New York Mellon, as depositary (the "**Depositary**"), and the holders and beneficial owners of the ADSs issued under such agreement, as supplemented by a letter agreement, dated as of February 16, 2018, between Parent and the Depositary and as further supplemented by a letter agreement to be dated the Closing Date (as defined below), between Parent and the Depositary (the "**Deposit Agreement**").

The undersigned (the "**Investor**"), for itself and, on behalf of the accounts (if any) listed on Exhibit A hereto, for whom the Investor has been duly authorized to enter into the Exchange (as defined below) (each, including the Investor if it is listed on Exhibit A, an "**Exchanging Holder**"), shall exchange 4.50% Convertible Senior Notes due 2023 (CUSIP: 05337YAA6 or 05337YAB4) of the Company (the "**Old Notes**") for an amount of (i) New Notes and (ii) cash, each as set forth herein (the "**Exchange**"), pursuant and subject to the terms and conditions set forth in this agreement (this "**Exchange Agreement**"). Reference is made to the Indenture (the "**Old Notes Indenture**"), dated February 16, 2018, by and among the Company, Parent and The Bank of New York Mellon, as Trustee (the "**Old Notes Trustee**"), which governs the Old Notes.

The Exchanging Holders (including the Investor, as applicable) are referred to collectively as the "**Purchasers,**" and each Purchaser (other than the Investor) is referred to herein as an "**Account**."

The Investor and each Account understands that the Exchange is being made without registration under the Securities Act of 1933, as amended (the "**Securities Act**"), or any securities laws of any state of the United States or of any other jurisdiction, and that the Exchange is only being made to investors who are "qualified institutional buyers" (as defined in Rule 144A under the Securities Act) in reliance upon an exemption from registration under the Securities Act. The Exchange is described in, and is being made pursuant to, the draft Indenture relating to the New Notes (the **"Indenture**") to be entered into as of the Closing Date (as defined below) among the Company, Parent and The Bank of New York Mellon, as Trustee (the "**New Notes Trustee**"), as supplemented by the Pricing Term Sheet, dated as of the date hereof (the "**Pricing Term Sheet**" and, together with the Indenture and the Guarantee, the **"Transaction Documents**").

1. The Exchange. On the basis of the representations, warranties and agreements contained in this Exchange Agreement and subject to the terms and conditions of this Exchange Agreement, each of the Exchanging Holders hereby agrees to deliver, assign and transfer to the Company all right, title and interest in the aggregate principal amount of Old Notes for such Exchanging Holder set forth in column 2 of Exhibit A hereto (such aggregate principal amount of Old Notes, the "**Exchanged Old Notes**") in exchange for (i) New Notes having an aggregate principal amount, for each Exchanging Holder, as set forth in Exhibit A (such aggregate principal amount of New Notes, the "**Exchanged New Notes**") and (ii) an amount of cash as set forth in Exhibit A (such aggregate principal amount of cash, the "**Cash Consideration**" and the Cash Consideration,

together with the Exchanged New Notes, the "**Exchange Consideration**"), and the Company agrees to issue such Exchanged New Notes and deliver such Cash Consideration to the Exchanging Holders in exchange for such Exchanged Old Notes.

For the avoidance of doubt, Exchanged New Notes will be issued in denominations of $200,000 principal amount and integral multiples of $1,000 in excess thereof, and the Company will not make any separate cash payment in respect of rounded amounts, interest (including Additional Interest (as defined in the Old Notes Indenture)**)** accrued and unpaid to the Closing Date (as defined below) or Defaulted Amounts for the Exchanged Old Notes. Instead, such amounts will be deemed to be paid in full rather than cancelled, extinguished or forfeited upon exchange of the Exchanged Old Notes for the Exchange Consideration. Subject to the terms and conditions of this Exchange Agreement, the Investor, on behalf of itself and each Exchanging Holder, hereby (a) waives any and all other rights with respect to such Exchanged Old Notes, and (b) releases and discharges the Company and Parent from any and all claims the Investor and any other Exchanging Holder may now have, or may have in the future, arising out of, or related to, such Exchanged Old Notes, including, without limitation, any claim to "Defaulted Amounts" or "Additional Interest," in respect of such Exchanged Old Notes, in each case, arising under and defined in, the Old Notes Indenture. The Old Notes Trustee may rely on the immediately preceding sentence with the same force and effect as if such representation or warranty were made directly to the Old Notes Trustee. The Old Notes Trustee shall be a third party beneficiary to this Exchange Agreement to the extent provided in the immediately preceding sentence.

2. [Reserved].

3. The Closing. The closing of the Exchange (the "**Closing**") shall take place at the offices of Goodwin Procter LLP, 100 Northern Avenue, Boston, MA 02210, at 10:00 a.m., New York City time, on April 4, 2022 or at such other time and place as the Company may designate by notice to the Investor (the "**Closing Date**").

