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, 2020

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: 000-28508

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: +011-1-485-1200

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 $466,741,289 based on the closing sale price of the registrant's American Depositary Shares as reported by the Nasdaq Global Market on June 30, 2020. Such market value excludes 364,026 ordinary shares, $0.01 per share nominal value, 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 4, 2021 was 58,465,151.

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, 2020, 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 II, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. The principal risks and uncertainties affecting our business include the following:

- Our lead product candidate and future product candidates will generally be subject to regulatory approval. If we or our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our ability to generate future revenues may be adversely affected.
- Our lead product candidate and future product candidates may be subject to continuing regulation, and we on our own, and in conjunction with our pharmaceutical partners, may be subject to adverse consequences if we or they fail to comply with applicable regulations.
- Disruptions at the United States ("U.S.") Food and Drug Administration ("FDA"), the Drug Enforcement Administration and other government agencies caused by funding shortages or global health concerns, including coronavirus disease (COVID-19), could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.
- We are subject to U.S. federal and state and international laws and regulations prohibiting "kickbacks" and false claims that, if violated, could subject us to substantial penalties, and any challenges to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.
- We may rely on collaborations with third parties to commercialize certain of our product candidates in development and such strategy involves risks that could impair our prospects for realizing profits from such products.
- We depend on a single provider of certain services related to the development of our product candidate, and any interruption of operations of such provider could significantly delay or have a material adverse effect on our business.
- We depend on a limited number of suppliers for the manufacturing of our product candidate and certain raw materials and any failure of such suppliers to manufacture or supply sufficient quantities of product or these raw materials could have a material adverse effect on our business.
- Clinical development of drugs is costly and time-consuming, and the outcomes are uncertain. A failure to prove that our product candidate and future product candidates are safe and effective in clinical trials could materially and adversely affect our business, financial condition, results of operations and growth prospects.
- 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 our product candidate or future product candidates.
- 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 or future product candidates.
- 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.
- 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.
- Our future products may not gain market acceptance.
- COVID-19 may materially and adversely affect our business and our financial results.
- We and companies to which we have licensed or will license our future products or drug delivery technologies and subcontractors we engage for services related to the development and manufacturing of our product candidate and 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.

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, or 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, and our ability to obtain regulatory approval of and successfully commercialize FT218, including any delays in approval related to COVID-19;
- 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 our lead product candidate and certain raw materials in our lead product candidate 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 our product candidate;
- Any further restructuring actions that may be required and our ability to obtain any required consents (including any consents required pursuant to the Indenture governing our exchange notes due 2023, or the 2023 Notes);
- Our ability to continue to service 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 retain members of our management team and our employees; 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.avadelpharmaceuticals.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") and 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, the Company submitted a New Drug Application ("NDA") to the FDA for FT218 to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy.The NDA for FT218 was accepted by the FDA in February 2021 and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021.

Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio. As of December 31, 2020, we do not have any approved and 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 and 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. Sodium oxybate is approved in the U.S. for the treatment of EDS and 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 with an assigned PDUFA target action date of October 15, 2021.

The REST-ON trial was a randomized, double-blind, placebo-controlled study that enrolled 212 patients 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 a statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test, or MWT, clinical global impression-improvement, or CGI-I, and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g also demonstrated a 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, which makes the drug 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 initiating an open-label extension ("OLE")/switch study of FT218 as a potential treatment for EDS and 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 if they participated in REST-ON or not. We anticipate that the study will enroll up to 250 patients, many of which will be enrolled in North American clinical trial sites that participated in the REST-ON study.

We believe FT218 has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standard of care for EDS and cataplexy in patients with narcolepsy, which is a twice-nightly sodium oxybate formulation. If approved, we believe FT218 has the potential to take a significant share of the sodium oxybate market. The current market size for the twice-nightly administration of sodium oxybate is estimated at an annualized revenue run rate of $1.8 billion.

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 reduce safety issues and improve a number of things like efficacy, dosing compliance and patient satisfaction. Beyond FT218, we believe there could be other product development opportunities for our Micropump drug-delivery technology, representing either i) life cycle opportunities, whereby additional intellectual property-protected drug delivery technology can be added to a pharmaceutical product to extend the commercial viability of that product, or ii) innovative formulation opportunities for known active pharmaceutical ingredients as well as new chemical entities.

Previously Approved FDA Products

On June 30, 2020 (the "Closing Date"), Avadel Legacy Pharmaceuticals, LLC (the "Avadel Seller") announced the sale of the portfolio of sterile injectable drugs used in the hospital setting (the "Hospital Products"), which included our three commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, which was approved by the U.S. FDA to Exela Sterile Medicines LLC ("Exela Buyer") pursuant to an asset purchase agreement by and among the Avadel Seller, Avadel US Holdings, Inc., the Exela Buyer and Exela Holdings, Inc. This sale included the following FDA approved products:

- **Bloxiverz (neostigmine methylsulfate injection) -** Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery.

- **Vazculep (phenylephrine hydrochloride injection) -** Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

- **Akovaz (ephedrine sulfate injection) -** Akovaz was the first FDA approved formulation of ephedrine sulfate, an alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

- **Nouress (cysteine hydrochloride injection) -** Nouress is a sterile injectable product for use in the hospital setting to provide parenteral nutrition to neonates.

Corporate Information

We are registered as an Irish public limited company. Our principal place of business is located at 10 Earlsfort Terrace, Dublin 2, Ireland and our phone number is 00 353 1 920 1000. We file annual, quarterly and current reports, proxy statements and other documents with the U.S. Securities and Exchange Commission ("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 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 Specialty Pharmaceuticals, LLC, (ii) Avadel Legacy Pharmaceuticals, LLC, (iii) Avadel Management Corporation, and (iv) 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.

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, armodafinil, solriamfetol and pitolisant, which are widely prescribed, or 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 sodium oxybate market prior to FT218's potential FDA approval, including, for example, reboxetine, orexin 2 receptor agonists, flecainide / modafinil combination, histamine H3 antagonists/inverse agonists, or $GABA_B$ agonists.

Market Opportunities

In today's pharmaceutical market, a drug has to demonstrate significant therapeutic improvements over the current standard of care in order to obtain third party payer coverage. Alternatively, changes in the delivery of a drug must create a demonstrable reduction in costs. Dosing convenience, by itself, is not sufficient to gain reimbursement acceptance. Biopharmaceutical companies must demonstrate, through extensive clinical trials, the therapeutic efficacy of their new formulations. The FDA has encouraged drug companies developing enhanced formulations to use a condensed regulatory pathway: the 505(b)(2) NDA. Many biopharmaceutical companies today are using this approach or the supplemental NDA pathway ("sNDA"). An NDA or sNDA is necessary to market an already approved drug for a new indication, or in a different dosage form or formulation. However, the sNDA approach requires cross-referencing the originator's drug dossier, and eventually an alliance with the originator for commercialization.

Avadel's Drug Delivery Technologies

We own drug delivery technologies that address key 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.

Proprietary 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 will rely on a limited number of suppliers for sourcing active pharmaceutical ingredients ("APIs").

We will outsource the production of FT218 to current good manufacturing practices ("cGMP") -compliant and FDA-audited contract manufacturing organizations ("CMOs") pursuant to supply agreements and have no present plans to acquire manufacturing facilities.

Government Regulation

The design, testing, manufacturing and marketing of certain new or substantially modified drugs, biological products or medical devices must be approved, cleared or certified by regulatory agencies, regulatory authorities and notified bodies under applicable laws and regulations, the requirements of which may vary from country to country. This regulatory process is lengthy, expensive and uncertain. In the U.S., the FDA regulates such products under various federal statutes, including the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Public Health Service Act.

New Drug Product Development and Approval Process

Regulation by governmental authorities in the U.S. and other countries has a significant impact on the development, manufacture, and marketing of drug products and on ongoing research and product development activities. The products of Avadel's pharmaceutical partners as well as its own products require regulatory approval by governmental agencies and regulatory authorities prior to commercialization. In particular, these products are subject to stringent manufacturing requirements known as cGMP which are promulgated by the FDA in the U.S. and by other authorities in other jurisdictions, and rigorous, pre-clinical and clinical testing and other pre-market approval requirements by the FDA, the European Commission and regulatory authorities in other countries. In the U.S. and the European Union, various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources.

Regulatory approval, when and if obtained, may be limited in scope. In particular, regulatory approvals may restrict the marketing of a product to specific uses. Approved drugs, as well as their manufacturers, are subject to ongoing review (including requirements and restrictions related to record keeping and reporting, FDA, European Commission and EU Member States competent authorities' approval of certain changes in manufacturing processes or product labeling, product promotion and advertising, and pharmacovigilance, which includes monitoring and reporting adverse reactions, maintaining safety measures, and conducting dossier reviews for marketing authorization renewal). Discovery of previously unknown problems with these products may result in restrictions on their manufacture, sale or use, or in their withdrawal from the market. Failure to comply with regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other actions affecting the potential products and commercial prospects of Avadel or Avadel's pharmaceutical partners who may utilize Avadel's technologies. Any failure by Avadel or our pharmaceutical partners to comply with current or new and changing regulatory obligations, and any failure to obtain and maintain, or any delay in obtaining, regulatory approvals, could materially adversely affect our business.

The process for new drug product development and approval has many steps, including:

Chemical and Formulation Development. Pharmaceutical formulation taking into account the chemistry and physical characteristics of the drug or biological substance, is the beginning of a new product. If initial laboratory experiments reveal that the concept for a new drug product looks promising, then a variety of further development steps and tests complying with internationally recognized guidance documents will have to be continued, in order to provide for a product ready for testing in animals and, after sufficient animal test results, also in humans.

Concurrent with pre-clinical studies and clinical trials, companies must continue to develop information about the properties of the drug product and finalize a process for manufacturing the product in accordance with cGMP. The manufacturing process must be capable of consistently producing quality batches of the product, and the manufacturer must develop and validate methods for testing the quality, purity and potency of the final products. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

Pre-Clinical Testing. Once a drug candidate is identified for development, the candidate enters the pre-clinical testing stage. This includes laboratory evaluation of product chemistry and formulation, as well as animal studies of pharmacology (mechanism of action, pharmacokinetics) and toxicology which may have to be conducted over lengthy periods of time, to assess the potential safety and efficacy of the product as formulated. Pre-clinical tests must be conducted in compliance with good laboratory practice regulations, the Animal Welfare Act and its regulations in the U.S. and the Clinical Trials Directive and related national laws and guidelines in the EU Member States. Violations of these laws and regulations can, in some cases, lead to invalidation of the studies, then requiring such studies to be replicated. In some cases, long-term pre-clinical studies are conducted while clinical studies are ongoing.

Investigational New Drug Application.

U.S. The entire body of chemical or biochemical, pharmaceutical and pre-clinical development work necessary to administer investigational drugs to human volunteers or patients is summarized in an Investigational New Drug ("IND") application to the FDA. The IND becomes effective, if not rejected by the FDA within thirty (30) days after filing. There is no assurance that the submission of an IND will eventually allow a company to commence clinical trials. All clinical trials must be conducted under the supervision of a qualified investigator in accordance with good clinical practice regulations to ensure the quality and integrity of clinical trial results and data. These regulations include the requirement that, with limited exceptions, all subjects provide informed consent. In addition, an institutional review board ("IRB"), composed primarily of physicians and other qualified experts at the hospital or clinic where the proposed studies will be conducted, must review and approve each human study. The IRB also continues to monitor the study and must be kept aware of the study's progress, particularly as to adverse events and changes in the research. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events occur. Failure to adhere to good clinical practices and the protocols, and failure to obtain IRB approval and informed consent, may result in FDA rejection of clinical trial results and data, and may delay or prevent the FDA from approving the drug for commercial use.

European Union. The European equivalent to the IND is the Investigational Medicinal Product Dossier ("IMPD") which likewise must contain pharmaceutical, pre-clinical and, if existing, previous clinical information on the drug substance and product. An overall risk-benefit assessment critically analyzing the non-clinical and clinical data in relation to the potential risks and benefits of the proposed trial must also be included. The intended clinical trial must be submitted for authorization by the regulatory authority(ies) of each EU Member States in which the trial is intended to be conducted prior to its commencement. The trial must be conducted in accordance with the protocol as approved by an Ethics Committee(s) in each EU Member State

(EU equivalent to IRBs). Before submitting an application to the competent authority, the sponsor must register the trial in the EudraCT database where in the U.S. it will be provided with a unique EudraCT number.

Clinical Trials. Typically, clinical testing involves the administration of the drug product first to healthy human volunteers and then to patients with conditions needing treatment under the supervision of a qualified principal investigator, usually a physician, pursuant to a 'protocol' or clinical plan reviewed by the FDA and the competent authorities of the EU Member States along with the IRB or Ethics Committee (via the IND or IMPD submission). The protocol details matter such as a description of the condition to be treated, the objectives of the study, a description of the patient population eligible for the study, and the parameters to be used to monitor safety and efficacy.

Clinical trials are time-consuming and costly, and typically are conducted in three sequential phases, which sometimes may overlap. Phase I trials consist of testing the product in a small number of patients or normal volunteers, primarily for safety, in one or more dosages, as well as characterization of a drug's pharmacokinetic and/or pharmacodynamic profile. In Phase 2, in addition to safety, the product is studied in a patient population to evaluate the product's efficacy for the specific, targeted indications and to determine dosage tolerance and optimal dosage. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded patient population at geographically dispersed sites. With limited exceptions, all patients involved in a clinical trial must provide informed consent prior to their participation. Meeting clinical endpoints in early stage clinical trials does not assure success in later stage clinical trials. Phase 1, 2, and 3 testing may not be completed successfully within any specified time period, if at all.

The FDA and the competent authorities of EU Member States monitor the progress of each clinical trial phase conducted under an IND or IMPD and may, at their discretion, reevaluate, alter, suspend or terminate clinical trials at any point in this process for various reasons, including a finding that patients are being exposed to an unacceptable health risk or a determination that it is unethical to continue the study. The FDA, the European Commission and the competent authorities of EU Member States can also request that additional clinical trials be conducted as a condition to product approval. The IRB, the Ethics Committee, and sponsor also may order the temporary or permanent discontinuance of a clinical trial at any time for a variety of reasons, particularly if safety concerns arise. Such holds can cause substantial delay and, in some cases, may require abandonment of product development. These clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations, the EU Clinical Trials Directive and/or internationally recognized guidance such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH").

New Drug Application. After the completion of the clinical trial phases of development, if the sponsor concludes substantial evidence exists that the drug candidate is effective and that the drug is safe for its intended use, a new Drug Application ("NDA") may be submitted to the FDA. The application must contain all of the information on the drug candidate gathered to that date, including data from the pre-clinical and clinical trials, information pertaining to the preparation of the drug, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and stability (shelf-life). NDAs are often over 100,000 pages in length. If FDA determines that a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to ensure that the benefits of the drug outweigh the risks, a sponsor may be required to include as part of the application a proposed REMS, including a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug's distribution, or a medication guide to provide better information to consumers about the drug's risks and benefits. Submission of an NDA does not assure FDA approval for marketing.

The FDA reviews all submitted NDAs before it accepts them for filing (the U.S. prerequisite for dossier review). The FDA may refuse to file the application and request additional information rather than accepting an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA to determine, among other things, whether a product is safe and effective for its intended use. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. There is a strong presumption for advisory committee review for any drug containing an active ingredient not previously approved. The FDA is not bound by the recommendation of an advisory committee. Under the Prescription Drug User Fee Act ("PDUFA"), submission of an NDA with clinical data requires payment of a fee. In return, the FDA assigns an action date of 10 months from acceptance of the application to return of a first 'complete response,' in which the FDA may approve the product or request additional information (PDUFA also provides for an expedited, six-month, "priority review" process. There can be no assurance an application will be approved within the performance goal timeframe established under PDUFA, if at all. If the FDA's evaluation of the NDA is not favorable, the FDA usually will outline the deficiencies in the submission and request additional testing or information. Notwithstanding the submission of any requested additional information, or even in lieu of asking for additional information, the FDA may decide the marketing application does not satisfy the regulatory criteria for approval and issue a complete response letter, communicating the Agency's decision not to approve the application.

FDA approval of an NDA will be based, among other factors, on the Agency's review of the pre-clinical and clinical data submitted, a risk/benefit analysis of the product, and an evaluation of the manufacturing processes and facilities. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its NDA. For instance, FDA may require Avadel to provide data from additional preclinical studies or clinical trials to support approval of certain development steps or the NDA itself. Among the conditions for NDA approval is the requirement that each prospective manufacturer's quality control and manufacturing procedures conform to cGMP standards and requirements. Manufacturing establishments often are subject to Pre-Approval Inspections prior to NDA approval to assure compliance with cGMP manufacturing commitments made in the relevant marketing application.

Patent Restoration and Exclusivity. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, establishes two abbreviated approval pathways for drug products that are in some way follow-on versions of already approved products.

Generic Drugs. A generic version of an approved drug is approved by means of an Abbreviated New Drug Application ("ANDA"), by which the sponsor demonstrates the proposed product is the same as the approved, brand-name drug, which is referred to as the "Reference Listed Drug" ("RLD"). Generally, an ANDA must contain data and information showing the proposed generic product and RLD (1) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (2) are intended for the same uses, and (3) are bioequivalent. This is instead of independently demonstrating the proposed product's safety and effectiveness, which are inferred from the product being the same as the RLD, which the FDA previously found to be safe and effective.

505(b)(2) NDAs. If a product is similar, but not identical, to an already approved product, it may be submitted for approval via an NDA under Section 505(b)(2) of the Act. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on published scientific literature and the FDA's finding that the RLD is safe and effective, and must submit its own data of safety and effectiveness to an extent necessary because of the differences between the products.

RLD Patents. An NDA sponsor must advise the FDA about patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is referred to as the "Orange Book". The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is a challenge to the patent; it is an assertion that the patent does not block approval of the later product, because the patent is invalid, unenforceable, and/or not infringed by the new product.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD NDA holder and patent owner that the application with patent challenge has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid, unenforceable, or not infringed. If the NDA holder or patent owner file suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months from the date of receipt of the notice. If the RLD has new chemical entity ("NCE") exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the 30-month stay does not begin until five years after the RLD approval. The FDA may approve the proposed product before the expiration of the 30-month stay i) if a court finds the patent invalid, unenforceable, or not infringed, ii) if the court shortens the period because the parties have failed to cooperate in expediting the litigation, or iii) if the parties reach a settlement agreement and notify the FDA of same.

As an alternative to Paragraph IV certification, and only with respect to method of use patents, an applicant can 'carve around' a "Patent Use Code" associated with a particular patent in the FDA's Orange Book. A Patent Use Code is supposed to describe an indication/use of the RLD that is i) set forth in the RLD label and ii) covered by the corresponding method of use patent. As such, in lieu of a Paragraph IV certification, an applicant can demonstrate to the FDA that its proposed label does not include the method of use described by the RLD's Patent Use Code for the corresponding method of use patent and, thus, 'carve around' that Patent Use Code. If a 'carve around' is successful, the notice requirement and 30-month stay on FDA approval of the application described above with respect to a Paragraph IV certification for that particular method of use patent does not apply.

Regulatory Exclusivities. The Hatch-Waxman Act may provide periods of regulatory exclusivity for products that would serve as RLDs. If a product is a "new chemical entity," or NCE, - generally meaning that the active moiety has never before been approved in any drug - there may be a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor makes a Paragraph IV certification challenging a listed patent.

An RLD that is not an NCE may qualify for a three-year period of exclusivity, if the NDA contains clinical data necessary for approval. In that instance, the exclusivity period does not preclude filing or review of the ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data. For example, if an NDA is submitted for an RLD that is not an NCE, but that seeks approval for a new indication, and clinical data were required to demonstrate the safety or effectiveness of the RLD for that use, the FDA could not approve an ANDA or 505(b)(2) application for another product with that active moiety for that use. For example, Coreg CR™ received three-year exclusivity for the clinical trials that demonstrated the safety and efficacy of the new, controlled-release dosage form; that exclusivity, which has expired, blocked other controlled-release products.

For a brief discussion of potential marketing exclusivity that could be available under certain conditions with respect to Avadel's lead product candidate FT218, please see the information set forth under the caption "Risks Related to Regulatory and Legal Matters – If FT218 is approved by the FDA, we may not obtain orphan drug marketing exclusivity" in the "Risk Factors" included in Part I, Item 1A of this Annual Report on Form 10-K.

Patent Term Restoration. Under the Hatch-Waxman Act, a portion of the patent term lost during product development and FDA review of an NDA or 505(b)(2) application is restored if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. In the event that Avadel applies for patent term extensions on patents covering Avadel's products, the FDA and the USPTO may not agree with Avadel's assessment of whether such extensions are available, and may refuse to grant extensions to Avadel's patents, or may grant more limited extensions than Avadel requests. Moreover, Avadel may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements.

Regulation of Combination Drugs. Medical products containing a combination of drugs, biologic, or device products may be regulated as 'combination products' in the U.S. A combination product generally is defined as a product comprising components from two or more regulatory categories (*e.g.*, drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic or device.

To determine which FDA center or centers will review a combination product submission, companies may submit a request for assignment to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation.

In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of both components. The determination whether a product is a combination product or two separate products is made by the FDA on a case-by-case basis. It is possible that Avadel's delivery platforms, when coupled with a drug or medical device component, could be considered and regulated by the FDA as a combination product.

If the primary mode of action is determined to be a drug, the product will be reviewed by the Center for Drug Evaluation and Research ("CDER") either in consultation with another center or independently. If the primary mode of action is determined to be a medical device, the product would be reviewed by Center for Devices and Radiological Health ("CDRH") either in consultation with another center, such as CDER, or independently. In addition, FDA could determine that the product is a

biologic and subject to the jurisdiction of the Center for Biologic Evaluation and Research ("CBER"), although it is also possible that a biological product will be regulated by CDER.

Marketing Approval and Reporting Requirements. If the FDA approves an NDA, the product becomes available for physicians to prescribe. The FDA may require post-marketing studies, also known as Phase IV studies, as a condition of approval to develop additional information regarding the safety of a product. These studies may involve continued testing of a product and development of data, including clinical data, about the product's effects in various populations and any side effects associated with long-term use. After approval, the FDA may require post-marketing studies or clinical trials, as well as periodic status reports, if new safety information develops. These post-marketing studies may include clinical trials to investigate known serious risks or signals of serious risks or identify unexpected serious risks. Failure to conduct these studies in a timely manner may result in substantial civil fines and can result in withdrawal of approval. Avadel has several Phase IV obligations with its current approvals.

In addition, the FDA may require distribution to patients of a medication guide such as a Risk Evaluation and Mitigation Strategies ("REMS") for prescription products that the agency determines pose a serious and significant health concern in order to provide information necessary to patients' safe and effective use of such products. We expect our FT218 product, if approved by the FDA will be subject to a REMS program.

In the European Union, the marketing authorization of a medicinal product may be made conditional on the conduct of Phase IV post-marketing studies. Failure to conduct these studies in relation to centrally authorized products can lead to the imposition of substantial fines. Moreover, Phase IV studies are often conducted by companies in order to obtain further information on product efficacy and positioning on the market in view of competitors and to assist in application for pricing and reimbursement.

Other Post-Marketing Obligations. Any products manufactured and/or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements, reporting of adverse experiences with the product, submitting other periodic reports, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, submitting periodic reports to the FDA, maintaining and providing updated safety and efficacy information to the FDA, and complying with FDA promotion and advertising requirements. For example, the FDA has required Avadel to conduct post-marketing clinical and non-clinical studies for several of its products completed between 2016 and 2019.

Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and to list their products with the FDA. The FDA periodically inspects manufacturing facilities in the U.S. and elsewhere in order to assure compliance with the applicable cGMP regulations and other requirements. Facilities also are subject to inspections by other U.S. federal, foreign, state or local agencies. In complying with the cGMP regulations, manufacturers must continue to expend time, money and effort in recordkeeping and quality control to assure that the product meets applicable specifications and other post-marketing requirements. Failure of Avadel or its licensees to comply with FDA's cGMP regulations or other requirements could have a significant adverse effect on Avadel's business, financial condition and results of operations.

Also, newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, additional pre-clinical or clinical studies, or even in some instances, revocation or withdrawal of the approval. Violations of regulatory requirements at any stage, including after approval, may result in various adverse consequences, including the FDA's delay in approving or refusal to approve a product, withdrawal or recall of an approved product from the market, other voluntary or FDA-initiated action that could delay or restrict further marketing, and the imposition of civil fines and criminal penalties against the manufacturer and NDA holder. In addition, later discovery of previously unknown problems may result in restrictions on the product, manufacturer or NDA holder, including withdrawal of the product from the market. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of Avadel's products under development, or affect the conditions under which approved products are marketed.

The Food and Drug Administration Amendments Act of 2007 ("FDAAA") provides the FDA with expanded authority over drug products after approval. This legislation enhances the FDA's authority with respect to post-marketing safety surveillance, including, among other things, the authority to require additional post-marketing studies or clinical trials, labeling changes as a result of safety findings, registering clinical trials, and making clinical trial results publicly available.

In the European Union, stringent pharmacovigilance regulations oblige companies to appoint a suitably qualified and experienced Qualified Person resident in the European Economic Area, to prepare and submit to the competent authorities

adverse event reports within specific time lines, prepare Periodic Safety Update Reports ("PSURs") and provide other supplementary information, report to authorities at regular intervals and take adequate safety measures agreed with regulatory agencies as necessary. Failure to undertake these obligations can lead to the imposition of substantial fines.

Other Regulation

Controlled Substances Act. Narcotics and other APIs, such as sodium oxybate and ephedrine sulfate are "controlled substances" under the Controlled Substances Act. The U.S. federal "Controlled Substances Act" ("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. Avadel had several products marketed under this Act and have at least one product under development.

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 and allots quotas of controlled drugs to manufacturers and marketers' 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.

cGMP. Current Good Manufacturing Practices rules apply to the manufacturing of drugs and medical devices. In addition to regulations enforced by the FDA, Avadel is also subject to French, U.S. and other countries' rules and regulations governing permissible laboratory activities, waste disposal, handling of toxic, dangerous or radioactive materials and other matters. Avadel's R&D involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds. Although Avadel believes that its safety procedures for handling and disposing of such materials comply with the standards prescribed by French, EU, U.S. and other foreign rules and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated.

Health Care Fraud and Abuse. Avadel is subject to a number of federal and state laws pertaining to health care "fraud and abuse," such as anti-kickback and false claims laws. Under anti-kickback laws, it is illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance via regulations and that there are few court decisions addressing industry practices, it is possible that Avadel's practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (such as the Medicare and Medicaid programs) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Avadel's sales and marketing activities relating to its products could be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal health care programs (including Medicare and Medicaid) and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. In addition, similar sanctions and penalties can be imposed upon executive officers and employees, including criminal sanctions against executive officers. As a result of the potential penalties that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the U.S. government were to allege or convict Avadel or its executive officers of violating these laws, Avadel's business could be harmed. In addition, private individuals have the ability to bring similar actions. In addition to the reasons noted above, Avadel's activities could be subject to challenge due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities. There also are an increasing number of U.S. federal and state laws that require manufacturers to make reports to states on pricing, marketing information, and payments and other transfers of value to healthcare providers. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, Avadel's reporting actions could be subject to the penalty provisions of the pertinent authorities.

Healthcare Privacy and Security Laws. Avadel may be subject to, or its marketing activities may be limited by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology and

Clinical Health Act and their respective implementing regulations, which established uniform standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. Among other things, HIPAA's privacy and security standards are directly applicable to "business associates" – independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. In addition to possible civil and criminal penalties for violations, state attorney generals are authorized to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. In the EU/EEA, Directive 95/46/EEC (as amended) or its successor applies to identified or identifiable personal data processed by automated means (*e.g.*, a computer database of customers) and data contained in, or intended to be part of, non-automated filing systems (traditional paper files) as well as transfer of such data to a country outside of the EU/EEA.

"Sunshine" and Marketing Disclosure Laws. There are an increasing number of U.S. federal and state "sunshine" laws that require pharmaceutical manufacturers to make reports to states on pricing and marketing information. Several U.S. states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, and make periodic public disclosures on sales and marketing activities, and prohibiting certain other sales and marketing practices. In addition, a similar recently implemented federal requirement requires manufacturers, including pharmaceutical manufacturers, to track and report to the federal government certain payments and other transfers of value made to physicians and other healthcare professionals and teaching hospitals and ownership or investment interests held by physicians and their immediate family members. The U.S. federal government began disclosing the reported information on a publicly available website in 2014. These laws may adversely affect Avadel's sales, marketing, and other activities with respect to its medicines in the U.S. by imposing administrative and compliance burdens on us. If Avadel fails to track and report as required by these laws or otherwise comply with these laws, it could be subject to the penalty provisions of the pertinent U.S. state and federal authorities.

Government Price Reporting. For those marketed medicines which are covered in the U.S. by the Medicaid programs, Avadel has various obligations, including government price reporting and rebate requirements, which generally require medicines be offered at substantial rebates/discounts to Medicaid and certain purchasers (including "covered entities" purchasing under the 340B Drug Discount Program). Avadel is also required to discount such medicines to authorized users of the Federal Supply Schedule of the General Services Administration, under which additional laws and requirements apply. These programs require submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations, and the guidance governing such calculations is not always clear. Compliance with such requirements can require significant investment in personnel, systems and resources, but failure to properly calculate Avadel's prices, or offer required discounts or rebates could subject it to substantial penalties. One component of the rebate and discount calculations under the Medicaid and 340B programs, respectively, is the "additional rebate", a complex calculation which is based, in part, on the rate at which a branded drug price increases over time more than the rate of inflation (based on the CPI-U). This comparison is based on the baseline pricing data for the first full quarter of sales associated with a branded drug's NDA, and baseline data cannot generally be reset, even on transfer of the NDA to another manufacturer. This "additional rebate" calculation can, in some cases where price increases have been relatively high versus the first quarter of sales of the NDA, result in Medicaid rebates up to 100 percent of a drug's "average manufacturer price" and 340B prices of one penny.

Healthcare Reimbursement

In both U.S. and non-U.S. markets, sales of Avadel's potential products as well as products of pharmaceutical and biotechnology companies that incorporate Avadel's technology into their products, if any, will depend in part on the availability of reimbursement by third-party payers, such as government health administration authorities, private health insurers and other organizations. The U.S. market for pharmaceutical products is increasingly being shaped by managed care organizations, pharmacy benefit managers, cooperative buying organizations and large drugstore chains. Third-party payers are challenging the price and cost effectiveness of medical products and services. Uncertainty particularly exists as to the reimbursement status of newly approved healthcare products. There can be no assurance reimbursement will be available to enable Avadel to maintain price levels sufficient to realize an appropriate return on our product development investment. Legislation and regulations affecting the pricing of pharmaceuticals may change before Avadel's proposed products are approved for marketing and any such changes could further limit reimbursement for medical products and services.

Human Capital Resources

As of December 31, 2020, we had approximately 32 employees, all of which were full-time. None of our employees are subject to a union or other collective bargaining agreement. We believe that our relations with our employees are satisfactory.

At Avadel, the way we work is as important as the results we achieve. Avadel is patient-focused, results-oriented, resilient, and ethical (the "Avadel Values"). In everything we do, we live the Avadel Values. 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.

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 stock-based compensation packages for all levels of employees within the organization as well as a company match for employee retirement programs. We also offer competitive health, dental and life insurance and vacation pay, for all employees.

We expect to add employees in 2021 in anticipation of the potential launch of FT218, pending FT218's approval by the FDA.

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 Product Candidate and Future Product Candidates and Clinical Development

Our product candidate and future product candidates will generally be subject to regulatory approval. If we or our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our ability to generate future revenues may be adversely affected.

Our lead product candidate, FT218, as well as product candidates we may wish to market in the future, may not gain regulatory approval and reach the commercial market for a variety of reasons. We submitted a NDA, for FT218 in December 2020. In February 2021, the FDA assigned FT218 a PDUFA target action date of October 15, 2021.

In the U.S., federal, state and local government agencies, primarily the FDA, regulate all pharmaceutical products, including existing products and those under development. Neither we nor our pharmaceutical and biotechnology partners can control whether we obtain regulatory approval for any of these products or, if obtained, the timing thereof. There may be significant delays in expected product releases while attempting to obtain regulatory approval for products incorporating our technologies. If we or our partners are not successful in timely obtaining such approvals, our revenues and profitability may decline.

Applicants for FDA approval often must submit to the FDA extensive clinical and pre-clinical data, as well as information about product manufacturing processes and facilities and other supporting information. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. The FDA also may require us, or our partners to conduct additional pre-clinical studies or clinical trials.

Similarly, although we anticipate submitting applications for approval for our development products that rely on existing data to demonstrate safety and effectiveness, the FDA may determine that additional studies particular to our product candidate and future product candidates are necessary. If the FDA requires such additional studies, it would impact development plans for those products.

Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new product application, also may delay an approval or result in rejection of an application. For instance, under the FDAAA, we or our partners may be required to develop REMS to ensure the safe use of our lead product candidate. If the FDA disagrees with such REMS proposals, it may be more difficult and costly to obtain regulatory approval for our lead product candidate. Similarly, FDAAA provisions may make it more likely that the FDA will refer a marketing application for a new product to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. This review may add to the time for approval, and, although the FDA is not bound by the recommendation of an advisory committee, objections or concerns expressed by an advisory committee may cause the FDA to delay or deny approval.

The FDA has substantial discretion in the approval process and may disagree with our or our partners' interpretations of data and information submitted in an application, which also could cause delays of an approval or rejection of an application. Even if the FDA approves a product, the approval may limit the uses or indications for which the product may be marketed, restrict distribution of the product or require further studies.

The FDA may also withdraw product approvals for failure to comply with regulatory requirements or if problems follow initial marketing. In the same way, medicinal products for supply on the EU market are subject to marketing authorization by either the European Commission, following an opinion by the European Medicines Agency ("EMA"), or by the competent authorities of EU Member States. Applicants for marketing authorization must submit extensive technical and clinical data essentially in the form of the ICH Common Technical Document. The data is subject to extensive review by the competent authorities, and after such review the data may be considered inappropriate or insufficient. If applications for marketing authorization by pharmaceutical and biotechnology company partners are delayed or rejected, if the therapeutic indications for which the product is approved are limited, or if conditional marketing authorization imposing post-marketing clinical trials or surveillance is

imposed, our revenues, operating results and liquidity may decline and earnings may be negatively impacted.

We must invest substantial sums in research and development ("R&D") in order to remain competitive, and we may not fully recover these investments.

To be successful in the highly-competitive pharmaceutical industry, we must commit substantial resources each year to R&D in order to develop new products and enhance our technologies. In 2020, we spent $20,442 on R&D, the majority of which was on our lead product candidate, FT218. Our ongoing investments in R&D for FT218 as well as possible future products could result in higher costs without a proportionate increase, or any increase, in revenues. The R&D process is lengthy and carries a substantial risk of failure. If our R&D does not yield sufficient products that achieve commercial success, our future operating results will be adversely affected.

Risks Related to Regulation

Our 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 R&D 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 Institutional Review Board ("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 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.

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.

As of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the 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 this pace and delays or setbacks are possible in the future. On July 10, 2020, the FDA announced its goal of restarting domestic on-site inspections during the week of July 20, but such activities will depend on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020, several 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 will be able to complete any required inspections or take other necessary actions in respect to our product candidate or future product candidates.

Our product candidate and future product candidates, if approved by the FDA, may not obtain desired regulatory exclusivities, including orphan drug exclusivity.

Orphan drug status may be granted by the FDA to certain products intended to treat diseases and conditions that affect fewer than 200,000 individuals in the U.S. or, if they affect more than 200,000 individuals in the U.S., there is no reasonable expectation of recovering the cost of developing and making the product available in the U.S. for the applicable disease or condition.

Our lead product candidate, FT218, obtained orphan drug designation for the treatment of narcolepsy from the FDA in January 2018. Generally, a product with orphan drug designation that subsequently receives the first FDA approval for the disease or condition for which it has such designation will be entitled to certain U.S. marketing exclusivity for a period of seven years. FT218 would not be the first sodium oxybate product with such FDA approval. However, if the FDA concludes that FT218 is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care, the FDA could award FT218 with such marketing exclusivity. A designated orphan drug may not however receive orphan drug exclusivity. Among other factors, the FDA will consider the results of our FT218 Phase 3 clinical trial with respect to the efficacy and safety of the previously approved sodium oxybate product. Thus, there can be no assurance that FT218 will receive orphan drug status exclusivity, if approved. In addition, even if such orphan drug marketing exclusivity rights were granted by the FDA, such exclusivity rights may be lost if the FDA later determines that our request for such 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 to be treated with the product. Further, even with respect to the indications for which we have received orphan designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus, for example, approval of our lead product candidate could be blocked for seven years if another company previously obtained approval and orphan drug exclusivity in the U.S. for the same drug and same condition.

We are subject to U.S. federal and state and international laws and regulations prohibiting "kickbacks" and false claims that, if violated, could subject us to substantial penalties, and any challenges to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

We are subject to extensive and complex U.S. federal and state and international laws and regulations, including but not limited to, healthcare "fraud and abuse" laws, such as anti-kickback and false claims laws and regulations pertaining to government benefit program reimbursement, price reporting and regulations, and sales and marketing practices. These laws and regulations are broad in scope and subject to evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our revenues, profitability, and financial condition. In the current environment, there appears to be a greater risk of investigations of possible violations of these laws and regulations. This increased risk is reflected by recent enforcement activity and pronouncements by the US Office of Inspector General of the Department of Health and Human Services that it intends to continue to vigorously pursue fraud and abuse violations by pharmaceutical companies, including through the potential to impose criminal penalties on pharmaceutical company executives. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Healthcare reform and restrictions on reimbursements may limit our financial returns.

Our ability to successfully commercialize our product candidate and future product candidates and technologies, if approved, may depend on the extent to which the government health administration authorities, the health insurance funds in the EU Member States, private health insurers and other third-party payor in the U.S. will reimburse consumers for the cost of these products, which would affect the volume of drug products sold by pharmaceutical and biotechnology companies that incorporate our technology into their products. Third party payor are increasingly challenging both the need for, and the price of, novel therapeutic drugs and uncertainty exists as to the reimbursement status of newly approved therapeutics. The commercial success of our product candidate and future product candidates, if approved, depends in part on the conditions under which products incorporating our technology are reimbursed. Adequate third-party reimbursement may not be available for such drug products to enable us to maintain price levels sufficient to realize an appropriate return on our investments in research and product development, which could materially and adversely affect our business. We cannot predict the effect that changes in the healthcare system, especially cost containment efforts, may have on our business. Any changes or changes due to future legislation governing the pricing and reimbursement of healthcare products in the EU Member States may adversely affect our business.

Regulatory reforms may adversely affect our ability to sell our future products profitably.

From time to time, the U.S. Congress, the Council of the European Union and the European Parliament, as well as the legislators of the EU Member States, adopt changes to the statutes that the FDA, the European Commission and the competent authorities of the EU Member States enforce in ways that could significantly affect our business. In addition, the FDA, the European Commission and the competent authorities of the EU Member States often issue new regulations or guidance, or revise or reinterpret their current regulations and guidance in ways that may significantly affect our business and our product candidate and future product candidates. It is impossible to predict whether legislative changes will be enacted or FDA, EU or EU Member State's regulations, guidance or interpretations changed, and what the impact of any such changes may be. Any such changes could have a significant impact on the path to approval of our proposed products or of competing products, and on our obligations and those of our pharmaceutical industry partners.

Even if we receive marketing approval for our product candidates in the U.S., we may never seek or receive regulatory approval to market our product candidates outside of the U.S., or receive pricing and reimbursement outside the U.S. at acceptable levels. We cannot be certain that we will be able, or willing, to support the submission of a marketing authorization application, or MAA, to the EMA for FT218, or that we will decide to file an MAA with the EMA, or that any such MAA will ever be approved.