4. Closing Mechanics.

   a. The Depository Trust Company ("**DTC**") will act as securities depositary for the New Notes.

   b. At or prior to the times set forth in the Exchange Procedures set forth in Exhibit B hereto (the "**Exchange Procedures**"), the Investor, on behalf of itself and/or any other Account, shall deliver and/or cause the Exchanging Holders to deliver the Exchanged Old Notes, by book entry transfer through the facilities of DTC, to The Bank Of New York Mellon, in its capacity as trustee of the Old Notes (in such capacity, the "**Old Notes Trustee**"), for the account/benefit of the Company for cancellation as instructed in the Exchange Procedures.

   c. On the Closing Date, subject to satisfaction of the conditions precedent specified in Section 7 hereof, and the prior receipt by the Old Notes Trustee from each Exchanging Holder of the Exchanged Old Notes pursuant to clause (b) above:

      (i) the Company and Parent shall execute and deliver the Indenture, dated as of the Closing Date, among the Company, Parent and the New Notes Trustee;

      (ii) the Company shall execute, cause the New Notes Trustee to authenticate and cause to be delivered to the DTC account(s) specified by the Investor or the relevant Account in Exhibit C hereto, the Exchanged New Notes; and

      (iii) the Company shall deliver or cause to be delivered the Cash Consideration pursuant to the wire instructions specified by the Investor or the relevant Account in Exhibit C hereto.

All questions as to the form of all documents and the validity and acceptance of the Old Notes and the New Notes will be determined by the Company, in its sole discretion, which determination shall be final and binding.

5. Representations and Warranties and Covenants of the Company and Parent. Each of the Company and Parent, jointly and severally, represent and warrant to and covenant with the Investor (and each Account, as applicable) that:

   a. *Organization*. The Company is duly incorporated and is validly existing under the laws of the Cayman Islands. Parent is duly organized and is validly existing under the laws of Ireland.

   b. *Due Authorization*. This Exchange Agreement has been duly authorized, executed and delivered by each of the Company and Parent.

   c. *New Notes and the Guarantee.* The New Notes have been duly authorized by the Company and, when duly executed by the Company in accordance with the terms of the Indenture, assuming due authentication of the New Notes by the New Notes Trustee, upon delivery to the Purchasers in accordance with the terms of the Exchange, will be validly issued and delivered and will constitute valid and binding obligations of the Company entitled to the benefits of the Indenture, enforceable against the Company in accordance with their terms, except as such enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium, and other laws relating to or affecting creditors' rights generally and by general equitable principles (regardless of whether such enforceability is considered in a proceeding in equity or at law) (collectively, the "**Enforceability Exceptions**"). The register of the New Notes will at all times be maintained outside of the Republic of Ireland. The Guarantee has been duly authorized by Parent and, when the New Notes are duly executed by the Company in accordance with the terms of the Indenture, assuming due authentication of the New Notes by the New Notes Trustee, upon delivery to the Purchasers in accordance with the terms of the Exchange, the Guarantee will constitute a valid and binding obligation of Parent, enforceable against Parent in accordance with its terms, subject to the Enforceability Exceptions. The maximum number of Underlying ADSs (including the Ordinary Shares represented thereby) initially issuable upon exchange of the New Notes (assuming settlement solely in ADSs and taking into account the maximum make-whole adjustment under the Indenture) have been duly and validly authorized and reserved for by Parent and, when issued upon exchange of the New Notes in accordance with the terms of the New Notes and the Deposit Agreement, will be validly issued, fully paid and non-assessable, and the issuance of any Underlying ADSs (including the Ordinary Shares represented thereby) will not be subject to any preemptive, participation, rights of first refusal or similar rights.

   d. *Indenture.* Each of the Company and Parent has all requisite organizational power and authority to perform its obligations under the Indenture. The Indenture has been duly authorized by the Company and Parent, and will have been duly executed and delivered by the Company and Parent on or prior to the Closing. Assuming due authorization, execution and delivery by the New Notes Trustee thereto, the Indenture, upon execution and delivery thereof by the Company and Parent, will constitute the valid and binding agreement of the Company and Parent, enforceable against the Company and Parent in accordance with its terms, subject to the Enforceability Exceptions.

   e. *Exemption from Registration.* Assuming the accuracy of the representations and warranties of the Investor and each other investor executing an Exchange Agreement, (i) the issuance of the Exchanged New Notes, pursuant to this Exchange Agreement is exempt from the registration requirements of the Securities Act; (ii) the Indenture is not required to be qualified under the Trust Indenture Act of 1939, as amended; (iii) the Exchanged New Notes will, at the Closing, be free of any restrictions on resale by such Holder pursuant to Rule 144 promulgated under the Securities Act; and (iv) will be issued in compliance with all applicable U.S. state and federal laws concerning the issuance of the Exchanged New Notes.

   f. *New Class.* The New Notes, when issued, will not be of the same class as securities listed on a national securities exchange registered under Section 6 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), or quoted in a U.S. automated inter-dealer quotation system, within the meaning of Rule 144A(d)(3)(i) under the Securities Act.