Even if we receive marketing approval for FT218 or any of our other product candidates in the U.S., we may not seek, or may seek but never receive, regulatory approval to market our product candidates outside of the U.S. or in any particular country or region, including in the EU. In order to market any product outside of the U.S., we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other countries. Approval procedures vary among countries and can involve additional non-clinical studies or clinical trials, additional work related to manufacturing and analytical testing on controls, and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in other countries. The marketing approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. In particular, in many countries outside of the U.S., products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval may require additional studies and data, and can result in substantial delays in bringing products to market in such countries and such investment may not be justified from a business standpoint given the market opportunity or level of required investment. For example, we anticipate having additional discussions with the EMA to further clarify and evaluate what additional data and information would be required and what other requirements would need to be met for a possible MAA submission for FT218 in the EU, and potential post-marketing clinical development obligations if we file an MAA and our application is approved. We may not find an acceptable regulatory path forward for FT218 in the EU. Even if after additional feedback from the EMA, we decide to generate any required additional data and information and meet any other requirements to be able to file an MAA and the MAA is approved, we may have significant post-approval obligations.

Even if we are able to successfully develop our product candidates and obtain marketing approval in a country, we may not be able to obtain pricing and reimbursement approvals in such country at acceptable levels or at all, and any pricing and reimbursement approval we may obtain may be subject to onerous restrictions such as caps or other hurdles or restrictions on reimbursement. Failure to obtain marketing and pricing approval in countries outside the U.S. without onerous restrictions or limitations related to pricing or any delay or other setback in obtaining such approval, would impair our ability to market our product candidates successfully or at all in such foreign markets. Any such impairment would reduce the size of our potential market or revenue potential, which could have a material adverse impact on our business, results of operations and prospects. Any setback or delay in obtaining regulatory approval for our product candidates or in our ability to commence marketing of our products, if approved, may have a material adverse effect on our business and prospects.

Risks Related to our Reliance on Third-Parties

We may rely on collaborations with third parties to commercialize certain of our product candidates in development and such strategy involves risks that could impair our prospects for realizing profits from such products.

We expect that the commercialization of some of our products in development, which utilize our drug delivery technologies, 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 depend on a single provider of certain services related to the development of our product candidate and any interruption of operations of such provider could significantly delay or have a material adverse effect on our business.

Currently, we use a single source provider for the development, supply of clinical materials and potentially the supply of commercial batches for our lead product candidate, FT218. 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, 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 of our lead product candidate could be delayed. These delays could be extensive and expensive, especially in situations where a substitution was not readily available or required variations of existing regulatory approvals and certifications or additional regulatory approval. 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 our product candidate by our contract, development, and manufacturing organizations ("CDMOs"). 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 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.

Our success depends in large part upon our ability to attract and retain highly qualified personnel. During our operating history, we have assigned many key responsibilities within our Company to a relatively small number of individuals, each of whom has played key roles in executing various important components of our business. We do not maintain material key person life insurance for any of our key personnel. If we lose the services of Greg Divis, our Chief Executive Officer, or other members of our senior executive team, we may have difficulty executing our business plan in the manner we currently anticipate. Further, because each of our key personnel is involved in numerous roles in various components of our business, the loss of any one or more of such individuals could have an adverse effect on our business.

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

Clinical trials are expensive and can take many years to complete, and the outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of potential medicine candidates may not be predictive of the results of later-stage clinical trials. Drug 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 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. 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:

- failure in obtaining regulatory approval to commence a trial;
- failure in 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;
- failure in obtaining institutional review board or ethics committee approval at each site;

- failure in recruiting suitable patients to participate in a trial;
- failure in having patients complete a trial or return for post-treatment follow-up;
- failure in clinical sites dropping out of a trial;
- failure in adding new sites; or
- failure in manufacturing sufficient quantities of medicine candidates for use in clinical trials.

We rely and expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our future clinical trials and while we have and intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

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 our product candidate 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 non-U.S. 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 non-U.S. 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 non-U.S. regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the U.S. Our failure, or the failure of our product suppliers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

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, including any CDMOs that we use, fail to comply with these laws and regulations, the FDA, the European Commission, competent authorities of EU Member States, or other regulatory organizations, may take actions that could significantly restrict or prohibit commercial distribution of our product candidate, future product candidates and products that incorporate our technologies. If the FDA, the European Commission or competent authorities of EU Member States 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, the U.S. or the E.U.;
- suspend or limit our production;
- withdraw or vary approval of marketing applications;
- order the competent authorities of EU Member States to withdraw or vary national authorization; and
- initiate criminal prosecutions.

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. 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.

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.

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

Our future products may not gain market acceptance.

Our future products and technologies may not gain market acceptance among physicians, patients, healthcare payor and medical communities. The degree of market acceptance of any product or technology will depend on a number of factors, including, but not limited to:

- the scope of regulatory approvals, including limitations or warnings in a product's regulatory-approved labeling; or other restrictions under a FDA Risk Evaluations and Mitigations Strategies ("REMS"), program;
- in the case of our product candidates that are controlled substances regulated by the U.S. Drug Enforcement Agency ("DEA"), scheduling classification;
- 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;
- 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; and

- the marketing and distribution support it receives.

If any of our future products or technologies fail to achieve market acceptance, our ability to generate revenue will be limited, which would have a material adverse effect on our business.

If our competitors develop and market technologies or products that are safer or more effective than ours, or obtain regulatory approval and market such technologies or 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.

Our drug delivery technologies compete with technologies provided by several other companies. In particular, delivery technologies and products, could be developed that, if successful, could compete against our drug delivery technologies or future products.
Many of our competitors have substantially greater financial, technological, manufacturing, marketing, managerial and R&D resources and experience than we do. Furthermore, acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance our competitors' resources. Accordingly, our competitors may succeed in developing competing technologies and products, obtaining regulatory approval and gaining market share for their products more rapidly than we do.

Our future revenues may be negatively affected by healthcare reforms and increasing pricing pressures.

Future prices for our pharmaceutical products, if approved, will be substantially affected by reimbursement policies of third-party payors such as government healthcare programs, private insurance plans and managed care organizations; by our contracts with the drug wholesalers who will distribute our products; and by competitive market forces generally. In recent years, third-party payors have been exerting downward pressure on prices at which products will be reimbursed, and the drug wholesale industry has been undergoing consolidation which gives greater market power to the remaining, larger drug wholesalers. Further, the trend toward increased availability of generic products has contributed to overall pricing pressures in the pharmaceutical industry. In the United States, the Medicare Modernization Act ("MMA"), contains provisions that call for the promulgation of regulations that expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. Further, the MMA provides that these changes to U.S. importation laws will not take effect, unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of the HHS made such certification to Congress, and on October 1, 2020, FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. Since the issuance of the final rule, several industry groups have filed federal lawsuits challenging multiple aspects of the final rule, and authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. 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. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code ("NDC"), for an FDA-approved drug that was originally intended to be marketed in a non-U.S. country and that was authorized for sale in that country. The market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability. Similarly, any future changes in laws, regulations, practices or policies, in the drug wholesale industry, or in the prevalence of generic products, may adversely affect our financial condition and results of operations.

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.

If we are unable to establish effective sales, marketing and distribution capabilities for our product candidate, 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 such product candidate, 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 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. 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 unexpected limitations in the scope, breadth or amount of reimbursement covering FT218 or other limitations or issues related to the price. Any of these issues could impair our ability to successfully commercialize the product 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.

Even if we receive marketing approval for our product candidate, we may still face significant post-marketing obligations and future development and regulatory difficulties.

Even if we receive marketing approval for our product candidates, regulatory authorities may impose significant and potentially costly post-marketing obligations, including post-marketing studies and additional CMC work. For example, we expect to have post-marketing commitments if FT218 is approved by the FDA. Regulatory authorities may also impose significant restrictions on our products, including restrictions on indicated uses or marketing.

Our products, if approved, will also be subject to ongoing FDA requirements governing the labeling, packaging, storage and promotion of the product and record keeping and submission of safety and other post-market information. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks, safety and efficacy in pediatric populations or alternate doses or dose regimens. The FDA also has the authority to require, as part of an NDA or post-approval, the submission of a REMS. For example, FT218 will require such a REMS, if approved. Any REMS required by the FDA may lead to increased costs to assure compliance with additional post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs and other regulations. If we or a regulatory agency discover problems with our products, if approved, such as adverse events of unanticipated severity or frequency, or problems with the facility where our products are manufactured or in the manufacturing process, a regulatory agency may impose restrictions on our products, the manufacturer or us, including requiring withdrawal of such products from the market or suspension of manufacturing. If we, our product candidates or approved products, or the manufacturer for our product candidates or products, fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require that we initiate a product recall.

We will need to develop and expand our company to support the commercial launch of our product candidate, if approved, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

We expect that we will continue to increase our workforce and the scope of our operations, including as we build our commercial sales capabilities. To manage our anticipated development and expansion, we must continue to implement and

improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure; or give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than anticipated, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize FT218, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Risks Related to Our 2020 Net Income and 2019 Restructuring Plan

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

We reported net income of $7,028 in 2020, which includes a $45,760 gain from the sale of the Hospital Products. We reported cash used in operating activities of $48,734. Cash and marketable securities as of December 31, 2020 totaled $221,402 driven by the February 2020 Private Placement, the May 2020 Public Offering, and proceeds from the June 30, 2020 sale of the Hospital Products. Our business strategy is to primarily focus on the development and potential FDA approval of FT218 for the treatment of cataplexy or excessive daytime sleepiness ("EDS") in adults with narcolepsy. The successful pursuit of all components of our strategy will require substantial financial resources, and there can be no assurance that our existing cash and marketable securities assets and the cash generated by our operations will be adequate for these purposes. We will likely incur a net loss in 2021 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.

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 (the "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 2023 Notes in order to avoid a default under the Indenture governing such 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 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 our OLE/switch study of FT218, initiate and complete any future clinical trials, manufacture sufficient supply of our lead product candidate or to manufacture FT218 at sufficient scale for commercialization, if approved. We submitted our New Drug Application ("NDA") for FT218 in December 2020, and although the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic, the FDA may not be able to continue its current pace and review timelines could be extended, which could adversely affect our ability to obtain regulatory approval for and to commercialize FT218, particularly on our current projected timelines, increase our operating expenses and have a material adverse effect on our business and financial results.

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.

Two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized in the coming months. 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, which could lead to delays in this trial.

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 or the effectiveness of actions to contain and treat COVID-19, particularly in the geographies where we or our third party suppliers and contract manufacturers, or contract research organizations 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.

We may fail to effectively execute our business strategy.

Our business strategy is to continue to seek FDA approval for FT218. There can be no assurance that we will be successful in this objective; and failure in could negatively impact our business and operating results.

Risks Related to Data Security

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 GDPR, we will face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

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.

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 American Depositary Shares representing our ordinary shares ("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, 2020, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged from $4.06 to $11.75. During the year ended December 31, 2019, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged from $1.09 to $7.70. 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.

Our largest shareholders own a significant percentage of the share capital and voting rights of the Company.

As of December 31, 2020, RTW Investments LP. owned approximately 9.3% of Avadel's outstanding shares (in the form of ADSs), Avoro Capital Advisors LLC owned approximately 7.5% of our outstanding shares (in the form of ADSs) and Vivo Opportunity, LLC and certain of its affiliates owned approximately 6.1% of our outstanding shares (in the form of ADSs). To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, they will remain in a position to exert heightened influence in the election of the directors of the Company and in other corporate actions that require shareholder approval, as well as change of control transactions.

Risks Related to Our Financial Condition

We realized net income in 2020 due to the gain on the sale of the Hospital Products, but we will likely incur a net loss in 2021, and if we are not able to regain profitability in the future, the value of our shares may fall.

We reported net income of $7,028 and a net loss $33,226 for the years ended December 31, 2020 and 2019, respectively. In addition, we will incur substantial expenses to develop our product candidate and we will likely incur a net loss in 2021 as well, the amount of which is not known to us at this time. We cannot predict if we will be able to regain profitability. If we are unable to earn a profit in future periods, the market price of our shares may fall. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

- our ability to develop partnerships and additional commercial applications for our future products;
- our ability to control our costs; and
- general economic conditions.

We may not be successful in our transition to a commercial company.

We do not know when, or if, we will generate any revenue from FT218. There can be no guarantee that the FDA will approve our NDA for FT218 by the target action PDUFA date of October 15, 2021, or if at all, and, if approved, there can be no guarantee that we will be able to launch and successfully commercialize FT218.

We do not expect to generate significant revenue, or any revenue at all, unless or until we obtain marketing approval of, and begin to sell, FT218. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain marketing approval for FT218;
- set an acceptable price for FT218;
- obtain commercial quantities of FT218 at acceptable cost levels;
- commercialize FT218 in the United States or in other key territories by entering into partnership or co-promotion arrangements with third parties;
- obtain third-party coverage or adequate reimbursement for FT218;
- achieve market acceptance of FT218 in the medical community and with third-party payers, including placement in accepted clinical guidelines for the conditions for which FT218 is intended to target; and
- lawfully prevent/delay the introduction by third parties of competitive once-nightly (e.g., generic) products to FT218.

If FT218 is approved by the FDA and becomes available for commercial sale, we expect to incur significant sales and marketing costs to both prepare for and support its commercialization. Even if we receive marketing approval and expend these costs, FT218 may not be commercially successful. We may not generate revenue from FT218 if approved. If we are unable to generate product revenue, we may be unable to continue operations without continued funding.

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. 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. See also the discussion elsewhere in these Risk Factors under the caption "*Our net income and use of cash in operating activities may limit our ability to fully pursue our business strategy.*"

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 R&D 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.

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

As of December 31, 2020, we had $46,003 of net operating losses in the U.S. Of the $46,003 of net operating losses in the U.S., $10,365 were acquired due to the acquisition of FSC and $35,638 are due to the losses at US Holdings. 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 $35,638 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, 2020, we had approximately $118,070 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.

Risks Related to the 2023 Notes

Servicing our 2023 Notes may require a significant amount of cash, and we may not have sufficient cash or the ability to raise the funds necessary to settle exchanges of the 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 Senior Exchangeable Notes. Prior to February 2023, the 2023 Notes are convertible at the option of the holders only under certain conditions or upon the occurrence of certain events. 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 we will likely incur 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.

Under Accounting Standards Codification 470-20, Debt with Conversion and Other Options, which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of the convertible or exchangeable debt instruments (such as the 2023 Notes) that may be settled entirely or partially in cash upon conversion or exchange in a manner that reflects the issuer's economic interest cost. However, entities must first consider the guidance in ASC 815-15, Embedded Derivatives ("ASC 815-15"), to determine if an 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. Should this exception apply, the effect of ASC 470-20 on the accounting for the 2023 Notes is that the equity component would be required to be included in the additional paid-in capital section of shareholders' equity on Avadel's consolidated balance sheet, and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the 2023 Notes. As a result, Avadel would be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the 2023 Notes to their face amount over the term of the 2023 Notes. Avadel would report lower net income in its financial results because ASC 470-20 would require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect Avadel's reported or future financial results, the trading price of the ADSs and the trading price of the 2023 Notes.

In addition, under certain circumstances, convertible or exchangeable debt instruments (such as the 2023 Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the ADSs deliverable upon exchange of the 2023 Notes are not included in the calculation of diluted earnings per share except to the extent that the exchange value of the 2023 Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of ADSs that would be necessary to settle such excess, if we elected to settle such excess in ADSs, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If Avadel is unable to use the treasury stock method in

accounting for the ADSs deliverable upon exchange of the 2023 Notes, then Avadel's diluted earnings per share would be adversely affected.

Exchanges of the 2023 Notes will dilute the ownership interest of Avadel's existing shareholders and holders of the ADSs, including holders who had previously exchanged their 2023 Notes and received 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 Avadel's 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 or Avadel. 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.

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. See "Material U.S. Federal Income Tax Considerations for U.S. Holders—PFIC rules."

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 do not anticipate 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 2020 taxable year, but that our non-U.S. subsidiaries were CFCs in the 2020 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 2021 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.

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.

Not applicable.

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. Additionally, we maintained the lease on the former headquarters of FSC Laboratories, Inc. located in Charlotte, North Carolina. This office space consisted of 6,300 square feet and the lease expired on December 31, 2020.

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.

While we may be engaged in various claims and legal proceedings in the ordinary course of business, we are not involved (whether as a defendant or otherwise) in, and, we have no knowledge of any threat of, any litigation, arbitration or administrative or other proceeding that management believes will have a material adverse effect on our consolidated financial position or results of operations.

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. Each ADS is evidenced by an ADR. The Bank of New York Mellon is the Depositary for the ADRs.

As of March 4, 2021, there were 58,465,151 ordinary shares outstanding, and our closing stock price was $7.56 per share.

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

	2020 Price Range		2019 Price Range	
	High	Low	High	Low
First quarter	$ 10.64	$ 4.06	$ 3.29	$ 1.44
Second quarter	11.75	7.25	3.19	1.09
Third quarter	8.98	5.02	4.47	1.92
Fourth quarter	7.95	5.03	7.70	3.34

Holders

As of March 4, 2021, there were 78 holders of record of our ordinary shares and 65 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, 2020.

Recent Sales of Unregistered Securities

Securities Purchase Agreement

On February 21, 2020, we announced that we entered into a definitive agreement for the sale of our 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.

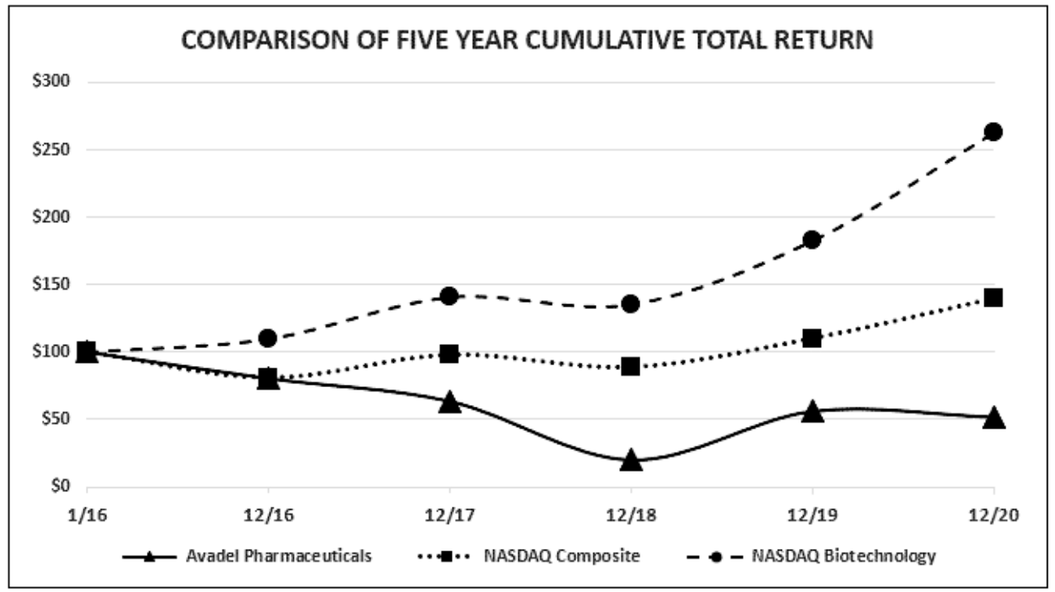
Pursuant to the terms of the private placement, we issued 8,680,225 ADSs and 487,614 shares of Series A Preferred at a price of $7.09 per share, priced at-the-market under Nasdaq rules. Each share of non-voting Series A Preferred is convertible into one ADS, provided that conversion will be prohibited 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. Proceeds from the private placement will be used to fund continued clinical and program development of FT218, including our open-label extension study for REST-ON, a switch study to evaluate patients switching from twice-nightly sodium oxybate to once-nightly FT218, as well as for general corporate purposes.

The private placement was exempt from registration pursuant to Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering.

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, 2016 and our relative performance is tracked through December 31, 2020. 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. Quarterly Financial Data (Unaudited):

The following tables present certain unaudited consolidated quarterly financial information for each quarter of 2020 and 2019. Year-to-date net income (loss) per share amounts may be different than the sum of the applicable quarters due to differences in weighted average shares outstanding for the respective periods.