g. *Listing*. At the Closing, the Underlying ADSs are listed on the Nasdaq Global Market (the "**Nasdaq**"), and the Company has taken no action designed to, or likely to have the effect of, delisting the Underlying ADSs from the Nasdaq nor has the Company received any notification that the Nasdaq is contemplating terminating such listing.

h. *No Conflicts*. The issue of the New Notes pursuant to the Exchange Agreements, the execution, delivery and performance, as applicable, by the Company and Parent of their respective obligations under the New Notes, the Indenture, the Guarantee, each Exchange Agreement, and the consummation of the transactions contemplated hereby and thereby, as the case may be, will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, impose any lien, charge or encumbrance upon any property or assets of Parent or its subsidiaries, or constitute a default under, any indenture, mortgage, deed of trust, loan agreement, license, lease or other agreement or instrument to which Parent or any of its subsidiaries is a party or by which Parent or any of its subsidiaries is bound or to which any of the property or assets of Parent or any of its subsidiaries is subject, (ii) result in any violation of the provisions of the memorandum and articles of association, charter or by-laws or similar organizational document of Parent or any of its subsidiaries or (iii) result in any violation of any statute or any judgment, order, decree, rule or regulation of any court or arbitrator or U.S. federal, state, local or non-U.S. governmental agency or regulatory authority having jurisdiction over the properties or assets of Parent or any of its subsidiaries or any of their properties or assets, except, with respect to clauses (i) and (iii), conflicts, breaches, violations, impositions or defaults that would not reasonably be expected to have a material adverse effect on the condition (financial or otherwise), results of operations, stockholders' equity, properties, business or prospects of Parent and its subsidiaries taken as a whole or a material adverse effect on the performance by Parent or the Company of their respective obligations under any Exchange Agreement, the Old Notes Indenture, the Indenture, the Guarantee or the New Notes or the consummation of any of the transactions contemplated hereby or thereby.

i. *Exchange*. Parent and the Company each acknowledge that the terms of the Exchange have been mutually negotiated between the parties.

j. *Deposit Agreement*. The Company and Parent shall (i) have taken all actions necessary to permit the deposit of the Ordinary Shares and the issuance of the ADSs representing such Ordinary Shares in accordance with the Deposit Agreement and (ii) do and perform, or cause to be done and performed, all such acts and things (including to execute and deliver any documents and provide any consent or confirmation and to satisfy any other procedural or substantive requirements under the Deposit Agreement) to effect the issuance of ADSs, and otherwise comply with the terms of the Deposit Agreement, including without limitation, the covenants set forth in the Deposit Agreement.

k. *No Rights of Immunity*. Except as provided by laws or statutes generally applicable to transactions of the type described in this Exchange Agreement, neither the Company nor any of its subsidiaries or any of their respective properties, assets or revenues has any right of immunity under Irish, French, Cayman Islands, New York or United States law, from any legal action, suit or proceeding, from the giving of any relief in any such legal action, suit or proceeding, from set-off or counterclaim, from the jurisdiction of any Irish, French, Cayman Islands, New York or United States federal court, from service of process, attachment upon or prior judgment, or attachment in aid of execution of judgment, or from execution of a judgment, or other legal process or proceeding for the giving of any relief or for the enforcement of a judgment, in any such court, with respect to its obligations, liabilities or any other matter under or arising out of or in connection with this Exchange Agreement or the Deposit Agreement. To the extent that the Company or any of its subsidiaries or any of their respective properties, assets or revenues may have or may hereafter become entitled to any such right of immunity in any such court in which proceedings may at any time be commenced each of the Company and each subsidiary, the Company waives or will waive such right to the extent permitted by law and has consented to such relief and enforcement as provided in Section 15 of this Agreement.

l. *Enforceability of Judgments*. Any final judgment for a fixed or readily calculable sum of money rendered by a New York Court having jurisdiction under its own domestic laws and recognized by the Irish courts as having jurisdiction (according to Irish conflicts of laws principles and rules of Irish private international law at the time when proceedings

were initiated) to give such final judgment in respect of any suit, action or proceeding against the Company based upon this Exchange Agreement or the Deposit Agreement and any instruments or agreements entered into for the consummation of the transactions contemplated herein and therein would be declared enforceable against the Company, without re-examination or review of the merits of the cause of action in respect of which the original judgment was given or re-litigation of the matters adjudicated upon, by the courts of Ireland.

6. Representations and Warranties and Covenants of the Investor. The Investor hereby represents and warrants to and covenants with the Company and Parent, on behalf of itself and each Account, as applicable, that:

   a. The Investor is a corporation, limited partnership, limited liability company or other entity, as the case may be, duly formed, validly existing and in good standing under the laws of the jurisdiction of its formation.

   b. If the Investor is participating in the Exchange, the Investor has full power and authority to deliver, assign and transfer the Exchanged Old Notes in exchange for the Exchange Consideration pursuant to this Exchange Agreement and to enter into this Exchange Agreement and perform all obligations required to be performed by the Investor hereunder. If the Investor is executing this Exchange Agreement on behalf of an Account, (i) the Investor has all requisite authority to enter into this Exchange Agreement on behalf of, and, bind, each Account to the terms of this Exchange Agreement and (ii) Exhibit A hereto is a true, correct and complete list of (A) the name of each Exchanging Holder, and (B) the principal amount of each Exchanging Holder's Exchanged Old Notes.

   c. Each Exchanging Holder participating in the Exchange is the current beneficial owner of the Exchanged Old Notes. When the Exchanged Old Notes are exchanged, the Company will acquire good, marketable and unencumbered title thereto, free and clear of all liens, restrictions, charges, encumbrances, adverse claims, rights or proxies.

   d. Participation in the Exchange will not contravene (1) any law, rule or regulation binding on the Investor or any investment guideline or restriction applicable to the Investor (or, if applicable, any Account) and (2) the charter or bylaws or similar organizational documents of the Investor (or, if applicable, any Account).

   e. The Investor (or applicable Account) is a resident of the jurisdiction set forth in Exhibit C and, unless otherwise set out in Exhibit A hereto, is not acquiring the Exchanged New Notes as a nominee or agent or otherwise for any other person.

   f. The Investor and each Account will comply with all applicable laws and regulations in effect in any jurisdiction in which the Investor or such Account purchases or acquires pursuant to the Exchange or sells New Notes and will obtain any consent, approval or permission required for such purchases, acquisitions or sales under the laws and regulations of any jurisdiction to which the Investor or such Account is subject or in which the Investor or such Account makes such purchases, acquisitions or sales, and Parent and the Company shall not have any responsibility therefor.

   g. The Investor and each Account has received a copy of the Transaction Documents. The Investor acknowledges that: (1) no person has been authorized to give any information or to make any representation concerning the Exchange, Parent or any of its subsidiaries, including the Company, other than as contained in this Exchange Agreement or the Transaction Documents or in the information given by Parent's or the Company's duly authorized officers and employees in connection with the Investor's examination of Parent and its subsidiaries and the terms of the Exchange; and (2) Parent and its subsidiaries do not take any responsibility for, and cannot provide any assurance as to the reliability of, any other information that may have been provided to the Investor. The Investor hereby acknowledges that J. Wood Capital Advisors LLC (the "**Placement Agent**") does not take any responsibility for, and can provide no assurance as to the reliability of, the information set forth in the Transaction Documents or any such other information provided or deemed provided to the Investor by Parent or the Company.

h. The Investor and each Account understands and accepts that acquiring the New Notes in the Exchange involves risks. The Investor and each Account has such knowledge, skill and experience in business, financial and investment matters that the Investor and each Account is capable of evaluating the merits and risks of the Exchange and an investment in the New Notes. With the assistance of its own professional advisors (to the extent the Investor and each Account has deemed appropriate), the Investor and each Account has made its own legal, tax, accounting and financial evaluation of the merits and risks of an investment in the New Notes and the consequences of the Exchange and this Exchange Agreement. The Investor and each Account has considered the suitability of the New Notes as an investment in light of its own circumstances and financial condition, and the Investor and each Account is able to bear the risks associated with an investment in the New Notes.

i. The Investor confirms that neither it nor any Account is relying on any communication (written or oral) of Parent, the Company or the Placement Agent or any of their respective agents (including authorized officers and employees) or affiliates as investment advice or as a recommendation to participate in the Exchange and receive the Exchange Consideration pursuant to the terms hereof. It is understood that information provided in the Transaction Documents, or by Parent, the Company or the Placement Agent or any of their respective agents or affiliates, shall not be considered investment advice or a recommendation with respect to the Exchange, and that none of Parent, the Company, the Placement Agent or any of their respective agents or affiliates is acting or has acted as an advisor to the Investor or any Account in deciding whether to participate in the Exchange. The Investor and each Account acknowledges and the Investor agrees that the Placement Agent has not acted as a financial advisor or fiduciary to the Investor or any Account and that the Placement Agent, its affiliates and its or their directors, officers, employees, representatives and controlling persons have no responsibility for making, and have not made, any independent investigation of the information contained herein or in Parents filings with the Securities and Exchange Commission and make no representation or warranty to the Investor or any Account, express or implied, with respect to Parent, the Company, the Exchanged Old Notes or the ADSs or the accuracy, completeness or adequacy of the information provided to the Investor or any Account or any other publicly available information, nor shall any of the foregoing persons be liable for any loss or damages of any kind in connection with the Exchange.

j. The Investor confirms, for itself and for each Account, that none of Parent, the Company or the Placement Agent has (1) given any guarantee or representation as to the potential success, return, effect or benefit (either legal, regulatory, tax, financial, accounting or otherwise) of an investment in the New Notes (except for the Guarantee provided by Parent pursuant to the Indenture); or (2) made any representation to the Investor regarding the legality of an investment in the New Notes under applicable investment guidelines, laws or regulations. In deciding to participate in the Exchange, neither the Investor nor any Account is relying on the advice or recommendations of Parent, the Company or the Placement Agent, and the Investor and each Account has made its own independent decision that the investment in the New Notes is suitable and appropriate for the Investor or such Account.