2020:	**March 31**	**June 30**	**September 30**	**December 31**
Revenues	$ 12,243	$ 10,091	$ —	$ —
Gross profit [(a)]	9,786	6,806	—	—
Operating (loss) income [(b)]	(6,497)	40,269	(13,697)	(14,260)
Net (loss) income	(865)	30,874	(11,703)	(11,278)
Net (loss) income per share - basic	(0.02)	0.57	(0.20)	(0.19)
Net (loss) income per share - diluted	(0.02)	0.49	(0.20)	(0.19)

2019:	**March 31**	**June 30**	**September 30**	**December 31**
Revenues	$ 16,437	$ 17,554	$ 14,229	$ 10,995
Gross profit [(a)]	13,171	13,932	11,406	8,581
Operating loss	(8,167)	(4,451)	(4,147)	(7,347)
Net loss	(13,018)	(8,605)	(8,864)	(2,739)
Net loss per share - basic	(0.35)	(0.23)	(0.24)	(0.07)
Net loss per share - diluted	(0.35)	(0.23)	(0.24)	(0.07)

[(a)] Gross profit is computed by subtracting cost of products from total revenues.
[(b)] Operating income for the quarter ended June 30, 2020 includes a gain on the sale of the hospital business of $45,760.

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

MANAGEMENT'S DISCUSSION AND ANALYSIS

(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 2018 was included in the Company's Annual Report on Form 10-K for the year-ended December 31, 2019, on pages 42 through 56, 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 16, 2020.

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") and 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, the Company submitted a New Drug Application ("NDA") to the FDA for FT218 to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy.The NDA for FT218 was accepted by the FDA in February 2021 and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021.

Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio. As of December 31, 2020, we do not have any approved and 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 and 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. Sodium oxybate is approved in the U.S. for the treatment of EDS and 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 with an assigned PDUFA target action date of October 15, 2021.

The REST-ON trial was a randomized, double-blind, placebo-controlled study that enrolled 212 patients 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 a statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test, or MWT, clinical global impression-improvement, or CGI-I, and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g also demonstrated a 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, which makes the drug 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 initiating an open-label extension ("OLE")/switch study of FT218 as a potential treatment for EDS and 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 if they participated in REST-ON or not. We anticipate that the study will enroll up to 250 patients, many of which will be enrolled in North American clinical trial sites that participated in the REST-ON study.

We believe FT218 has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standard of care for EDS and cataplexy in patients with narcolepsy, which is a twice-nightly sodium oxybate formulation. If approved, we believe FT218 has the potential to take a significant share of the sodium oxybate market. The current market size for the twice-nightly administration of sodium oxybate is estimated at an annualized revenue run rate of $1.8 billion.

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 reduce safety issues and improve a number of things like efficacy, dosing compliance and patient satisfaction. Beyond FT218, we believe there could be other product development opportunities for our Micropump drug-delivery technology, representing either i) life cycle opportunities, whereby additional intellectual property-protected drug delivery technology can be added to a pharmaceutical product to extend the commercial viability of that product, or ii) innovative formulation opportunities for known active pharmaceutical ingredients as well as new chemical entities.

Previously Approved FDA Products

On June 30, 2020 (the "Closing Date"), Avadel Legacy Pharmaceuticals, LLC (the "Avadel Seller") announced the sale of the portfolio of sterile injectable drugs used in the hospital setting (the "Hospital Products"), which included our three commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, which was approved by the U.S. FDA to Exela Sterile Medicines LLC ("Exela Buyer") pursuant to an asset purchase agreement by and among the Avadel Seller, Avadel US Holdings, Inc., the Exela Buyer and Exela Holdings, Inc. This sale included the following FDA approved products:

- **Bloxiverz (neostigmine methylsulfate injection) -** Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery.

- **Vazculep (phenylephrine hydrochloride injection) -** Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

- **Akovaz (ephedrine sulfate injection) -** Akovaz was the first FDA approved formulation of ephedrine sulfate, an alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

- **Nouress (cysteine hydrochloride injection) -** Nouress is a sterile injectable product for use in the hospital setting to provide parenteral nutrition to neonates.

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 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 our 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. Specifically, we have seen, or likely will see, additional generic competition to our current and future products and we continue to expect generic competition 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 and/or expensive and, as a result, could create liquidity challenges for us.

- **Net Loss from Operations in 2021**: We sold our Hospital Products at June 30, 2020 and will no longer generate revenue from sales of these products. We will incur substantial expenses to further the clinical development and prepare for the launch of FT218, if approved, and expect to incur a net loss in 2021, which we are unable to estimate at this time.

Impact of COVID-19

Since early 2020, we have seen the profound impact that the novel coronavirus ("COVID-19") is having on human health, the global economy and society at large. We have been actively monitoring the COVID-19 situation and have taken measures to mitigate the potential impacts to our employees and business, such as implementing a work from home policy. We believe the impact of COVID-19 and measures to prevent its spread could impact our business in a number of ways, including: i) possibly delaying any remaining development activities for FT218, the FDA review timeline of FT218, and/or our ongoing RESTORE open-label extension/switch study, ii) disruptions to our supply chain and third parties; and iii) requiring our employees to work from home for an extended period of time. 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.

Financial Highlights

Highlights of our consolidated results for the year ended December 31, 2020 are as follows:

- Revenue was $22,334 for the year ended December 31, 2020 compared to $59,215 in the same period last year. This year over year decrease was primarily the result of the sale of the Hospital Products on June 30, 2020 and increased competition driving lower prices as noted above in our discussion of *Key Business Trends and Highlights*.

- Operating income was $5,815 for the year ended December 31, 2020 compared to an operating loss of $24,112 for the year ended December 31, 2019. The change from operating loss to operating income was due to the gain on the sale of the Hospital Products of $45,760. R&D expenses decreased in the current year by $12,475 and restructuring expenses decreased by $6,484, which also contributed to the change. Further, there was a decline in gross margin in the current year (i.e., total revenues minus cost of products) of $30,498 due to the June 30, 2020 sale of the Hospital Products.

- Net income was $7,028 for the year ended December 31, 2020 compared to net loss of $33,226 in the same period last year.

- Diluted net income per share was $0.13 for the year ended December 31, 2020 compared to diluted net loss per share of $0.89 in the same period last year.

- Cash and marketable securities increased by $157,244 to $221,402 at December 31, 2020 from $64,158 at December 31, 2019. This increase was largely driven by the February 2020 private placement which resulted in proceeds, net of placement agent and other expenses of approximately $61,000, the May 2020 public offering, which resulted in proceeds, net of expenses and underwriting fees of approximately $117,000, cash proceeds from the disposition of the Hospital Products of $25,500, partially offset by $48,734 use of cash in operations during the year ended December 31, 2020.

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. Actual results could differ from those estimates under different assumptions or conditions.

The following accounting policies are based on, among other things, judgments and assumptions made by management that include inherent risks and uncertainties. Management's estimates are based on the relevant information available at the end of each period.

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.

Product Sales

Prior to June 30, 2020, we sold products primarily through wholesalers and considered these wholesalers to be our customers. Under ASC 606, 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 are subject to a variety of price adjustments in arriving at reported net product sales. These adjustments include 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.

License and Milestone Revenue

From time to time we may enter into out-licensing agreements which are within the scope of ASC 606 under which it licenses to third parties certain rights to its products or intellectual property. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, upfront license fees; development, regulatory, and commercial milestone payments; and sales-based royalty payments. Each of these payments results in license revenue. During the years ended December 31, 2020 and 2019, we did not recognize any revenue from license agreements.

Research and Development ("R&D"). R&D expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, 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 R&D tax credits received from the French and Irish government for spending on innovative R&D as an offset of R&D expenses.

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

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. At December 31, 2020, we had unremitted earnings of $3,725 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.

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 test goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. We performed our required impairment test of goodwill and have determined that no impairment of goodwill existed at December 31, 2020 and 2019.

Long-Lived Assets. Long-lived assets include fixed assets and intangible assets. Prior to the sale of the 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. During the fourth quarter of 2018, we recorded a $66,087 impairment charge to the entire acquired developed technology related to Noctiva. We determined that no impairment existed at December 31, 2019. On June 30, 2020, we transferred our remaining intangible asset to the Exela Buyer as part of the disposition of the Hospital Products. We determined that no impairment existed at December 31, 2020 on our remaining long-lived assets.

Acquisition-related Contingent Consideration. Prior to the sale of the Hospital Products on June 30, 2020, the acquisition-related contingent consideration payables arising from the acquisition of Éclat Pharmaceuticals (i.e., our hospital products) and FSC (our pediatrics products), which was assumed by the buyer as part of the disposition of the pediatrics products on February 16, 2018, were accounted for at fair value (see *Note 13: Contingent Consideration Payable* and *Note 18: Divestiture of the Pediatric Assets*). The fair value of the warrants issued in connection with the Éclat acquisition were estimated using a Black-Scholes model. A portion of these warrants were exercised on February 23, 2018 and the remaining warrants expired on March 12, 2018. See *Note 13: Contingent Consideration Payable*. The fair value of acquisition-related contingent consideration payable is estimated using a discounted cash flow model based on the long-term sales or gross profit forecasts of the specified hospital or pediatric products using an appropriate discount rate. There are a number of estimates used when determining the fair value of these earn-out payments. These estimates include, but are not limited to, the long-term pricing environment, market size, market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows. These estimates can and often do change based on changes in current market conditions, competition, management judgment and other factors. Changes to these estimates can have and have had a material impact on our consolidated statements of income (loss) and balance sheets. Changes in fair value of these liabilities are recorded in the consolidated statements of income (loss) within operating expenses as changes in fair value of contingent consideration.

Financing-related Royalty Agreements. We were previously a party to two royalty agreements in connection with certain financing arrangements. We elected the fair value option for the measurement of the financing-related contingent consideration payable associated with the royalty agreements with certain Deerfield and Broadfin entities (the "Deerfield and Broadfin Royalty Agreements") (see *Note 13: Contingent Consideration Payable*). Prior to the sale of the Hospital Products on June 30, 2020, the fair value of financing-related royalty agreements was estimated using the same components used to determine the fair value of the acquisition-related contingent consideration noted above, with the exception of cost of products sold. Changes to these components can also have a material impact on our consolidated statements of income (loss) and balance sheets. Changes in the fair value of this liability are recorded in the consolidated statements of income (loss) as other (expense) income - changes in fair value of contingent consideration payable. In connection with the disposition of the Hospital Products on June 30, 2020 as discussed in *Note 4: Disposition of the Hospital Products,* the Deerfield and Broadfin Royalty Agreements were assigned to the Exela Buyer and the Exela Buyer assumed and shall pay, perform, satisfy and discharge the liabilities and obligations of the Company under the Deerfield and Broadfin Royalty Agreements.

Results of Operations

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

	Years Ended December 31,		Increase / (Decrease)	
Comparative Statements of Income (Loss):	**2020**	**2019**	**$**	**%**
Product sales	$ 22,334	$ 59,215	$ (36,881)	(62.3)%
Operating expenses:				
Cost of products	5,742	12,125	(6,383)	(52.6)%
Research and development expenses	20,442	32,917	(12,475)	(37.9)%
Selling, general and administrative expenses	32,405	30,183	2,222	7.4 %
Intangible asset amortization	406	816	(410)	(50.2)%
Changes in fair value of contingent consideration	3,327	845	2,482	293.7 %
Gain on sale of Hospital Products	(45,760)	—	(45,760)	(100.0)%
Restructuring (income) costs	(43)	6,441	(6,484)	(100.7)%
Total operating expenses	16,519	83,327	(66,808)	(80.2)%
Operating income (loss)	5,815	(24,112)	29,927	124.1 %
Investment and other (expense) income, net	(832)	1,069	(1,901)	(177.8)%
Interest expense	(12,994)	(12,483)	(511)	(4.1)%
Gain from release of certain liabilities	3,364	—	3,364	100.0 %
Loss on deconsolidation of subsidiary	—	(2,678)	2,678	100.0 %
Other expense - changes in fair value of contingent consideration payable	(435)	(378)	(57)	(15.1)%
Loss before income taxes	(5,082)	(38,582)	33,500	86.8 %
Income tax benefit	(12,110)	(5,356)	(6,754)	(126.1)%
Net income (loss)	$ 7,028	$ (33,226)	$ 40,254	121.2 %
Net income (loss) per share - diluted	$ 0.13	$ (0.89)	$ 1.02	114.6 %

The product sales for each of our significant products were as follows:

Product Sales	Years Ended December 31, 2020	2019	Increase / (Decrease) $	%
Bloxiverz	$ 2,201	$ 7,479	$ (5,278)	(70.6)%
Vazculep	10,429	33,152	(22,723)	(68.5)%
Akovaz	9,545	18,642	(9,097)	(48.8)%
Other	159	(58)	217	374.1 %
Product sales	22,334	59,215	(36,881)	(62.3)%

Total product sales were $22,334 for the year ended December 31, 2020, compared to $59,215 for the same prior year period. The decline in product sales is driven by the sale of the Hospital Products on June 30, 2020 as well as increased competition.

Cost of Products	Years Ended December 31, 2020	2019	Increase / (Decrease) $	%
Cost of products	$ 5,742	$ 12,125	$ (6,383)	(52.6)%
Percentage of sales	25.7 %	20.5 %		

Cost of products decreased by $6,383, or 52.6% during the year ended December 31, 2020 compared to the prior year driven by the June 30, 2020 sale of the Hospital Products.

Research and Development Expenses	Years Ended December 31, 2020	2019	Increase / (Decrease) $	%
Research and development expenses	$ 20,442	$ 32,917	$ (12,475)	(37.9)%

Research and development ("R&D") expenses decreased by $12,475 or 37.9% during the year ended December 31, 2020 as compared to the same period in 2019. The decline was driven by lower R&D expenses related to the development of FT218 of approximately $8,700 due to the completion of the Phase 3 clinical study during the first quarter of 2020, as well as lower payroll, benefits and share-based compensation of approximately $3,800 related to the 2019 Corporate and French restructuring plans. See *Note 19: Restructuring Costs*. The Company continues to invest a substantial portion of R&D in its FT218 development program.

Selling, General and Administrative Expenses	Years Ended December 31, 2020	2019	Increase / (Decrease) $	%
Selling, general and administrative expenses	$ 32,405	$ 30,183	$ 2,222	7.4 %

Selling, general and administrative ("SG&A") expenses increased by $2,222 or 7.4% during the year ended December 31, 2020 as compared to the prior year. This increase was primarily due to an increase in consulting and professional fees, marketing research costs, insurance costs and legal fees totaling approximately $8,800, partially offset by a decrease in payroll and benefits of approximately $2,200 due to the 2019 restructuring plans and a decrease in travel and entertainment costs of approximately $900 due to COVID. In addition, there was a decrease of approximately $2,200 of sales and marketing costs related to the exit of Noctiva during the first quarter 2019 and a decrease of approximately $1,000 related to non-recurring adjustments to certain liabilities related to the Hospital Products.

Intangibles Asset Amortization	Years Ended December 31, 2020	2019	Increase / (Decrease) $	%
Intangible asset amortization	$ 406	$ 816	$ (410)	(50.2)%

Intangible asset amortization expense for the years ended December 31, 2020 and 2019 relates to the amortization of our acquired developed technology - Vazculep. This intangible asset was written off as a result of the sale of the Hospital Products to the Exela Buyer on June 30, 2020. See *Note 4: Disposition of the Hospital Products*.

Changes in Fair Value of Contingent Consideration	Years Ended December 31, 2020	2019	Increase / (Decrease) $	%
Changes in fair value of contingent consideration	$ 3,327	$ 845	$ 2,482	293.7 %

Prior to the sale of the Hospital Products on June 30, 2020, we computed the fair value of the contingent consideration using several significant assumptions and when these assumptions change, due to underlying market conditions, the fair value of these liabilities change as well. Each of the underlying assumptions used to determine the fair values of these contingent liabilities can, and often do, change based on adjustments in current market conditions, competition and other factors. These changes had a material impact on our consolidated statements of income (loss) 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.

As a result of changes in the underlying assumptions used to determine the estimated fair values of our acquisition-related contingent consideration earn-out payments - Éclat, we recorded expense of $3,327 and $845 and increased the fair value of the acquisition-related contingent consideration earn-out payments - Éclat for the years ended December 31, 2020 and 2019, respectively. Subsequent to June 30, 2020, we had no remaining liability.

Gain on the Sale of the Hospital Products	Years Ended December 31, 2020	2019	Increase / (Decrease) $	%
Gain on the sale of the Hospital Products	$ (45,760)	$ —	$ (45,760)	(100.0)%

On June 30, 2020, we sold our assets, rights and interests related to Bloxiverz, Vazculep, Akovaz and Nouress to the Exela Buyer pursuant to an asset purchase agreement by and among us and the Exela Buyer. We recognized a net gain of $45,760 on this transaction. See *Note 4: Disposition of the Hospital Products*.

Restructuring (Income) Costs	Years Ended December 31, 2020	2019	Increase / (Decrease) $	%
Restructuring (income) costs	$ (43)	$ 6,441	$ (6,484)	(100.7)%

Restructuring income of $43 and costs of $6,441 were recognized during the years ended December 31, 2020 and 2019, respectively. Restructuring income during the year ended December 31, 2020, was driven by share-based compensation forfeitures as a result of the 2019 Corporate restructuring actions. Restructuring costs for the year ended December 31, 2019 were primarily related to the 2019 French and Corporate restructuring plans and mainly included severance, legal costs. See *Note 19: Restructuring Costs* for further details.

Investment and Other (Expense) Income, net	Years Ended December 31, 2020	2019	Increase / (Decrease) $	%
Investment and other (expense) income, net	$ (832)	$ 1,069	$ (1,901)	(177.8)%

Investment and other expense was $832 for the year ended December 31, 2020 as compared to investment and other income of $1,069 for the year ended December 31, 2019. Expense in the current year was driven by an $800 legal settlement related to a bankruptcy claim, an increase in net unrealized losses and net realized losses on our marketable securities during the current period when compared to the prior period of approximately $2,100, and higher currency remeasurement losses of

approximately $400 due to the weakening of the U.S. dollar during the year ended December 31, 2020, partially offset by a legal settlement of $1,750 which was incurred during the twelve months ended December 31, 2020.

	Years Ended December 31,		Increase / (Decrease)	
Interest Expense	**2020**	**2019**	**$**	**%**
Interest expense	$ (12,994)	$ (12,483)	$ (511)	(4.1)%

Interest expense of $12,994 and $12,483 for the years ended December 31, 2020 and 2019, respectively, is related to interest on the 2023 Notes that were issued in February 2018.

	Years Ended December 31,		Increase / (Decrease)	
Gain from release of certain liabilities	**2020**	**2019**	**$**	**%**
Gain from release of certain liabilities	$ 3,364	$ —	$ 3,364	100.0 %

Subsequent to the finalization of the bankruptcy, we recognized a non-cash gain of $3,364 from the release of certain liabilities that had been retained following the deconsolidation of Specialty Pharma in February 2019.

	Years Ended December 31,		Increase / (Decrease)	
Loss on Deconsolidation of Subsidiary	**2020**	**2019**	**$**	**%**
Loss on deconsolidation of subsidiary	$ —	$ (2,678)	$ 2,678	100.0 %

As a result of Specialty Pharma's bankruptcy filing on February 6, 2019, we concluded that we no longer controlled its operations and accordingly deconsolidated this subsidiary. We recorded a loss during the year ended December 31, 2019 on the deconsolidation as a result of removing the net assets and certain liabilities of this subsidiary from our consolidated financial statements. See *Note 3: Subsidiary Bankruptcy and Deconsolidation* for more discussion.

	Years Ended December 31,		Increase / (Decrease)	
Other Expense - Changes in Fair Value of Contingent Consideration Payable	**2020**	**2019**	**$**	**%**
Other expense - changes in fair value of contingent consideration payable	$ (435)	$ (378)	$ (57)	(15.1)%

We recorded expense of $435 and $378 to increase the fair value of these liabilities during the years ended December 31, 2020 and 2019, respectively, due to the same reasons associated with changes in certain underlying market conditions as described in the section "Changes in Fair Value of Contingent Consideration" for these periods.

	Years Ended December 31,		Increase / (Decrease)	
Income Taxes	**2020**	**2019**	**$**	**%**
Income tax benefit	$ (12,110)	$ (5,356)	$ (6,754)	(126.1)%
Percentage of income (loss) before income taxes	238.3 %	13.9 %		

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 our hospital products and passage of the Coronavirus Aid, Relief and Economic Security Act (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. See *Note 14: Income Taxes* for more discussion.