k. The Investor and each Account is a sophisticated participant in the transactions contemplated hereby and has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of an investment in the New Notes, is experienced in investing in capital markets and is able to bear the economic risk of an investment in the New Notes. The Investor and each Account is familiar with the business and financial condition and operations of the Company and its subsidiaries, including the Company, and has conducted its own investigation of Parent and its subsidiaries and the New Notes and has consulted with its own advisors concerning such matters and shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby. The Investor and each Account has had access to Parent's filings with the Securities and Exchange Commission and such other information concerning Parent and its subsidiaries and the New Notes as it deems necessary to enable it to make an informed investment decision concerning the Exchange. The Investor and each Account has been offered the opportunity to ask questions of Parent, the Company and their respective representatives and has received answers thereto as the Investor or such Account deems necessary to enable it to make its own informed investment decision concerning the Exchange and the New Notes. The

Investor and each Account acknowledges and understands that at the time of the Closing, Parent and the Company may be in possession of material non-public information not known to the Investor or any Account that may impact the value of the New Notes, the Exchanged Old Notes, and the ADSs ("**Information**") that the Company has not disclosed to the Investor or any Account. The Investor and each Account acknowledges that they have not relied upon the non-disclosure of any such Information for purposes of making their decision to participate in the Exchange. The Investor and each Account understands, based on its experience, the disadvantage to which the Investor and each Account is subject due to the disparity of information between Parent and the Company, on the one hand, and the Investor and each Account, on the other hand. Notwithstanding this, the Investor and each Account has deemed it appropriate to participate in the Exchange. The Investor agrees that Parent and the Company and their directors, officers, employees, agents, stockholders and affiliates shall have no liability to the Investor or any Account or their respective beneficiaries whatsoever due to or in connection with Parent or the Company's use or non-disclosure of the Information or otherwise as a result of the Exchange, and the Investor hereby irrevocably waives any claim that it or any Account might have based on the failure of Parent or the Company to disclose the Information.

l. The Investor and each Account understands that no U.S. federal, state, local or non-U.S. agency has passed upon the merits or risks of an investment in the New Notes or made any finding or determination concerning the fairness or advisability of such investment.

m. The Investor and each Account is a "qualified institutional buyer" as defined in Rule 144A under the Securities Act. The Investor, for itself and on behalf of each Account, agrees to furnish any additional information reasonably requested by the Company or any of its affiliates to assure compliance with applicable U.S. federal and state securities laws in connection with the Exchange.

n. The Investor and each Account is not directly, or indirectly through one or more intermediaries, controlling or controlled by, or under direct or indirect common control with, Parent or the Company and is not, and has not been for the immediately preceding three months, an "affiliate" (within the meaning of Rule 144 under the Securities Act) of Parent or the Company.

o. The Investor and each Account is acquiring the New Notes solely for the Investor's or such Account's own beneficial account, or for an account with respect to which the Investor or such Account exercises sole investment discretion, for investment purposes, and not with a view to, or for resale in connection with, any distribution of the New Notes. The Investor and each Account understands that the offer and sale of the New Notes have not been registered under the Securities Act or any state securities laws by reason of specific exemptions under the provisions thereof that depend in part upon the investment intent of the Investor or each Account and the accuracy of the other representations made by the Investor and each Account in this Exchange Agreement.

p. The Investor and each Account understands that each of Parent and the Company is relying upon the representations and agreements contained in this Exchange Agreement (and any supplemental information) for the purpose of determining whether the Investor's and such Account's participation in the Exchange meets the requirements for the exemptions referenced in clause 6(o) above. In addition, the Investor and each Account acknowledges and agrees that any hedging transactions engaged in by the Investor or such Account after the confidential information (as described in the confirmatory email received by the Investor from the Placement Agent (the "**Wall Cross Email**")) was made available to the Investor and prior to the Closing in connection with the issuance and sale of the New Notes have been and will be conducted in compliance with the Securities Act and the rules and regulations promulgated thereunder.

q. The Investor and each Account acknowledges that the New Notes have not been registered under the Securities Act.

r. The Investor and each Account acknowledges that the terms of the Exchange have been mutually negotiated between the Investor (for itself and on behalf of each Account), and

the Company. The Investor was given a meaningful opportunity to negotiate the terms of the Exchange on behalf of itself and each Account.

s. The Investor and each Account acknowledges the Company intends to pay an advisory fee to the Placement Agent.

t. The Investor will, for itself and on behalf of each Account, upon request, execute and deliver any additional documents, information or certifications reasonably requested by the Company, the Old Notes Trustee or the New Notes Trustee to complete the Exchange.

u. The Investor and each Account understands that, unless the Investor notifies the Company in writing to the contrary before the Closing, each of the Investor's representations and warranties contained in this Exchange Agreement will be deemed to have been reaffirmed and confirmed as of the Closing, taking into account all information received by the Investor.

v. The participation in the Exchange by any Exchanging Holder was not conditioned by the Company on such Exchanging Holders' exchange of a minimum principal amount of Exchanged Old Notes.

w. The Investor acknowledges that it and each Account had a sufficient amount of time to consider whether to participate in the Exchange and that neither the Company nor the Placement Agent has placed any pressure on the Investor or any Account to respond to the opportunity to participate in the Exchange. The Investor acknowledges that neither it nor any Account did become aware of the Exchange through any form of general solicitation or advertising within the meaning of Rule 502 under the Securities Act.

x. The operations of the Investor and each Account have been conducted in material compliance with the rules and regulations administered or conducted by the U.S. Department of Treasury Office of Foreign Assets Control ("**OFAC**") applicable to the Investor. The Investor has performed due diligence necessary to reasonably determine that its (or, where applicable, any Account's) beneficial owners are not named on the lists of denied parties or blocked persons administered by OFAC, resident in or organized under the laws of a country that is the subject of comprehensive economic sanctions and embargoes administered or conducted by OFAC ("**Sanctions**"), or otherwise the subject of Sanctions.

7. Conditions to Obligations of the Investor and the Company and Parent. The obligations of the Investor to deliver, or to cause the Accounts to deliver, the Exchanged Old Notes, and of the Company to deliver the Exchange Consideration are subject to the satisfaction at or prior to the Closing of the condition precedent that the representations and warranties of the Company and Parent on the one hand, and of the Investor on the other contained in Sections 5 and 6, respectively, shall be true and correct as of the Closing in all material respects with the same effect as though such representations and warranties had been made as of the Closing.

8. Covenants and Acknowledgment of the Company and Parent. Parent hereby agrees to publicly disclose at or before 9:00 a.m., New York City time (the "**Release Time**"), on the first business day after the date hereof, the Exchange as contemplated by this Exchange Agreement in a press release or a Current Report on Form 8-K filed with the Securities and Exchange Commission. Parent hereby acknowledges and agrees that, as of the Release Time, Parent will disclose all confidential information to the extent Parent believes such confidential information constitutes material non-public information, if any, with respect to the Exchange or that was otherwise communicated by the Company and/or Parent to the Investor or any Account in connection with the Exchange. For the avoidance of doubt, each of Parent and the Company may be aware of material non-public information regarding Parent and/or the Company at the time of Closing that has not been communicated to the Investor or any Account. Parent will, within two (2) business days after the Closing, file a Current Report on Form 8-K publicly disclosing the closing of the Exchange as contemplated by this Exchange Agreement.

9. Covenant of the Investor. No later than one (1) business day after the date hereof, the Investor agrees to deliver settlement instructions for each Purchaser to the Company substantially in the form of Exhibit C hereto.

10. Waiver, Amendment. Neither this Exchange Agreement nor any provisions hereof shall be modified, changed, discharged or terminated except by an instrument in writing, signed by the party against whom any waiver, change, discharge or termination is sought.

11. Assignability. Neither this Exchange Agreement nor any right, remedy, obligation or liability arising hereunder or by reason hereof shall be assignable by Parent, the Company or the Investor without the prior written consent of the other parties.

12. Reserved.

13. Waiver of Jury Trial. EACH OF PARENT, THE COMPANY AND THE INVESTOR (FOR ITSELF AND, IF APPLICABLE, ON BEHALF OF EACH ACCOUNT) IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY WITH RESPECT TO ANY LEGAL PROCEEDING ARISING OUT OF THE TRANSACTIONS CONTEMPLATED BY THIS EXCHANGE AGREEMENT.

14. Governing Law. THIS EXCHANGE AGREEMENT SHALL BE GOVERNED BY THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO CONFLICT OF LAW PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAW OTHER THAN THE LAW OF THE STATE OF NEW YORK.

15. Submission to Jurisdiction. Each of Parent, the Company and the Investor (for itself and, if applicable, on behalf of each Account) (a) agrees that any legal suit, action or proceeding arising out of or relating to this Exchange Agreement or the transactions contemplated hereby shall be instituted exclusively in the courts of the State of New York located in the City and County of New York or in the United States District Court for the Southern District of New York; (b) waives any objection that it may now or hereafter have to the venue of any such suit, action or proceeding; and (c) irrevocably consents to the jurisdiction of the aforesaid courts in any such suit, action or proceeding. Each of Parent, the Company and the Investor (for itself and, if applicable, on behalf of each Account) agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

16. Venue. Each of Parent, the Company and the Investor (for itself and, if applicable, on behalf of each Account) irrevocably and unconditionally waives, to the fullest extent it may legally and effectively do so, any objection which it may now or hereafter have to the laying of venue of any suit, action or proceeding arising out of or relating to this Exchange Agreement in any court referred to in Section 15. Each of Parent, the Company and the Investor (for itself and, if applicable, on behalf of each Account) irrevocably waives, to the fullest extent permitted by law, the defense of an inconvenient forum to the maintenance of such action or proceeding in any such court.