Liquidity and Capital Resources

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	**2020**	**2019**	**$**	**%**
Operating activities	$ (48,734)	$ (38,325)	$ (10,409)	(27.2)%
Investing activities	(69,721)	38,723	(108,444)	(280.1)%
Financing activities	179,683	(27)	179,710	665,592.6 %

Operating Activities

Net cash used in operating activities of $48,734 for the year ended December 31, 2020 increased from net cash used in operating activities of $38,325 in the prior year. This increase in cash used in operating activities is due to the decrease in accounts payable and accrued expenses of $21,012, partially offset by lower earn-out and royalty payments of $6,547 related to our contingent consideration liabilities due to the sale of the Hospital Products and increased cash provided by accounts receivable of $5,810 due to the collection of all outstanding accounts receivable balances during the year ended December 31, 2020.

Investing Activities

Cash used in investing activities was $69,721 for the year ended December 31, 2020 compared to cash provided by investing activities of $38,723 in the same prior year period. In 2020, we had net purchases of marketable securities of $95,123, partially offset by proceeds of $25,500 received from the sale of the Hospital Products. In 2019, we had net proceeds of $38,598 for the sale of marketable securities

Financing Activities

Cash provided by financing activities was $179,683 for the year ended December 31, 2020 compared to cash used in financing activities of $27 for the same prior year period. Cash provided by financing activities for the year ended December 31, 2020 was driven by the May public offering that resulted in net proceeds of $116,924, the February private placement that resulted in net proceeds of $60,570, and proceeds from the issuance of ordinary shares of $2,189.

Liquidity and Risk Management

The adequacy of our cash resources depends on the outcome of certain business conditions including the cost of our FT218 clinical development plan, 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 plan 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 that COVID-19, which may have a material adverse impact on our business.

In February 2020, we announced that we had entered into a definitive agreement for the sale of our 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.

Also, in February 2020, we filed a shelf registration statement on Form S-3 (the "2020 Shelf Registration Statement") that allows issuance and sale by us, from time to time, of :

- up to $250,000 in aggregate of ordinary shares, nominal value US$0.01 per share, each of which may be represented by ADSs, preferred shares, nominal value US$0.01 per share, debt securities, warrants to purchase ordinary shares, ADSs, preferred shares and/or debt securities, 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

- 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 2020 Shelf Registration Statement, the Base Prospectus and the terms of the sales agreement prospectus contained in the 2020 Shelf Registration Statement.

On April 28, 2020, we 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 being offered by Avadel. The gross proceeds to us from the offering were approximately $125,000, before deducting underwriting discounts and commissions and estimated offering expenses, which resulted in net proceeds of $116,924.

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

Cash, cash equivalent and marketable security balances as of December 31, 2020 and unused financing sources are expected to provide the Company with the flexibility to meet its liquidity needs in 2021, including its operating requirements related to the development 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, 2020 and December 31, 2019, 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.

Material Commitments

At December 31, 2020, we have one commitment with a 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 $4,000 and is expected to be started and completed during the year ending December 31, 2021.

The Company also has a commitment with a contract manufacturer related to the construction and preparation of a production suite at the contract manufacturer's facility, which is substantially complete at December 31, 2020. Subsequent to the initial build and preparation of the production suite, this commitment also includes annual fees which would commence at the start of production of validation batches and continue thereafter for five years.

We and our subsidiaries lease office facilities under non-cancellable operating leases expiring at various dates. See *Note 11: Leases*.

Aggregate Contractual Obligations

The following table presents our contractual obligations at December 31, 2020:

	Payments Due by Period				
Contractual Obligations:	**Total**	**Less than 1 Year**	**1 to 3 Years**	**3 to 5 Years**	**More than 5 Years**
Long-term debt and interest	$ 159,922	$ 6,469	$ 153,453	$ —	$ —
Purchase commitments	4,000	4,000	—	—	—
Operating leases	2,590	578	1,192	820	—
Total contractual cash obligations	$ 166,512	$ 11,047	$ 154,645	$ 820	$ —

See *Note 12: Long-Term Debt* to our consolidated financial statements contained in Item 8 – Financial Statements for obligations with respect to the respective items within the above table.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

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, 2020 would have had an immaterial impact on net income for the year ended December 31, 2020.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in investment and other (expense) income, net in the consolidated statements of income (loss). As of December 31, 2020, 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, 2020.

Item 8. Financial Statements and Supplementary Data.

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

	Years ended December 31,		
	2020	**2019**	**2018**
Revenues:			
Product sales	$ 22,334	$ 59,215	$ 101,423
License revenue	—	—	1,846
Total revenues	22,334	59,215	103,269
Operating expenses:			
Cost of products	5,742	12,125	17,516
Research and development expenses	20,442	32,917	39,329
Selling, general and administrative expenses	32,405	30,183	100,359
Intangible asset amortization	406	816	6,619
Changes in fair value of contingent consideration	3,327	845	(22,731)
Gain on sale of Hospital Products	(45,760)	—	—
Impairment of intangible asset	—	—	66,087
Restructuring (income) costs	(43)	6,441	1,016
Total operating expenses	16,519	83,327	208,195
Operating income (loss)	5,815	(24,112)	(104,926)
Investment and other (expense) income, net	(832)	1,069	452
Interest expense	(12,994)	(12,483)	(10,622)
Gain from release of certain liabilities	3,364	—	—
Loss on deconsolidation of subsidiary	—	(2,678)	—
Other (expense) income - changes in fair value of contingent consideration payable	(435)	(378)	1,899
Loss before income taxes	(5,082)	(38,582)	(113,197)
Income tax benefit	(12,110)	(5,356)	(17,893)
Net income (loss)	$ 7,028	$ (33,226)	$ (95,304)
Net income (loss) per share - basic	$ 0.13	$ (0.89)	$ (2.55)
Net income (loss) per share - diluted	$ 0.13	$ (0.89)	$ (2.55)
Weighted average number of shares outstanding - basic	52,996	37,403	37,325
Weighted average number of shares outstanding - diluted	54,941	37,403	37,325

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2020	**2019**	**2018**
Net income (loss)	$ 7,028	$ (33,226)	$ (95,304)
Other comprehensive income (loss), net of tax:			
Foreign currency translation gain (loss)	1,111	(117)	(419)
Net other comprehensive income, net of $(202), $(43), $(18) tax, respectively	644	727	269
Total other comprehensive income (loss), net of tax	1,755	610	(150)
Total comprehensive income (loss)	$ 8,783	$ (32,616)	$ (95,454)

See accompanying notes to consolidated financial statements.

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 71,722	$ 9,774
Marketable securities	149,680	54,384
Accounts receivable	—	8,281
Inventories, net	—	3,570
Research and development tax credit receivable	3,326	2,107
Prepaid expenses and other current assets	38,726	4,264
Total current assets	263,454	82,380
Property and equipment, net	359	544
Operating lease right-of-use assets	2,604	3,612
Goodwill	16,836	18,491
Intangible assets, net	—	813
Research and development tax credit receivable	3,445	6,322
Other non-current assets	24,939	39,274
Total assets	$ 311,637	$ 151,436
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term contingent consideration payable	$ —	$ 5,554
Current portion of operating lease liability	474	645
Accounts payable	2,934	6,100
Accrued expenses	6,501	19,810
Other current liabilities	5,200	3,875
Total current liabilities	15,109	35,984
Long-term debt	128,210	121,686
Long-term contingent consideration payable, less current portion	—	11,773
Long-term operating lease liability	1,840	2,319
Other non-current liabilities	4,212	8,873
Total liabilities	149,371	180,635
Shareholders' equity (deficit):		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at December 31, 2020 and 0 issued and outstanding at December 31, 2019	5	—
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 58,396 issued and outstanding at December 31, 2020, and 42,927 issued and 37,520 outstanding at December 31, 2019	583	429
Treasury shares, at cost, 0 and 5,407 shares held at December 31, 2020 and December 31, 2019, respectively	—	(49,998)
Additional paid-in capital	566,916	434,391
Accumulated deficit	(384,187)	(391,215)
Accumulated other comprehensive loss	(21,051)	(22,806)
Total shareholders' equity (deficit)	162,266	(29,199)
Total liabilities and shareholders' equity (deficit)	$ 311,637	$ 151,436

See accompanying notes to consolidated financial statements.

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

	Ordinary shares Shares	Ordinary shares Amount	Preferred shares Shares	Preferred shares Amount	Treasury Shares Shares	Treasury Shares Amount	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total shareholders' equity (deficit)
Balance, December 31, 2017	41,463	$ 414	—	$ —	2,117	$ (22,361)	$ 393,478	$ (262,685)	$ (23,266)	$ 85,580
Net loss	—	—	—	—	—	—	—	(95,304)	—	(95,304)
Other comprehensive loss	—	—	—	—	—	—	—	—	(150)	(150)
Exercise of stock options	82	1	—	—	—	—	534	—	—	535
Exercise of warrants	603	6	—	—	—	—	2,905	—	—	2,911
Expiration of warrants	—	—	—	—	—	—	2,167	—	—	2,167
Vesting of restricted shares	547	6	—	—	—	—	(6)	—	—	—
Employee share purchase plan share issuance	25	—	—	—	—	—	127	—	—	127
Share-based compensation expense	—	—	—	—	—	—	7,852	—	—	7,852
Equity component of 2023 Notes	—	—	—	—	—	—	26,699	—	—	26,699
Share repurchases	—	—	—	—	3,290	(27,637)	—	—	—	(27,637)
Balance, December 31, 2018	42,720	427	—	—	5,407	(49,998)	433,756	(357,989)	(23,416)	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	—	$ —	5,407	$ (49,998)	$ 434,391	$ (391,215)	$ (22,806)	$ (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)	—	—	(5,407)	49,998	(49,944)	—	—	—
Balance, December 31, 2020	58,396	$ 583	488	$ 5	—	$ —	$ 566,916	$ (384,187)	$ (21,051)	$ 162,266

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2020	**2019**	**2018**
Cash flows from operating activities:			
Net income (loss)	$ 7,028	$ (33,226)	$ (95,304)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:			
Depreciation and amortization	1,690	2,486	7,430
Impairment of intangible asset	—	—	66,087
Remeasurement of acquisition-related contingent consideration	3,327	845	(22,731)
Remeasurement of financing-related contingent consideration	435	378	(1,899)
Amortization of debt discount and debt issuance costs	6,524	5,995	4,830
Changes in deferred tax	(7,431)	(6,334)	(19,152)
Share-based compensation expense	2,999	519	7,852
Gain on the disposition of the Hospital Products	(45,760)	—	—
Loss on deconsolidation of subsidiary	—	1,750	—
Gain from the release of certain liabilities	(3,364)	—	—
Other adjustments	142	(254)	4,188
Net changes in assets and liabilities			
Accounts receivable	8,281	2,471	3,452
Inventories, net	(1,352)	1,155	711
Prepaid expenses and other current assets	1,863	(1,187)	3,577
Research and development tax credit receivable	2,213	(1,014)	(2,545)
Accounts payable & other current liabilities	(2,788)	4,641	(2,032)
Deferred revenue	—	(114)	(1,892)
Accrued expenses	(13,226)	357	(10,640)
Earn-out payments for contingent consideration in excess of acquisition-date fair value	(5,323)	(10,988)	(19,468)
Royalty payments for contingent consideration payable in excess of original fair value	(866)	(1,748)	(2,838)
Other assets and liabilities	(3,126)	(4,057)	(2,342)
Net cash used in operating activities	(48,734)	(38,325)	(82,716)
Cash flows from investing activities:			
Purchases of property and equipment	(98)	(29)	(178)
Proceeds from disposal of property and equipment	—	154	—
Proceeds from the disposition of the Hospital Products	25,500	—	—
Purchase of intangible assets	—	—	(20,000)
Proceeds from sales of marketable securities	36,284	63,246	359,507
Purchases of marketable securities	(131,407)	(24,648)	(376,310)
Net cash (used in) provided by investing activities	(69,721)	38,723	(36,981)
Cash flows from financing activities:			
Proceeds from debt issuance	—	—	143,750
Payments for debt issuance costs	—	—	(6,190)
Exercise of warrants	—	—	2,911
Proceeds from the February 2020 private placement	60,570	—	—
Proceeds from the May 2020 public offering	116,924	—	—
Proceeds from issuance of ordinary shares	2,189	118	577
Share repurchases	—	—	(27,637)
Other financing activities, net	—	(145)	(752)
Net cash provided by (used in) financing activities	179,683	(27)	112,659
Effect of foreign currency exchange rate changes on cash and cash equivalents	720	78	(201)
Net change in cash and cash equivalents	61,948	449	(7,239)
Cash and cash equivalents at January 1	9,774	9,325	16,564
Cash and cash equivalents at December 31	$ 71,722	$ 9,774	$ 9,325
Supplemental disclosures of cash flow information:			
Income taxes (refund) paid, net	$ (1,701)	$ 140	$ 776
Interest paid	6,469	6,469	3,359

See accompanying notes to consolidated financial statements.

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

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. Our lead product candidate, FT218, is an investigational once-nightly, extended-release formulation of sodium oxybate for the treatment of excessive daytime sleepiness ("EDS") and 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, the Company submitted a New Drug Application ("NDA") to the FDA for FT218 to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy.The NDA for FT218 was accepted by the FDA in February 2021 and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021.

Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio. As of December 31, 2020, we do not have any approved and commercialized products in our portfolio.

We are registered as an Irish public limited company. Our headquarters are in Dublin, Ireland and we have operations in St. Louis, Missouri, U.S.

FT218

FT218 is a once-nightly formulation of sodium oxybate that uses our Micropump controlled release drug-delivery technology for the treatment of EDS and 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. Sodium oxybate is approved in the U.S. for the treatment of EDS and 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 with an assigned PDUFA target action date of October 15, 2021.

The REST-ON trial was a randomized, double-blind, placebo-controlled study that enrolled 212 patients 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 a statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test, or MWT, clinical global impression-improvement, or CGI-I, and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g also demonstrated a 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, which makes the drug 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 initiating an open-label extension ("OLE")/switch study of FT218 as a potential treatment for EDS and 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 if they participated in REST-ON or not. We anticipate that the study will enroll up to 250 patients, many of which will be enrolled in North American clinical trial sites that participated in the REST-ON study.

Previously Approved FDA Products

On June 30, 2020 (the "Closing Date"), Avadel Legacy Pharmaceuticals, LLC (the "Avadel Seller") announced the sale of the portfolio of sterile injectable drugs used in the hospital setting (the "Hospital Products"), which included our three commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, which was approved by the U.S. FDA to Exela Sterile Medicines LLC ("Exela Buyer") pursuant to an asset purchase agreement by and among the Avadel Seller, Avadel US Holdings, Inc., the Exela Buyer and Exela Holdings, Inc. This sale included the following FDA approved products:

- **Bloxiverz (neostigmine methylsulfate injection) -** Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery.

- **Vazculep (phenylephrine hydrochloride injection) -** Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

- **Akovaz (ephedrine sulfate injection) -** Akovaz was the first FDA approved formulation of ephedrine sulfate, an alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

- **Nouress (cysteine hydrochloride injection) -** Nouress is a sterile injectable product for use in the hospital setting to provide parenteral nutrition to neonates.

See *Note 4: Disposition of the Hospital Products.*

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.

Our results of operations for the period January 1, 2019 through February 6, 2019 and for year ended December 31, 2018 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.*

Our results of operations for the period January 1, 2018 through February 16, 2018 include the results of FSC Therapeutics and FSC Laboratories, Inc., (collectively "FSC"), prior to its February 16, 2018 disposition date. See *Note 18: Divestiture of the Pediatric Assets*, for additional information.

Reclassifications

Certain reclassifications are made to prior year amounts whenever necessary to conform with the current year presentation. Certain adjustments have been made to the Consolidated Statements of Cash Flows for the fiscal year ended December 31, 2020 and balances within *Note 16: Other Assets and Liabilities* for the year ended December 31, 2019 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. We made certain reclassifications within *Note 10: Goodwill and Intangible Assets*, to the gross value and total accumulated amortization balances of the Vazculep intangible asset as of December 31, 2019. We made certain adjustments to *Note 24: Company Operations by Product, Customer, and Geographic Area* to include comparable information for customers that became significant for the year ended December 31, 2020.

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.

Effective January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers" ("ASC 606") using the modified retrospective transition method applied to all open contracts as at December 31, 2017. The adoption of the new standard did not have a material effect on the overall timing or amount of revenue recognized when compared to prior accounting standards. See *Note 5: Revenue Recognition.*

ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when the performance obligations to the customer have been satisfied through the transfer of control of the goods or services. To determine the appropriate revenue recognition for arrangements that the Company believes are within the scope of ASC 606,

we perform the following five steps: (i) Identify the contract(s) with a customer; (ii) Identify the performance obligations in the contract; (iii) Determine the transaction price; (iv) Allocate the transaction price to the performance obligations in the contract; and (v) Recognize revenue when (or as) the entity satisfies a performance obligation. The Company applies the five-step model to contracts only when the Company and its customer's rights and obligations under the contract can be determined, the contract has commercial substance, and it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. For contracts that are determined to be within the scope of ASC 606, the Company identifies the promised goods or services in the contract to determine if they are separate performance obligations or if they should be bundled with other goods and services into a single performance obligation. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Sales

Prior to June 30, 2020, we sold products primarily through wholesalers and considered these wholesalers to be our customers. Under ASC 606, 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 are subject to a variety of price adjustments in arriving at reported net product sales. These adjustments include 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.

License and Milestone Revenue

From time to time we may enter into out-licensing agreements which are within the scope of ASC 606 under which it licenses to third parties certain rights to its products or intellectual property. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, upfront license fees; development, regulatory, and commercial milestone payments; and sales-based royalty payments. Each of these payments results in license revenue.

For a complete discussion of the accounting for net product revenue and license revenues, see *Note 5: Revenue Recognition*.

Research and Development ("R&D"). R&D expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, 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 R&D tax credits received from the French and Irish government for spending on innovative R&D as an offset of R&D expenses.

Advertising Expenses. We expense the costs of advertising as incurred. Advertising expenses were $312, $372 and $17,562 for the years ended December 31, 2020, 2019 and 2018, respectively. The decrease in advertising for the years ended December 31, 2020 and 2019 is due to Specialty Pharma's bankruptcy and deconsolidation. See *Note 3: Subsidiary Bankruptcy and Deconsolidation*.

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

Income Taxes. We account 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, we determine 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.

We recognize deferred tax assets to the extent that we believe that these assets are more likely than not to be realized. In making such a determination, we consider 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 we determine that we would be able to realize our deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

We record uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) we determine 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, we recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

We recognize interest and penalties related to unrecognized tax benefits in the income tax expense line in the accompanying consolidated statements of income (loss). Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheets.

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

Marketable Securities. The Company's marketable securities are considered to be available for sale and are carried at fair value, with unrealized gains and losses, net of taxes, reported as a component of accumulated other comprehensive (loss) income ("AOCI") in shareholders' equity, with the exception of unrealized gains and losses on equity instruments and unrealized losses believed to be other-than-temporary, if any, which are reported in earnings in the current period. The cost of securities sold is based upon the specific identification method.

Accounts Receivable. Prior to the sale of the Hospital Products on June 30, 2020, accounts receivable were stated at amounts invoiced net of allowances for credit losses and certain other gross to net variable consideration deductions. 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. A majority of our accounts receivable were due from four significant customers.

Inventories. Prior to the sale of the Hospital Products on June 30, 2020, inventories consisted of raw materials and finished products, which were stated at lower of cost or net realizable value, using the first-in, first-out ("FIFO") method. The Company established reserves for inventory estimated to be obsolete, unmarketable or slow-moving on a case by case basis.

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

Software, office and computer equipment	3 years
Leasehold improvements, furniture, fixtures and fittings	5-10 years

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 test goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. We performed our required impairment test of goodwill and have determined that no impairment of goodwill existed at December 31, 2020 and 2019.

Long-Lived Assets. Long-lived assets include fixed assets and intangible assets. Prior to the sale of the 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. During the fourth quarter of 2018, we recorded a $66,087 impairment charge to the entire acquired developed technology related to Noctiva. We determined that no impairment existed

at December 31, 2019. On June 30, 2020, we transferred our remaining intangible asset to the Exela Buyer as part of the disposition of the Hospital Products. We determined that no impairment existed at December 31, 2020 on our remaining long-lived assets.