17. Service of Process. Each of Parent, the Company and the Investor (for itself and, if applicable, on behalf of each Account) irrevocably consents to service of process in the manner provided for notices in Section 20. Nothing in this Exchange Agreement will affect the right of any party to this Exchange Agreement to serve process in any other manner permitted by law.

18. Section and Other Headings. The section and other headings contained in this Exchange Agreement are for reference purposes only and shall not affect the meaning or interpretation of this Exchange Agreement.

19. Counterparts. This Exchange Agreement may be executed, either manually or by way of a digital signature provided by DocuSign (or similar digital signature provider), by one or more of the parties hereto in any number of separate counterparts (including by facsimile or other electronic means, including telecopy, email or otherwise), and all of said counterparts taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page of this Exchange Agreement (whether executed manually or by way of a digital signature as described herein this Section 19) by facsimile or other transmission (*e.g.*, "pdf" or "tif" format) shall be effective as delivery of a manually executed counterpart hereof.

20. Notices. All notices and other communications to the Company provided for herein shall be in writing and shall be deemed to have been duly given if delivered personally or sent by registered or certified mail, return receipt requested, postage prepaid to the following addresses, or, in the

case of the Investor or any Account, the address provided in Exhibit C (or such other address as either party shall have specified by notice in writing to the other):

If to the Company:	Avadel Finance Cayman Limited c/o Avadel Pharmaceuticals plc 10 Earlsfort Terrace Dublin 2, Ireland D02 T380 Attention: General Counsel; Christopher McLaughlin
In each case, with a copy to (which shall not constitute notice):	Goodwin Procter LLP 100 Northern Avenue, Boston, MA 02210 Attention: Jim Barri

21. Binding Effect. The provisions of this Exchange Agreement shall be binding upon and accrue to the benefit of the parties hereto and their respective heirs, legal representatives, successors and permitted assigns.

22. Notification of Changes. The Investor (for itself and, if applicable, on behalf of each Account) hereby covenants and agrees to notify the Company upon the occurrence of any event prior to the Closing that would cause any representation, warranty, or covenant of the Investor (and/or such Account) contained in this Exchange Agreement to be false or incorrect in any material respect.

23. Reliance by Placement Agent. The Placement Agent may rely on each representation and warranty of the Company, the Parent and the Investor made herein or pursuant to the terms hereof with the same force and effect as if such representation or warranty were made directly to the Placement Agent. The Placement Agent shall be a third party beneficiary to this Exchange Agreement to the extent provided in this Section 23.

24. Severability. If any term or provision (in whole or in part) of this Exchange Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Exchange Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.

[*Signature Pages Follow*]

IN WITNESS WHEREOF, the Investor (for itself and, if applicable, on behalf of each Account) has executed this Exchange Agreement as of the date first written above.

Legal Name of Executing Investor:

_____

By _____

Name:
Title:
Legal Name:

ACCEPTED AND AGREED:

AVADEL FINANCE CAYMAN LIMITED,
as the Company

By _____
Name:
Title:

AVADEL PHARMACEUTICALS PLC,
as Parent

By _____
Name:
Title:

EXHIBIT A TO THE EXCHANGE AGREEMENT

Name of Exchanging Holder (i.e., Beneficial Owner)	**Aggregate Principal Amount of Exchanged Old Notes**	**Aggregate Principal Amount of Exchanged New Notes**	**Aggregate Amount of Cash Consideration**
	$	$	$
Total:	$	$	

[*Signature Page to Exchange Agreement*]

EXHIBIT B TO THE EXCHANGE AGREEMENT

NOTICE OF EXCHANGE PROCEDURES

Attached are Exchange Procedures for the settlement of the Avadel Finance Cayman Limited (the "**Company**") exchange of its Exchangeable Senior Notes due 2023 (the "**New Notes**") pursuant to the Exchange Agreement, dated as of March 16, 2022, between you, the Company and Avadel Pharmaceuticals plc, which is expected to occur on or about April 4, 2022. To ensure timely settlement, please follow the instructions for exchanging your Avadel Finance Cayman Limited 4.50% Exchangeable Senior Notes due 2023 (the "**Old Notes**") as set forth on the following page.

These instructions supersede any prior instructions you received. Your failure to comply with the attached instructions may delay your receipt of the Exchange Consideration.

If you have any questions, please contact [NAME] at [TELEPHONE].

Thank you.

[*Signature Page to Exchange Agreement*]

Delivery of Old Notes

You must direct the eligible DTC participant through which you hold a beneficial interest in the Old Notes to post **on April 4, 2022, no later than 9:00 a.m., New York City time**, one-sided withdrawal instructions through DTC via DWAC for transfer to The Bank of New York Mellon (DTC Participant No. 901), the aggregate principal amount[1] of Exchanged Old Notes (CUSIP: 05337YAA5 or 05337YAB3) set forth in column 2 of Exhibit A ("Aggregate Principal Amount of Exchanged Old Notes") of the Exchange Agreement.