Lease Obligations. On January 1, 2019, the Company adopted ASU 2016-02, "*Leases*" which supersedes ASC 840 "Leases" and creates a new topic, ASC 842 "*Leases*". The Company adopted ASU 2016-02 using the modified retrospective transition approach and elected the transition option to recognize the adjustment in the period of adoption rather than in the earliest period presented. Results and disclosure requirements for reporting periods beginning after January 1, 2019 are presented under Topic 842, while prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under Topic 840. Upon adoption, we recognized total ROU assets of $5,046, with corresponding lease liabilities of $5,131 on the consolidated balance sheets. The adoption did not impact our beginning retained earnings, or our prior year consolidated statements of income (loss) and statements of cash flows.

The Company elected the package of practical expedients permitted under the transition guidance, which allowed us to carryforward our historical lease classification, our assessment on whether a contract was or contains a lease, and our initial direct costs for any leases that existed prior to January 1, 2019. The Company also elected to combine our lease and non-lease components and to keep leases with an initial term of 12 months or less off the balance sheet and recognize the associated lease payments in the consolidated statements of income (loss) on a straight-line basis over the lease term.

Under ASU 2016-02, 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. 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. Our 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 income (loss).

Acquisition-related Contingent Consideration. Prior to the sale of the Hospital Products on June 30, 2020, the acquisition-related contingent consideration payables arising from the acquisition of Éclat Pharmaceuticals (i.e., our hospital products) and FSC (our pediatrics products), which was assumed by the buyer as part of the disposition of the pediatrics products on February 16, 2018, were accounted for at fair value (see *Note 13: Contingent Consideration Payable* and *Note 18: Divestiture of the Pediatric Assets*). The fair value of the warrants issued in connection with the Éclat acquisition were estimated using a Black-Scholes model. A portion of these warrants were exercised on February 23, 2018 and the remaining warrants expired on March 12, 2018. See *Note 13: Contingent Consideration Payable*. The fair value of acquisition-related contingent consideration payable is estimated using a discounted cash flow model based on the long-term sales or gross profit forecasts of the specified hospital or pediatric products using an appropriate discount rate. There are a number of estimates used when determining the fair value of these earn-out payments. These estimates include, but are not limited to, the long-term pricing environment, market size, market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows. These estimates can and often do change based on changes in current market conditions, competition, management judgment and other factors. Changes to these estimates can have and have had a material impact on our consolidated statements of income (loss) and balance sheets. Changes in fair value of these liabilities are recorded in the consolidated statements of income (loss) within operating expenses as changes in fair value of contingent consideration.

Financing-related Royalty Agreements. We were previously a party to two royalty agreements in connection with certain financing arrangements. We elected the fair value option for the measurement of the financing-related contingent consideration payable associated with the royalty agreements with certain Deerfield and Broadfin entities (the "Deerfield and Broadfin Royalty Agreements") (see *Note 13: Contingent Consideration Payable*). Prior to the sale of the Hospital Products on June 30, 2020, the fair value of financing-related royalty agreements was estimated using the same components used to determine the fair value of the acquisition-related contingent consideration noted above, with the exception of cost of products sold. Changes to these components can also have a material impact on our consolidated statements of income (loss) and balance sheets. Changes in the fair value of this liability are recorded in the consolidated statements of income (loss) as other (expense) income - changes in fair value of contingent consideration payable. In connection with the disposition of the Hospital Products on June 30, 2020 as discussed in *Note 4: Disposition of the Hospital Products,* the Deerfield and Broadfin Royalty Agreements were assigned to the Exela Buyer and the Exela Buyer assumed and shall pay, perform, satisfy and discharge the liabilities and obligations of the Company under the Deerfield and Broadfin Royalty Agreements.

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 our consolidated statements of income (loss) 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 August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-13, "*Fair Value Measurement (Topic 820): Disclosure Framework— Changes to the Disclosure Requirement for Fair Value Measurement*" which amends certain disclosure requirements over Level 1, Level 2 and Level 3 fair value measurements. The amendments in ASU 2018-13 are effective for fiscal years beginning after December 15, 2019, with early adoption permitted. We adopted ASU 2018-13 in the first quarter of 2020.

In June 2016, the FASB issued ASU No. 2016-13, "*Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13")." This standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 will be effective for the Company for fiscal years beginning on or after January 1, 2020, including interim periods within those annual reporting periods and early adoption is permitted. We adopted the provisions of ASU 2016-13 in the first quarter of 2020. Adoption of the new standard did not have any impact on our consolidated financial statements.

Recent Accounting Guidance Not Yet Adopted

In December 2019, the FASB issued 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 will be effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years and early adoption is permitted. We are currently evaluating the impact of adopting ASU 2019-12; however, the impact is expected to be immaterial to our 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. This ASU will be effective for our 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. We are currently evaluating the impact of adopting ASU 2020-06.

NOTE 3: Subsidiary Bankruptcy and Deconsolidation

Bankruptcy Filing and Deconsolidation

As a result of Specialty Pharma's bankruptcy filing on February 6, 2019, Avadel ceded authority for managing the business to the Bankruptcy Court, and Avadel management could not carry on Specialty Pharma's activities in the ordinary course of business without Bankruptcy Court approval. Prior to Bankruptcy Court approval, Avadel managed the day-to-day operations of Specialty Pharma but did not have discretion to make significant capital or operating budgetary changes or decisions and purchase or sell significant assets, as Specialty Pharma's material decisions were subject to review by the Bankruptcy Court. For these reasons, we concluded that Avadel had lost control of Specialty Pharma, and no longer had significant influence over Specialty Pharma during the pendency of the bankruptcy. Therefore, we deconsolidated Specialty Pharma effective with the filing of the Chapter 11 bankruptcy in February 2019.

In order to deconsolidate Specialty Pharma, the carrying values of the assets and certain liabilities of Specialty Pharma were removed from our unaudited condensed consolidated balance sheet as of February 5, 2019, and we recorded our investment in Specialty Pharma at its estimated fair value of $0. As the estimated fair value of our investment in Specialty Pharma was lower than its net book value immediately prior to the deconsolidation, we recorded a non-cash charge of approximately $2,678 for the year ended December 31, 2019 associated with the deconsolidation of Specialty Pharma. Subsequent to the deconsolidation of Specialty Pharma, we are accounting for our investment in Specialty Pharma using the cost method of accounting because Avadel does not exercise significant influence over the operations of Specialty Pharma due to the Chapter 11 filing.

On April 26, 2019, Specialty Pharma sold its intangible assets and remaining inventory to an unaffiliated third party in exchange for aggregate cash proceeds of approximately $250, pursuant to an order approving such sale which was issued by the Bankruptcy Court on April 15, 2019. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business.

On July 2, 2019, Specialty Pharma was made aware of a $50,695 claim made by the Internal Revenue Service ("IRS") as part of the bankruptcy claims process against Specialty Pharma. On October 2, 2019 the IRS amended the original claim filed in July, reducing the claim to $9,302. Specialty Pharma filed its U.S. federal tax return as a member of the Company's consolidated U.S. tax group. As such, the IRS claim was filed against Specialty Pharma in the bankruptcy proceedings due to IRS tax law requirements for joint and several liability of all members in a consolidated U.S. tax group. On November 19, 2019, Specialty Pharma and the IRS resolved their dispute, subject to the Bankruptcy Court's approval of Specialty Pharma's Chapter 11 plan, and without prejudice to the claims, rights and defenses of the IRS and other Avadel entities outside of the bankruptcy case. The resolution provided for allowance of the IRS claim as a priority claim but for the IRS to receive a distribution of 50% of the proceeds, but in no event less than $125 from Specialty Pharma following confirmation of its disclosure statement and Chapter 11 plan of liquidation.

On July 24, 2020, Specialty Pharma sought bankruptcy court approval of a settlement agreement by and between it, Avadel US Holdings, Inc. and Serenity Pharmaceuticals, LLC ("Serenity") (the "Serenity Settlement Agreement"). Before the commencement of Specialty Pharma's bankruptcy case, Serenity asserted claims against Specialty Pharma and Avadel US Holdings collectively in an amount no less than $50,000, and after the commencement of the bankruptcy case, Serenity asserted a $3,096 claim against Specialty Pharma and voted to reject its Chapter 11 plan of liquidation. The Serenity Settlement Agreement provides for a global resolution of these disputes by way of an $800 payment from Avadel US Holdings to Serenity, a mutual exchange of general releases, and the withdrawal of Serenity's claim and vote in Specialty Pharma's bankruptcy case. The Serenity Settlement Agreement was approved by order of the Bankruptcy Court on August 12, 2020.

At a hearing conducted on October 6, 2020, the Bankruptcy Court granted final approval of Specialty Pharma's disclosure statement and confirmed its Chapter 11 plan of liquidation. Pursuant to the plan, the appointment of a Plan Administrator was also approved. The Plan Administrator will be responsible for making distributions to creditors, managing the final windup and dissolution of Specialty Pharma, and taking other steps in accordance with the plan of liquidation. The plan of liquidation became effective on October 21, 2020. Subsequent to the finalization of the bankruptcy, we recognized a non-cash gain of $3,364 from the release of certain liabilities that had been retained following the deconsolidation of Specialty Pharma. This gain is including in "Gain from release of certain liabilities" within non-operating income (loss) for the year ended December 31, 2020.

Debtor in Possession ("DIP") Financing – Related Party Relationship

In connection with the bankruptcy filing, Specialty Pharma entered into a Debtor in Possession Credit and Security Agreement with Avadel US Holdings ("DIP Credit Agreement") dated as of February 8, 2019, in an aggregate amount of up to $2,700, of which the funds are to be used by Specialty Pharma solely to fund operations through February 6, 2020. During the year ended December 31, 2019, the Company funded $407 under the DIP Credit Agreement. As the Company assessed that it is unlikely that Specialty Pharma will pay back the loan to Avadel, the $407 was recorded as part of the loss on deconsolidation of subsidiary within the consolidated statements of income (loss) during the year ended December 31, 2019. No amounts were funded under the DIP Credit Agreement during the year ended December 31, 2020. We do not expect any additional further liabilities from the DIP Credit Agreement.

NOTE 4: Disposition of the Hospital Products

On June 30, 2020 (the "Closing date"), we announced the sale of our Hospital Products to the Exela Buyer pursuant to the Purchase Agreement (the "Transaction").

Pursuant to the Purchase Agreement, 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 is to be paid in ten equal monthly installments. During the year ended December 31, 2020, we collected four installment payments, totaling $11,000. Subsequent to the year ended December 31, 2020 but prior to the filing of this Annual Report, we collected an additional $5,500 in installment payments. 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.

We were party to a Membership Interest Purchase Agreement, dated March 13, 2012, by and among us, 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 us, 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.

We were also party to a Royalty Agreement, dated December 3, 2013, by and between us, 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.

We 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 statement of income (loss). 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 us due to the sale of the Hospital Products, which are listed below.

	December 31, 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.

We 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 financial statements included below are being provided for information purposes only and are not necessarily indicative of the results of operations or financial position 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 Balance Sheet			
	As of December 31, 2019			
	As Reported	Pro Forma Adjustments	Notes	Pro Forma
ASSETS				
Cash and cash equivalents	$ 9,774	$ 12,935	(a)	$ 22,709
Inventories	3,570	(3,570)	(b)	—
Prepaid expenses and other current assets	4,264	27,500	(c)	31,764
Goodwill	18,491	(1,654)	(d)	16,837
Intangible assets, net	813	(813)	(e)	—
Other non-current assets	39,274	(9,702)	(f)	29,572
Total assets	$ 151,436	$ 24,696		$ 176,132
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)				
Current portion of long-term contingent consideration payable	$ 5,554	$ (5,054)	(g)	$ 500
Accrued expenses	19,810	2,800	(h)	22,610
Long-term contingent consideration payable, less current portion	11,773	(11,773)	(g)	—
Total liabilities	180,635	(14,027)		166,608
Shareholders' equity (deficit):				
Accumulated deficit	(391,215)	38,723	(i)	(352,492)
Total shareholders' (deficit) equity	(29,199)	38,723		9,524
Total liabilities and shareholders' equity (deficit)	$ 151,436	$ 24,696		$ 176,132

Adjustments to the pro forma unaudited condensed combined balance sheet

(a) This adjustment represents the receipt of $14,500 cash consideration from the Exela Buyer at the closing of the Transaction less $1,565 placed into escrow for the estimated earn outs and royalties payable to Breaking Stick Holdings L.L.C., Horizon Santé FLML, Sarl, Deerfield Private Design Fund II, L.P., all affiliates of Deerfield Capital L.P. ("Deerfield") and Broadfin Healthcare Master Fund ("Broadfin") for the current year ended.

(b) This adjustment reflects the elimination of Inventories that were purchased as part of the Transaction.

(c) This adjustment reflects the Transaction consideration in the form of ten monthly installment payments of $2,750 (totaling $27,500) beginning 90 days from the Closing date.

(d) This adjustment reflects the elimination of $1,654 of Goodwill based on the relative fair value of the Hospital Products as a portion of the overall value of the Company.

(e) This adjustment reflects the elimination of the unamortized balance of the Intangible asset on acquired developed technology for Vazculep.

(f) This adjustment reflects the elimination of $1,228 of other long-term assets and $8,474 of deferred tax assets at December 31, 2019. The eliminated deferred tax assets are tax attributes of the Hospital Products.

(g) This adjustment reflects the elimination of short and long term related party payables, less the expected amounts due to Deerfield and Broadfin after taking into consideration the escrow discussed in Note (a). As part of the Transaction, the buyer

agreed to assume the quarterly earn-out and royalty payments for periods after the close of the Transaction. The Company will no longer be responsible for these payments.

(h) This adjustment reflects the estimated transaction fees payable related to the Transaction.

(i) This adjustment reflects the estimated gain of $38,723 arising from the Transaction for the year ended December 31, 2019. This estimated gain has not been reflected in the pro forma unaudited condensed combined statements of loss as it is considered to be nonrecurring in nature. No adjustment has been made to the sale proceeds to give effect to any potential post-closing adjustments under the terms of the Purchase Agreement.

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

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

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

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

(k) 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.

(l) This amount reflects the adjustments noted in (j) and (k) 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.

(m) 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.

(n) This amount reflects the adjustments noted in (j) and (m) 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, we sold products primarily through wholesalers and considered these wholesalers to be our customers. Revenue from product sales was recognized when the customer obtained control of our product and our performance obligations were met, which occurred typically upon receipt of delivery to the customer. As is customary in the pharmaceutical industry, our 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 were 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 is payable to the customer, except in the case of the estimated reserve for future expired product returns, which are classified as a liability. The reserves are classified as a liability if the amount is payable to a party other than a customer. Where appropriate, these estimated reserves take into consideration relevant factors such as 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 reflect the Company's best estimates to reduce gross selling price to net selling price to which it expects to be entitled based on the terms of its contracts. The actual selling price ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company adjusts these estimates, which would affect earnings in the period such variances become known.

Product Returns

Consistent with industry practice, the Company maintains a returns policy that generally offers 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 is 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 our wholesale customers. Customers charge 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 are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargebacks, discounts and rebates are estimated at the time of sale to the customer.

Revenue from licensing arrangements

The terms of the Company's licensing agreements may contain multiple performance obligations, including certain R&D activities. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments. Each of these payments are recorded as license revenues. The Company did not have any license revenue during the years ended December 31, 2020 and 2019. License revenue during the year ended December 31, 2018 was $1,846.

License of Intellectual Property

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the

license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

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 24: 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, 2020 and 2019.

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 from performance obligations satisfied (or partially satisfied) in previous periods were immaterial.

For certain licenses of intellectual property, specifically those with performance obligations satisfied over time, the Company allocates a portion of the transaction price to that performance obligation and recognizes revenue using an appropriate measure of progress towards development of the product. In December 2018, we reached an agreement to exit a contract and our remaining performance obligations and recognized the remaining $1,600 of deferred revenue, which represented the unsatisfied performance obligations associated with a license agreement. At December 31, 2020 and 2019, the deferred revenue balance related to this obligation is $0.

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

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

- Income approach, which is based on the present value of a future stream of net cash flows.
- Market approach, which is based on market prices and other information from market transactions involving identical or comparable assets or liabilities.

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

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

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

	As of December 31, 2020			As of December 31, 2019		
Fair Value Measurements:	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Marketable securities (see *Note 7)*						
Equity securities	$ —	$ —	$ —	$ 4,404	$ —	$ —
Money market and mutual funds	104,672	—	—	38,799	—	—
Corporate bonds	—	22,155	—	—	4,098	—
Government securities - U.S.	—	18,999	—	—	5,446	—
Other fixed-income securities	—	3,854	—	—	1,637	—
Total assets	$ 104,672	$ 45,008	$ —	$ 43,203	$ 11,181	$ —
Contingent consideration payable (see *Note 13)*	—	—	—	—	—	17,327
Total liabilities	$ —	$ —	$ —	$ —	$ —	$ 17,327

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, 2020, there were no transfers in and out of Level 1, 2, or 3. During the twelve months ended December 31, 2020, 2019 and 2018, we did not recognize any other-than-temporary impairment loss.

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

Debt

We estimate the fair value of our $143,750 aggregate principal amount of 4.50% exchangeable senior notes due 2023 (the "2023 Notes"), a Level 2 input, 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. The estimated fair value of the 2023 Notes at December 31, 2020 is $128,210, which is the same as book value.

See *Note 12: Long-Term Debt* for additional information regarding our debt obligations.

NOTE 7: Marketable Securities

The Company has investments in equity and available-for-sale debt securities which are recorded at fair market value. The change in the fair value of equity investments is recognized in our consolidated statements of income (loss) and the change in the fair value of available-for-sale debt investments is recorded as other comprehensive income (loss) in shareholders' equity (deficit), net of income tax effects. As of December 31, 2020, we considered any decreases in fair value on our marketable securities to be driven by factors other than credit risk, including market risk.

The following tables show the 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, 2020 and 2019, respectively:

	2020			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Money market and mutual 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

	2019			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Equity securities	$ 4,234	$ 170	$ —	$ 4,404
Money market and mutual funds	38,028	771	—	38,799
Corporate bonds	4,021	77	—	4,098
Government securities - U.S.	5,341	110	(5)	5,446
Other fixed-income securities	1,614	23	—	1,637
Total	$ 53,238	$ 1,151	$ (5)	$ 54,384

We determine realized gains or losses on the sale of marketable securities on a specific identification method. We reflect these gains and losses as a component of investment and other income in the accompanying consolidated statements of income (loss).

We recognized gross realized gains of $474, $483, and $317 for the twelve months ended December 31, 2020, 2019, and 2018, respectively. These realized gains were offset by realized losses of $912, $151, and $565 for the twelve-months ended December 31, 2020, 2019, and 2018, respectively.

The following table summarizes the estimated fair value of our 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, 2020:

	Maturities				
Marketable Debt Securities:	**Less than 1 Year**	**1-5 Years**	**5-10 Years**	**Greater than 10 Years**	**Total**
Corporate bonds	$ 6,054	$ 14,468	$ 1,633	$ —	$ 22,155
Government securities - U.S.	—	13,827	2,038	3,134	18,999
Other fixed-income securities	1,017	2,837	—	—	3,854
Total	$ 7,071	$ 31,132	$ 3,671	$ 3,134	$ 45,008

We have classified our 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 our investment portfolio.

Total gross unrealized losses of our available-for-sale debt securities at December 31, 2020 were immaterial. The unrealized losses are driven by factors other than credit risk and have been in a unrealized loss position for less than one year. We do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost bases.

NOTE 8: Inventories

The principal categories of inventories, net of reserves of $0 and $914 at December 31, 2020 and 2019, respectively, are comprised of the following:

Inventory:	**2020**	**2019**
Finished goods	$ —	$ 3,020
Raw materials	—	550
Total	$ —	$ 3,570

The decrease in inventory at December 31, 2020 is a result of the June 30, 2020 disposition of the Hospital Products. See *Note 4: Disposition of the Hospital Products*.

NOTE 9: Property and Equipment, net

The principal categories of property and equipment, net at December 31, 2020 and 2019, respectively, are as follows:

Property and Equipment, net:	**2020**	**2019**
Software, office and computer equipment	$ 1,443	$ 1,258
Furniture, fixtures and fittings	300	300
Less - accumulated depreciation	(1,384)	(1,014)
Total	$ 359	$ 544

Depreciation expense for the years ended December 31, 2020, 2019 and 2018 was $287, $459 and $811, respectively.

NOTE 10: Goodwill and Intangible Assets

The Company's amortizable and unamortizable intangible assets at December 31, 2020 and 2019, respectively, are as follows:

	2020			2019		
Goodwill and Intangible Assets:	**Gross Value**	**Accumulated Amortization**	**Net Carrying Amount**	**Gross Value**	**Accumulated Amortization**	**Net Carrying Amount**
Acquired developed technology - Vazculep [1]	$ —	$ —	$ —	$ 12,061	$ (11,248)	$ 813
Unamortizable intangible assets - Goodwill [2]	$ 16,836	$ —	$ 16,836	$ 18,491	$ —	$ 18,491

[1] This intangible asset was assumed by the Exela Buyer as part of the disposition of the Hospital Products on June 30, 2020. See *Note 4: Disposition of the Hospital Products*.

[2] In connection with the disposition of the Hospital Products (see *Note 4: Disposition of the Hospital Products*), the Company allocated goodwill of $1,655 on a relative fair value basis to the Hospital Products and included this amount in the net gain on the disposition of the Hospital Products on the consolidated statement of income (loss) during the year ended December 31, 2020.

The Company recorded amortization expense related to amortizable intangible assets of $406, $816 and $6,619 for the years ended December 31, 2020, 2019 and 2018, respectively.

No impairment loss related to goodwill or intangible assets was recognized during the years ended December 31, 2020 or 2019.

NOTE 11: Leases

On January 1, 2019, the Company adopted ASU 2016-02, "*Leases*", using the modified retrospective transition approach and elected the transition option to recognize the adjustment in the period of adoption rather than in the earliest period presented. At December 31, 2020, the balances of the operating lease right-of-use asset and total operating lease liability were $2,604 and $2,314, respectively, of which $474 of the operating lease liability is classified as a current liability.

All of the Company's office spaces are leased. The Company also leases a production suite. All leased facilities are classified as operating leases with remaining lease terms between one and five years. The Company determines if a contract is a lease at the inception of the arrangement. The Company reviews all options to extend, terminate, or purchase its right-of-use assets at the inception of the lease and will include these options in the lease term when they are reasonably certain of being exercised. For all of the Company's leases, lease and non-lease components are accounted for as a single lease component, as all non-lease components are immaterial.

The components of lease costs, which are included in selling, general and administrative expenses in the consolidated statements of income (loss) of years ended December 31, 2020 and 2019 were as follows:

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

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

During the years ended December 31, 2020 and 2019, the Company reduced its operating lease liabilities by $769 and $1,480 for cash paid. During the year ended December 31, 2020, there were no new operating or finance leases entered into. As of December 31, 2020, the Company is aware of one additional potential embedded lease that has not yet commenced and will not commence until certain conditions are met. If these conditions are met and the start date is determined, annual fees would commence and at that time an operating lease right-of-use asset and corresponding operating lease liability will be recorded.

As of December 31, 2020, our operating leases have a weighted-average remaining lease term of 4.3 years and a weighted-average discount rate of 5.3%. Avadel's lease contracts do not provide a readily determinable implicit rate. Avadel'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**
2021	$ 578
2022	590
2023	602
2024	614
2025	206
Thereafter	—
Total lease payments	2,590
Less: interest	276
Present value of lease liabilities	$ 2,314

NOTE 12: Long-Term Debt

Long-term debt is summarized as follows:

	December 31, 2020	**December 31, 2019**
Principal amount of 4.50% exchangeable senior notes due 2023	$ 143,750	$ 143,750
Less: unamortized debt discount and issuance costs, net	(15,540)	(22,064)
Net carrying amount of liability component	128,210	121,686
Less: current maturities	—	—
Long-term debt	$ 128,210	$ 121,686
Equity component:		
Equity component of exchangeable notes, net of issuance costs	$ (26,699)	$ (26,699)

2023 Notes

On February 16, 2018, Avadel Finance Cayman Limited, a Cayman Islands exempted company (the "Issuer") and an indirect wholly-owned subsidiary of the Company, issued $125,000 aggregate principal amount of 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.

We 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. We determined that this exception applies due, in part, to our ability to settle the 2023 Notes in cash, ADSs or a combination of cash and ADSs, at our option. We have therefore applied the guidance provided by ASC 470-20, Debt with Conversion and Other Options which requires that the 2023 Notes be separated into debt and equity components at issuance and a value be assigned to each. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the 2023 Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the 2023 Notes and the fair value of the liability of the 2023 Notes on its issuance date. The excess of the principal amount of the liability component over its carrying amount (the "Debt Discount") is amortized to interest expense using the effective interest method over the term of the 2023 Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

NOTE 13: Contingent Consideration Payable

Contingent consideration payable and related activity are reported at fair value and consist of the following at December 31, 2020 and 2019, respectively:

		Activity during the Twelve Months Ended December 31, 2020				
			Changes in Fair Value of Contingent Consideration Payable			
	Balance, December 31, 2019	Payments	Operating Expense	Other Expense	Disposition of the Hospital Products	Balance, December 31, 2020
Acquisition-related contingent consideration:						
Earn-out payments - Éclat Pharmaceuticals [(a) (d)]	$ 15,472	$ (5,323)	$ 3,327	$ —	$ (13,476)	$ —
Financing-related:						
Royalty agreement - Deerfield [(b) (d)]	1,251	(587)	—	272	(936)	—
Royalty agreement - Broadfin [(c) (d)]	604	(279)	—	163	(488)	—
Total contingent consideration payable	17,327	$ (6,189)	$ 3,327	$ 435	$ (14,900)	—
Less: current portion	(5,554)					—
Total long-term contingent consideration payable	$ 11,773					$ —

(a) In March 2012, the Company acquired all of the membership interests of Éclat from Breaking Stick Holdings, L.L.C. ("Breaking Stick", formerly Éclat Holdings), an affiliate of Deerfield. Breaking Stick is majority owned by Deerfield, with a minority interest owned by the Company's former CEO, and certain other current and former employees. As part of the consideration, the Company committed to provide quarterly earn-out payments equal to 20% of any gross profit generated by certain Éclat products. These payments will continue in perpetuity, to the extent gross profit of the related products also continue in perpetuity. In connection with the disposition of the Hospital Products on June 30, 2020 as discussed in *Note 4: Disposition 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 and the Company under the Deerfield Royalty Agreement.

(b) As part of a February 2013 debt financing transaction conducted with Deerfield, the Company received cash of $2,600 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 1.75% royalty on the net sales of certain Éclat products until December 31, 2024. In connection with such debt financing transaction, the Company granted Deerfield a security interest in the product registration rights of the Éclat Pharmaceuticals products. In connection with the disposition of the Hospital Products on June 30, 2020 as discussed in *Note 4: Disposition 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 and the Company under the Deerfield Royalty Agreement.

(c) As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund, a former related party and shareholder, the Company received cash of $2,200 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 0.834% royalty on the net sales of certain Éclat products until December 31, 2024. In connection with the disposition of the Hospital Products on June 30, 2020 as discussed in *Note 4: Disposition 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 the Company under the Broadfin Royalty Agreement.

(d) Deerfield and Broadfin Healthcare Master Trust 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.

Prior to the sale of the Hospital Products on June 30, 2020, the fair value of each contingent consideration payable listed in (a), (b) and (c) above was estimated using a discounted cash flow model based on estimated and projected annual net revenues or gross profit, as appropriate, of each of the specified Éclat products using an appropriate risk-adjusted discount rate of 14%. These fair value measurements are based on significant inputs not observable in the market and thus represent a level 3 measurement as defined in ASC 820. Subsequent changes in the fair value of the acquisition-related contingent consideration payables, resulting primarily from management's revision of key assumptions, will be recorded in the consolidated statements of income (loss) in the line items entitled "Changes in fair value of contingent consideration" for items noted in (b) above and in "Other (expense) income - changes in fair value of contingent consideration payable" for items (b) and (c) above. See *Note 1: Summary of Significant Accounting Policies* under the caption Acquisition-related Contingent Consideration and Financing-related Royalty Agreements for more information on key assumptions used to determine the fair value of these liabilities.

Prior to June 30, 2020, the Company chose to make a fair value election pursuant to ASC 825, "Financial Instruments" for its royalty agreements detailed in items (b) and (c) above. These financing-related liabilities were recorded at fair market value on the consolidated balance sheets and the periodic change in fair market value is recorded as a component of "Other expense – change in fair value of contingent consideration payable" on the consolidated statements of income (loss).

The following table summarizes changes to the contingent consideration payables, a recurring Level 3 measurement, for the twelve-month periods ended December 31, 2020, 2019 and 2018:

Contingent Consideration Payable:	Balance
Balance at December 31, 2017	$ 98,925
Payments of related party payable	(22,951)
Fair value adjustments [1]	(24,630)
Expiration of warrants	(2,167)
Disposition of the pediatrics assets	(20,337)
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 income (loss).

NOTE 14: Income Taxes

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

(Loss) Income Before Income Taxes:	2020	2019	2018
Ireland	$ (27,205)	$ (50,134)	$ (42,604)
U.S.	22,335	10,401	(70,340)
France	(212)	1,151	(253)
Total loss before income taxes	$ (5,082)	$ (38,582)	$ (113,197)

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

Income Tax (Benefit) Provision:	2020	2019	2018
Current:			
U.S. - Federal	$ (12,810)	$ —	$ —
U.S. - State	20	97	330
Total current	(12,790)	97	330
Deferred:			
Ireland	—	(1,256)	—
U.S. - Federal	680	(4,093)	(19,503)
U.S. - State	—	(104)	1,280
Total deferred	680	(5,453)	(18,223)
Income tax benefit	$ (12,110)	$ (5,356)	$ (17,893)

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:	2020	2019	2018
Statutory tax rate	12.5 %	12.5 %	12.5 %
Differences in international tax rates	(34.5)%	3.2 %	8.0 %
Nondeductible changes in fair value of contingent consideration	(19.4)%	(0.3)%	4.0 %
Intercompany asset transfer	— %	21.2 %	— %
Change in valuation allowances	(83.3)%	(19.1)%	(5.3)%
Nondeductible stock-based compensation	(20.9)%	(2.7)%	(1.3)%
Hospital Products sale	183.5 %	— %	— %
Unrealized tax benefits	5.4 %	0.7 %	(1.3)%
State and local taxes (net of federal)	(0.4)%	— %	(0.3)%
Change in U.S. tax law	179.5 %	— %	(0.2)%
Nondeductible interest expense	(34.0)%	(2.5)%	(1.1)%
Orphan drug and R&D tax credit	55.0 %	— %	— %
Other	(5.1)%	0.9 %	0.7 %
Effective income tax rate	238.3 %	13.9 %	15.7 %
Income tax benefit - at statutory tax rate	$ (636)	$ (4,823)	$ (14,149)
Differences in international tax rates	1,755	(1,218)	(9,039)
Nondeductible changes in fair value of contingent consideration	988	121	(4,559)
Intercompany asset transfer	—	(8,190)	—
Change in valuation allowances	4,231	7,379	5,998
Nondeductible stock-based compensation	1,060	1,039	1,499
Hospital Products sale	(9,328)	—	—
Unrecognized tax benefits	(274)	(261)	1,440
State and local taxes (net of federal)	20	(7)	299
Change in U.S. tax law	(9,124)	—	274
Nondeductible interest expense	1,728	982	1,269
Orphan drug and R&D tax credit	(2,793)	—	—
Other	263	(378)	(925)
Income tax benefit - at effective income tax rate	$ (12,110)	$ (5,356)	$ (17,893)

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 our hospital products and passage of the Coronavirus Aid, Relief and Economic Security Act (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.

In 2019, the income tax benefit decreased by $12,537 when compared to the same period in 2018. The decrease in the income tax benefit in 2019 was primarily driven by the impairment of the Noctiva intangible asset in 2018, which did not recur in 2019. In addition to the non-recurring impairment, an increase in the valuation allowance in 2019, when compared to the same period in 2018 also contributed to the decrease in tax benefit recorded in 2019. As a part of a corporate reorganization, the Company entered into an internal sale transaction in December 2019. The internal sale transaction included transfer of intangible assets from an Irish entity to a U.S. entity. The internal sale transaction resulted in a decrease of $5,536 to Irish deferred tax asset with corresponding decrease of $5,536 to valuation allowance, an increase of $8,190 to U.S. deferred tax asset associated with amortization of intangible assets, and a $8,190 deferred tax benefit.

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 2016. 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 Company settled the $1,937 assessment. The French tax authority completed an examination of the Company's French tax returns for 2017 and 2018 during 2020, noting no change.

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	2020	2019	2018
Balance at January 1:	$ 6,465	$ 5,315	$ 3,954
Additions based on tax positions related to the current year	—	—	1,087
Increases for tax positions of prior years	—	2,416	274
Statute of limitations expiration	—	(1,266)	—
Settlements	(3,322)	—	—
Balance at December 31:	$ 3,143	$ 6,465	$ 5,315

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, 2020, 2019 and 2018, there are $2,483, $3,806 and $4,597 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, 2020, 2019 and 2018, the Company recognized approximately $203, $555 and $725 in interest and penalties. The Company had approximately $1,475 and $1,612 for the payment of interest and penalties accrued at December 31, 2020 and 2019, 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, 2020 and 2019 resulted from the following temporary differences:

Net Deferred Tax Assets and Liabilities:	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 31,302	$ 30,275
Amortization	3,701	11,602
Stock based compensation	2,626	3,577
Accounts receivable	—	53
Fair value contingent consideration	—	264
Orphan drug and R&D tax credit	2,793	—
Other	423	901
Gross deferred tax assets	40,845	46,672
Deferred tax liabilities:		
Amortization	—	(172)
Prepaid expenses	(75)	(35)
Other	(890)	—
Gross deferred tax liabilities	(965)	(207)
Less: valuation allowances	(21,624)	(17,038)
Net deferred tax assets	$ 18,256	$ 29,427

At December 31, 2020, the Company had $118,070 of net operating losses in Ireland that do not have an expiration date and $46,003 of net operating losses in the U.S. Of the $46,003 of net operating losses in the U.S., $10,365 were acquired due to the acquisition of FSC and $35,638 are due to the losses at US Holdings. The portion due to the acquisition of FSC will expire in 2034 through 2035. The Company also has $2,793 of U.S. tax credits available to reduce future income tax payable that have no expiration date. A valuation allowance is recorded if, based on the weight of available evidence, it is more likely than not that a deferred tax asset will not be realized. This assessment is based on an evaluation of the level of historical taxable income and projections for future taxable income. For the year ended December 31, 2020, the Company recorded $4,171 of valuation allowances related to Irish net operating losses and $60 of valuation allowances related French 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.

We recorded a valuation allowance against all of our net operating losses in Ireland and France as of December 31, 2020, and all of our net operating losses in Ireland as of December 31, 2019. We intend 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. In 2019, the Company removed $3,259 of French net operating losses and the corresponding valuation allowance as a result of the 2019 restructuring activities in France. See *Note 19: Restructuring Costs*.

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 our assessment of the realizability of our 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, 2020, the Company has unremitted earnings of $3,725 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 we were to sell our stock in the subsidiaries, net of any prior income taxes paid. It is not practicable to estimate the amount of deferred tax liability on such earnings, if any.

R&D Tax Credits Receivable

The French and Irish governments provide tax credits to companies for spending on innovative R&D. These credits are recorded as an offset of R&D expenses and are credited against income taxes payable in years after being incurred or, if not so utilized, are recoverable in cash after a specified period of time, which may differ depending on the tax credit regime. As of December 31, 2020, our 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. As of December 31, 2019, our net Research tax credit receivable amounts to $8,429 and represents a French gross research tax credit of $7,608 and an Irish gross research tax credit of $821.

In 2020, the Company recorded $2,793 for the U.S. Orphan Drug Tax Credit and the U.S. Research & Development Tax Credit. These credits are recorded as an income tax benefit in the year and are currently recorded as deferred tax assets because the credits are not recoverable in cash.

2020 CARES Act

The Coronavirus Aid, Relief and Economic Security 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 ("NOLs"). Under the temporary provisions of the CARES Act, NOL carryforwards and carrybacks may offset 100% of taxable income for taxable years beginning before 2021. In addition, NOLs 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 our ability under the CARES Act to carry back NOLs incurred to periods when the statutory U.S. Federal tax rate was 35% versus our 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 estimates it will file refund claims associated with the carryback of 2020 tax losses.

2017 Tax Cuts and Jobs Act

On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act includes significant changes to the U.S. corporate income tax system including: a federal corporate rate reduction from 35% to 21%; limitations on the deductibility of interest expense and executive compensation; creation of the base erosion anti-abuse tax ("BEAT") and a new minimum tax. As a result of the Tax Act being signed into law, we recognized a provisional charge of $274 in 2018 related to the re-measurement of its U.S. net deferred tax assets and certain unrecognized tax benefits at the lower enacted corporate tax rates. A majority of the provisions in the Tax Act were effective January 1, 2018.

NOTE 15: Post-Retirement Benefit Plans

Retirement Indemnity Obligation – France

French law requires the Company to provide for the payment of a lump sum retirement indemnity to French employees based upon years of service and compensation at retirement. The retirement indemnity has been actuarially calculated on the assumption of voluntary retirement at a government-defined retirement age. Benefits do not vest prior to retirement. Any actuarial gains or losses are recognized in the Company's consolidated statements of income (loss) in the periods in which they occur.

During the second quarter of 2019, the Company initiated a plan to substantially reduce all of its workforce at its Vénissieux, France site ("2019 French Restructuring"). As a result of this decision, the Company reversed the French retirement indemnity obligation and recorded a curtailment gain of $1,000 during the year ended December 31, 2019. At December 31, 2020, there are no future expected retirement indemnity benefits to be paid. See *Note 19: Restructuring Costs*.

NOTE 16: 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:	**2020**	**2019**
Valued-added tax recoverable	$ 341	$ 1,051
Prepaid and other expenses	1,018	2,116
Guarantee from Armistice	318	454
Income tax receivable (see *Note 14*)	18,615	536
Receivable from Exela (see *Note 4*)	16,500	—
Short-term deposit	1,477	—
Other	457	107
Total	$ 38,726	$ 4,264

Other Non-Current Assets:	**2020**	**2019**
Deferred tax assets	$ 18,256	$ 29,427
Long-term deposits	—	1,477
Guarantee from Armistice	1,050	1,367
Right of use assets at contract manufacturing organizations	5,201	6,428
Other	432	575
Total	$ 24,939	$ 39,274

Accrued Expenses:	**2020**	**2019**
Accrued compensation	$ 1,697	$ 3,944
Accrued restructuring (see *Note 19*)	520	2,949
Customer allowances	1,030	6,470
Accrued outsourced contract costs	473	2,833
Other	2,781	3,614
Total	$ 6,501	$ 19,810

Other Current Liabilities:	**2020**	**2019**
Accrued interest	$ 2,695	$ 2,695
Due to Exela	2,026	—
Guarantee to Deerfield	319	455
Other	160	725
Total	$ 5,200	$ 3,875

Other Non-Current Liabilities:	**2020**	**2019**
Customer allowances	$ —	$ 981
Unrecognized tax benefits	3,143	6,465
Guarantee to Deerfield	1,053	1,372
Other	16	55
Total	$ 4,212	$ 8,873

NOTE 17: Contingent Liabilities and Commitments

Litigation

The Company is subject to potential liabilities generally incidental to our business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The 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, 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 the Company's consolidated financial position, results of operations, cash flows or liquidity.

Subsidiary Bankruptcy and Deconsolidation

There is currently no pending or threatened litigation or disputes to which Specialty Pharma is or would be a party. All prior litigation and disputes involving Specialty Pharma have been dismissed or resolved. See *Note 3: Subsidiary Bankruptcy and Deconsolidation.*

Material Commitments

At December 31, 2020, we have one commitment with a 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 $4,000 and is expected to be started and completed during the year ending December 31, 2021.

The Company also has a commitment with a contract manufacturer related to the construction and preparation of a production suite at the contract manufacturer's facility, which is substantially complete at December 31, 2020. Subsequent to the initial build and preparation of the production suite, this commitment also includes annual fees which would commence at the start of production of validation batches and continue thereafter for five years.