It is important that this instruction be submitted and the DWAC posted on April 4, 2022, no later than 5:00 a.m., New York City time.

To receive Exchanged New Notes

You must direct your eligible DTC participant through which you wish to hold a beneficial interest in the Exchanged New Notes to post and accept **on April 4, 2022, no later than 9:00 a.m., New York City time**, a one-sided deposit instruction through DTC via DWAC from The Bank of New York Mellon for the aggregate principal amount[2] of Exchanged New Notes (CUSIP: 05337YAC2) set forth in column 3 of Exhibit A ("Aggregate Principal Amount of Exchanged New Notes") of the Exchange Agreement.

It is important that this instruction be submitted and the DWAC posted on April 4, 2022, no later than 5:00 a.m., New York City time.

To receive Cash Consideration

You must provide valid wire instructions to the Company. You will then receive the Cash Consideration from the Company on the Closing Date.

You must comply with both procedures described above in order to complete the Exchange and to receive the Exchanged New Notes and the Cash Consideration in respect of the Exchanged Old Notes.

[1] Note that the DWAC instruction should specify the principal amount, not the number, of Exchanged Old Notes.

[2] Note that the DWAC instruction should specify the principal amount, not the number, of Exchanged New Notes.

SETTLEMENT

On April 4, 2022, after the Company receives your Exchanged Old Notes and your delivery instructions as set forth above, and subject to the satisfaction of the conditions to closing as set forth in your Exchange Agreement, the Company will deliver your Exchange Consideration in accordance with the delivery instructions set forth above.

EXHIBIT C TO THE EXCHANGE AGREEMENT

Purchaser Settlement Details

These settlement instructions are to be delivered to the Company for each Purchaser no later than one (1) business day after the date of the Exchange Agreement.

Name of Purchaser: _____

Purchaser Address:

__
__
__

Telephone:__

Email Address:__

Country of Residence:__

Taxpayer Identification Number:__

Exchanged Old Notes
DTC Participant Number:
DTC Participant Name:
DTC Participant Phone Number:
DTC Participant Contact Email:
FFC Account #:
Account # at Bank/Broker:

Exchanged New Notes (if different from Exchanged Old Notes)
DTC Participant Number:
DTC Participant Name:
DTC Participant Phone Number:
DTC Participant Contact Email:
FFC Account #:
Account # at Bank/Broker:

Wire instructions for Cash Consideration:
Bank Name:
Bank Address:
ABA Routing #:
Account Name:
Account Number:
Contact Person:

ACTIVE/115855038.2

ACTIVE/115855038.2

Exhibit 21.1

List of Subsidiaries

Name	Jurisdiction
Avadel Pharmaceuticals plc (the Registrant):	Ireland
1) Avadel US Holdings, Inc. *(f/k/a Flamel US Holdings, Inc.)*	United States (Delaware)
B. Avadel Legacy Pharmaceuticals, LLC *(f/k/a Éclat Pharmaceuticals LLC)*	United States (Delaware)
C. Avadel Management Corporation	United States (Delaware)
D. Avadel CNS Pharmaceuticals, LLC	United States (Delaware)
2) Flamel Ireland Ltd. *(d/b/a Avadel Ireland)*	Ireland
3) Avadel Investment Company, Ltd.	Cayman Islands
4) Avadel France Holding SAS	France
A. Avadel Research SAS	France
5) Avadel Finance Ireland Designated Activity Company	Ireland
A. Avadel Finance Cayman Ltd.	Cayman Islands

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-213154, 333-212585, 333-177591, 333-219016, and 333-252956 on Form S-8, and 333-183961, 333-236258 and 333-237962 on Form S-3 of our reports dated March 16, 2022, relating to the consolidated financial statements of Avadel Pharmaceuticals plc (the "Company") and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K of Avadel Pharmaceuticals plc for the year ended December 31, 2021.

/s/ Deloitte and Touche LLP
St. Louis, Missouri
March 16, 2022

Exhibit 31.1

CERTIFICATION

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gregory J. Divis, certify that:

1. I have reviewed this Annual Report on Form 10-K of Avadel Pharmaceuticals plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2022

/s/ Gregory J. Divis
Gregory J. Divis
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas S. McHugh, certify that:

1. I have reviewed this Annual Report on Form 10-K of Avadel Pharmaceuticals plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2022

/s/ Thomas S. McHugh

Thomas S. McHugh
Senior Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Avadel Pharmaceuticals plc (the "Company") on Form 10-K for the period ending December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gregory J. Divis, Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. §1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Gregory J. Divis
Gregory J. Divis
Chief Executive Officer
Avadel Pharmaceuticals plc
March 16, 2022

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Avadel Pharmaceuticals plc (the "Company") on Form 10-K for the period ending December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas S. McHugh, Senior Vice President and Chief Financial Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Thomas S. McHugh
Thomas S. McHugh
Senior Vice President and Chief Financial Officer
Avadel Pharmaceuticals plc
March 16, 2022