NOTE 18: Divestiture of the Pediatric Assets

On February 12, 2018, the Company, together with its subsidiaries Avadel Pharmaceuticals (USA), Inc., Avadel Pediatrics, Inc., FSC Therapeutics, LLC ("FSC Therapeutics"), and Avadel US Holdings, Inc. ("Holdings"), as the "Sellers," entered into an asset purchase agreement (the "Purchase Agreement") with Cerecor, Inc. ("Cerecor"). The transaction closed on February 16, 2018 wherein Cerecor purchased from the Sellers four pediatric commercial stage assets – Karbinal™ ER, Cefaclor, Flexichamber™ and AcipHex® Sprinkle™, together with certain associated business assets – which were held by FSC. The Company acquired FSC in February 2016 from Deerfield and certain of its affiliates. Pursuant to the Purchase Agreement, Cerecor assumed the Company's remaining payment obligations to Deerfield under the Membership Interest Purchase Agreement, dated as of February 5, 2016, between Holdings, Flamel Technologies SA (the predecessor of the Company) and Deerfield and certain of its affiliates, which payment obligations consisted of the following (collectively, the "Assumed Obligations"): (i) a quarterly payment of $263 beginning in July 2018 and ending in October 2020, amounting to an aggregate payment obligation of $2,625; (ii) a payment in January 2021 of $15,263; and (iii) a quarterly royalty payment of 15% on net sales of the FSC products through February 5, 2026 ("FSC Product Royalties"), in an aggregate amount of up to approximately $10,300. Cerecor also assumed certain contracts and other obligations related to the acquired assets, and in that connection Holdings agreed to pay Cerecor certain make-whole payments associated with obligations Cerecor is assuming related to a certain supply contract related to Karbinal™ ER.

In conjunction with the divestiture, the Company also entered into the following arrangements:

License and Development Agreement

Flamel Ireland Limited, an Irish private limited company operating under the trade name of Avadel Ireland and a wholly-owned subsidiary of the Company, and Cerecor entered into a license and development agreement (the "License and Development Agreement") pursuant to which, among other things:

- Avadel Ireland will provide Cerecor with four product formulations utilizing Avadel Ireland's LiquiTime™ technology, and will complete pilot bioequivalence studies for such product formulations within 18 months;

- Cerecor will reimburse Avadel Ireland for development costs of the four LiquiTime™ products in excess of $1,000 in the aggregate;

- Upon transfer of the four product formulations, Cerecor will assume all remaining development costs and responsibilities for the product development, clinical studies, NDA applications and associated filing fees; and

- Upon regulatory approval and commercial launch of any LiquiTime™ products, Cerecor will pay Avadel Ireland quarterly royalties based on a percentage of net sales of any such products in the mid-single digit range.

Effective October 25, 2019, Cerecor and Avadel Ireland agreed to terminate the License and Development Agreement.

Deerfield Guarantee

The Company and Holdings provided their guarantee (the "Deerfield Guarantee") in favor of Deerfield. Under the Deerfield Guarantee, the Company and Holdings guaranteed to Deerfield the payment by Cerecor of the Assumed Obligations under the Membership Interest Purchase Agreement between the Company and Deerfield dated February 5, 2016. The Assumed Obligations include (i) a quarterly payment of $263 beginning in July 2018 and ending in October 2020, amounting to an aggregate payment obligation of $2,625; (ii) a payment in January 2021 of $15,263; and (iii) 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. In addition, under the Deerfield Guarantee, the Company and Holdings guaranteed that Deerfield would receive certain minimum annual FSC Product Royalties through February 6, 2026 (the "Minimum Royalties"). Given the Company's explicit guarantee to Deerfield, the Company recorded the guarantee in accordance with ASC 460. A valuation was performed, which was based largely on an analysis of the potential timing of each possible cash outflow described above and the likelihood of Cerecor's default on such payments assuming an S&P credit rating of CCC+. The result of this valuation identified a guarantee liability of $6,643. This liability is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

On October 10, 2019, Cerecor entered into a purchase and sale agreement with Aytu BioScience, Inc ("Buyer") pursuant to which the Buyer will purchase certain assets from Cerecor and assume certain of Cerecor's liabilities, including all of Cerecor's liabilities assumed as part of the Purchase Agreement noted above. As part of this transaction, on November 1, 2019, Armistice has agreed to deposit $15,000 in an escrow account governed by an escrow agreement between Armistice and Deerfield having the purpose of securing the $15,000 balloon payment due January 2021 as part of the Membership Interest Purchase Agreement. As part of the Cerecor transaction with the buyer, Deerfield contractually acknowledges and agrees that it will seek payment from the escrow funds before requesting payment from the Company pursuant to the Deerfield Guarantee discussed above. Due to the change in circumstances, a new valuation was performed based on an analysis of the possible timing of the updated possible cash flow which excludes the $15,000 that Armistice has deposited in an escrow account. The updated valuation identified an updated guarantee liability of $1,827 at December 31, 2019, which is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield. The balance of this guarantee liability was $1,372 at December 31, 2020.

Armistice Guarantee

Armistice Capital Master Fund, Ltd., the majority shareholder of Cerecor, guaranteed to Holdings the payment by Cerecor of the Assumed Obligations, including the Minimum Royalties. A valuation of the guarantee asset was performed in accordance with ASC 460 "*Guarantees*" and a guarantee asset of $6,620 was recorded. This asset is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield noted above.

As discussed above, based on the purchase and asset sale between Cerecor and the Buyer, an updated valuation was performed and identified an updated guarantee asset of $1,821 at December 31, 2019. The balance of this guarantee asset was $1,368 at December 31, 2020.

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

Based on management's review of ASU 2014-08, "*Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity*", the disposition of our pediatric assets and related liabilities did not qualify for discontinued operations reporting. Our results of operations for the year ended December 31, 2018 includes the results of FSC, prior to its February 16, 2018 disposition date.

The net impact of this transaction was not material to the consolidated statements of income (loss).

NOTE 19: Restructuring Costs

2019 French Restructuring

During the second quarter of 2019, the Company initiated a plan to substantially reduce all of its workforce at its Vénissieux, France site ("2019 French Restructuring"). This reduction was part of an effort to align the Company's cost structure with our ongoing and future planned projects. The reduction in workforce was completed during the year ended December 31, 2020. Restructuring charges associated with this plan of $172 and $4,855 of were recognized during the years ended December 31, 2020 and 2019, respectively. 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. The following table sets forth activities for the Company's cost reduction plan obligations for the years ended December 31, 2020 and 2019:

2019 French Restructuring Obligation:	**2020**	**2019**
Balance of restructuring accrual at January 1,	$ 1,922	$ —
Charges for employee severance, benefits and other costs	172	4,339
Payments	(1,813)	(2,441)
Foreign currency impact	(33)	24
Balance of restructuring accrual at December 31,	$ 248	$ 1,922

The 2019 French Restructuring liability of $248 is included in the consolidated balance sheet in accrued expenses at December 31, 2020.

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 our U.S. and Ireland locations with our 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 year ended December 31, 2020 was $215, which included a benefit of $421 related to share based compensation forfeitures. 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 following table sets forth activities for the Company's cost reduction plan obligations for the years ended December 31, 2020 and 2019:

2019 Corporate Restructuring Obligation:	**2020**	**2019**
Balance of restructuring accrual at January 1,	$ 1,080	$ —
Charges for employee severance, benefits and other costs	206	3,406
Payments	(1,014)	(2,326)
Balance of restructuring accrual at December 31,	$ 272	$ 1,080

The 2019 Corporate Restructuring liability of $272 is included in the consolidated balance sheet in accrued expenses at December 31, 2020.

NOTE 20: Equity Instruments and Transactions

Capital Shares

We have 500,000 shares of authorized ordinary shares with a nominal value of $0.01 per ordinary share. As of December 31, 2020, we had 58,396 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. We have 50,000 shares of authorized preferred shares, $0.01 nominal value, of which 488 are currently issued and outstanding as of December 31, 2020.

Shelf Registration Statement on Form S-3

In February 2020, we 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 us, 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, 2020.

February 2020 Private Placement

On February 21, 2020, we announced that we entered into a definitive agreement for the sale of our 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, we 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, we 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 us and the gross proceeds to us 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 our 5,407 treasury shares, or $49,998 previously repurchased ordinary shares. As a result, we 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 21: Share-Based Compensation

Compensation expense included in the Company's consolidated statements of income (loss) for all share-based compensation arrangements was as follows for the periods ended December 31, 2020, 2019 and 2018, respectively:

Share-based Compensation Expense:	2020	2019	2018
Research and development	$ 139	$ 429	$ 880
Selling, general and administrative	3,281	2,154	6,972
Restructuring costs	(421)	(2,064)	—
Total share-based compensation expense	$ 2,999	$ 519	$ 7,852

As of December 31, 2020, the Company expects $12,322 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 3.4 years.

The excess tax benefit related to share-based compensation recorded by the Company was not material for the years ended December 31, 2020, 2019 and 2018.

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, 2020, there were 4,122,315 shares authorized for stock option grants, restricted share award grants, and performance share unit award grants in subsequent periods.

Determining the Fair Value of Stock Options

The Company measures the total fair value of stock options on the grant date using the Black-Scholes option-pricing model and recognizes each grant's fair value as compensation expense over the period that the option vests. 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. The Company issues stock options to our Board of Directors as compensation for services rendered and generally become exercisable ratably over three years 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, 2020, 2019 and 2018, are as follows:

Stock Option Assumptions:	2020	2019	2018
Stock option grants:			
Expected term (years)	6.08	6.25	6.25
Expected volatility	75.76 %	56.48 %	56.59 %
Risk-free interest rate	0.72 %	2.52 %	2.68 %
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: We have not distributed any dividends since our 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, 2020 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, 2020	5,121	$ 7.51		
Granted	2,551	6.90		
Exercised	(403)	5.08		
Forfeited	(566)	3.24		
Expired	(805)	13.37		
Stock options outstanding, December 31, 2020	5,898	$ 7.02	7.96 years	$ 7,115
Stock options exercisable, December 31, 2020	2,172	$ 9.48	5.58 years	$ 1,841

The aggregate intrinsic value of options exercisable at December 31, 2020, 2019 and 2018 was $1,841, $572, and $0, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2020, 2019 and 2018 was $4.63, $1.24 and $3.60 per share, respectively.

Warrants

A summary of the combined warrant activity and other data for the year ended December 31, 2020 is as follows:

Warrant Activity and Other Data:	Number of Warrants	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Warrants outstanding, January 1, 2020	291	$ 13.59		
Granted	—	—		
Exercised	—	—		
Forfeited	—	—		
Expired	(291)	13.59		
Warrants outstanding, December 31, 2020	—	$ —	0.00 years	$ —
Warrants exercisable, December 31, 2020	—	$ —	0.00 years	$ —

All outstanding warrants expired in August 2020. Each of the above warrants was convertible into one ordinary share. There was no aggregate intrinsic value of warrants exercised during the years ended December 31, 2020, 2019 and 2018.

There were no warrants granted during the years ended December 31, 2020, 2019 and 2018.

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 during and after 2017 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 2018, the Company issued restricted share awards to our Board of Directors vesting over a three-year period; one-third (1/3) vesting on each of the three anniversaries of the grant date. Compensation expense for such awards granted during and after 2017 is recognized over the applicable vesting period.

A summary of the Company's restricted share awards as of December 31, 2020, 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, 2020	347	$ 4.73
Granted	186	7.69
Vested	(115)	6.01
Forfeited	(71)	4.83
Non-vested restricted share awards outstanding, December 31, 2020	347	$ 5.87

The weighted average grant date fair value of restricted share awards granted during the years ended December 31, 2020, 2019 and 2018 was $7.69, $2.47 and $5.87, 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. The Company has not yet recognized any PSU-related stock-based compensation expense as the regulatory milestones have not yet been met; however, in the event the performance conditions are met before a certain date, approximately 150% of the outstanding shares, or $2,734 of compensation expense will be recognized by the Company for the PSUs outstanding as of December 31, 2020.

A summary of the Company's performance share units awards as of December 31, 2020, 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, 2020	—	$ —
Granted	257	7.09
Vested	—	—
Forfeited	—	—
Non-vested performance share awards outstanding, December 31, 2020	257	$ 7.09

The weighted average grant date fair value of performance share awards granted during the year ended December 31, 2020 was $7.09 per share.

Employee Share Purchase Plan

In 2017, the Board of Directors approved of 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, 2020 and 2019, the Company issued 49 and 54 ordinary shares to employees, respectively. Expense related to the ESPP for the years ended December 31, 2020, 2019 and 2018 was immaterial.

NOTE 22: Net Income (Loss) Per Share

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

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

The dilutive effect of the warrants, stock options, restricted stock units, preferred shares and ordinary shares expected to be issued under or 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 income (loss) per share, together with the related shares outstanding in thousands for the years ended December 31, 2020, 2019 and 2018, is as follows:

Net Income (Loss) Per Share:	2020	2019	2018
Net income (loss)	$ 7,028	$ (33,226)	$ (95,304)
Weighted average shares:			
Basic shares	52,996	37,403	37,325
Effect of dilutive securities—employee and director equity awards outstanding	1,945	—	—
Diluted shares	54,941	37,403	37,325
Net income (loss) per share - basic	$ 0.13	$ (0.89)	$ (2.55)
Net income (loss) per share - diluted	$ 0.13	$ (0.89)	$ (2.55)

Potential ordinary shares of 14,915, 16,740, and 17,529 were excluded from the calculation of weighted average shares for the years ended December 31, 2020, 2019 and 2018, 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, 2019 and 2018, the effects of dilutive securities were entirely excluded from the calculation of net income (loss) per share as a net loss was reported in these periods.

NOTE 23: 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:	2020	2019	2018
Foreign currency translation adjustment:			
Beginning balance	$ (23,738)	$ (23,621)	$ (23,202)
Net other comprehensive income (loss)	1,111	(117)	(419)
Balance at December 31,	$ (22,627)	$ (23,738)	$ (23,621)
Unrealized gain (loss) on marketable securities, net			
Beginning balance	$ 932	$ 205	$ (64)
Net other comprehensive income, net of $(202), $(43), $(18), tax, respectively	644	727	269
Balance at December 31,	$ 1,576	$ 932	$ 205
Accumulated other comprehensive loss at December 31,	$ (21,051)	$ (22,806)	$ (23,416)

NOTE 24: Company Operations by Product, Customer and Geographic Area

We have determined that we operate in one segment, the development and commercialization of pharmaceutical products, including controlled-release therapeutic products based on our 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.

The following table presents a summary of total revenues by these products for the twelve months ended December 31, 2020, 2019, and 2018:

Revenue by Product:	2020	2019	2018
Bloxiverz	$ 2,201	$ 7,479	$ 20,850
Vazculep	10,429	33,152	42,916
Akovaz	9,545	18,642	33,759
Other	159	(58)	3,898
Product sales	22,334	59,215	101,423
License revenue	—	—	1,846
Total revenues	$ 22,334	$ 59,215	$ 103,269

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

The following table presents a summary of total revenues by significant customer for the twelve months ended December 31, 2020, 2019, and 2018:

Revenue by Significant Customer:	2020	2019	2018
McKesson Corporation	$ 5,758	$ 14,900	$ 26,794
Cardinal Health	5,155	15,088	25,413
AmerisourceBergen	3,155	12,059	18,620
QuVa Pharma	3,117	3,252	2,788
Others	5,149	13,916	27,808
Product sales	22,334	59,215	101,423
License revenue	—	—	1,846
Total revenues	$ 22,334	$ 59,215	$ 103,269

The following table summarizes revenues by geographic region for the twelve months ended December 31, 2020, 2019, and 2018:

Revenue by Geographic Region:	2020	2019	2018
U.S.	$ 22,334	$ 59,215	$ 101,423
Ireland	—	—	1,846
Total revenues	$ 22,334	$ 59,215	$ 103,269

Currently, we are working with contract manufacturing organizations for the manufacture of FT218. Additionally, we purchase 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, 2020, 2019, and 2018:

Long-lived Assets by Geographic Region:	2020	2019	2018
U.S.	$ 20,424	$ 22,254	$ 27,761
France	11	196	1,365
Ireland	6,047	7,244	6,028
Total	$ 26,482	$ 29,694	$ 35,154

NOTE 25: Related Party Transactions

As noted in *Note 4: Disposition of the Hospital Products,* we were party to a Membership Interest Purchase Agreement by and among us, 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 us, 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.

We were also party to a Royalty Agreement by and between us, 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.

Under the terms of the February 5, 2016 acquisition of FSC, which was completed on February 8, 2016, the Company was to pay $1,050 annually for five years with a final payment in January 2021 of $15,000 for a total of $20,250 to Deerfield for all of the equity interests in FSC. The Company would also pay Deerfield a 15% royalty per annum on net sales of the current FSC products, up to $12,500 for a period not exceeding ten years. These obligations were assumed by Cerecor in connection with the divestiture of the Company's pediatric products on February 16, 2018, as noted in *Note 18: Divestiture of the Pediatric Assets.*

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.

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, 2020 and 2019, the related consolidated statements of income (loss), comprehensive income (loss), shareholders' equity (deficit), and cash flows, for each of the three years in the period ended December 31, 2020, and the related notes and financial statement 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 9, 2021, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

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

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

Critical Audit Matter

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

Presentation of the Gain on Sale of Hospital Products - Refer to Note 4 to the financial statements

Critical Audit Matter Description

On June 30, 2020, the Company announced the sale of its sterile injectable drugs used in the hospital setting (the "Hospital Products"), including its three commercial products, Akovaz, Bloxiverz, and Vazculep, as well as Nouress, which is approved by the FDA to Exela Sterile Medicines LLC (the "Exela Buyer") pursuant to an asset purchase agreement between Avadel U.S. Holdings, Inc, Avadel Legacy Pharmaceuticals, LLC, Exela Holdings Inc., and the Exela Buyer.

We identified the presentation and disclosure of the sale of the Hospital Products as a critical audit matter due to the significant amount of judgement by management when evaluating the quantitative and qualitative factors to determine whether the criteria for presentation and disclosure as a discontinued operation had been met. This required a high degree of auditor judgement, an increased extent of effort, and the use of professionals with specialized skill and knowledge to assist in performing audit procedures to evaluate management's presentation and disclosure of the gain on sale of the Hospital Products.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the gain on sale of the Hospital Products included the following, among others:

- We tested the effectiveness of controls over management's review of the transaction, including their evaluation of whether the sale met the criteria for discontinued operations.
- With the assistance of professionals with specialized skill and knowledge, we evaluated management's assessment of the discontinued operations criteria, including the quantitative and qualitative factors surrounding the qualification for discontinued operations treatment.
- We evaluated the accuracy and completeness of management's disclosure for the disposition of the Hospital Products.

/s/ Deloitte and Touche LLP
St. Louis, Missouri
March 9, 2021

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, 2020, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, 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, 2020, of the Company and our report dated March 9, 2021, expressed an unqualified opinion on those financial statements.

Basis for Opinion

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

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

Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ Deloitte and Touche LLP
St. Louis, Missouri
March 9, 2021

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

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 15d -15(b) of the Exchange Act, we have evaluated, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, the effectiveness of the design and operation 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. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed by us in reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure and is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the U.S. Securities and Exchange Commission (the "SEC"). Based on that evaluation, our principal executive officer and principal financial officer concluded that as of the end of the period covered by this report our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Management of the Company 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. The Company's 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.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2020. In making this assessment, the Company's 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, 2020, the Company's internal control over financial reporting is effective based on those criteria.

Changes in Internal Control Over Financial Reporting

There have been no changes in the Company's internal control over financial reporting (as defined by Rule 13a-15(f)) that occurred during the year ended December 31, 2020 that have materially affected the Company's internal control over financial reporting. We continue to work from home due to the COVID-19 pandemic and will continue to monitor the impact on the design and operating effectiveness of our internal controls.

Item 9B. Other Information.

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 2021 annual general meeting of shareholders pursuant to Regulation 14A of the Securities Exchange Act of 1934 (our "Definitive 2021 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 2021 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 2021 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2020.

Item 11. Executive Compensation.

Information regarding Executive Compensation is hereby incorporated by reference to our Definitive 2021 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2020.

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 2021 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2020.

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 2021 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2020.

Item 14. Principal Accountant Fees and Services.

Information regarding Principal Accountant Fees and Services is hereby incorporated by reference to our Definitive 2021 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2020.

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
2020	$ 17,037	$ 2,805	$ —	$ 1,782	$ 21,624
2019	$ 21,199	$ 6,496	$ (4,762)	$ (5,896)	$ 17,037
2018	$ 15,354	$ 6,089	$ (75)	$ (169)	$ 21,199

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 information required by this Section (a)(3) of Item 15 is set forth on the exhibit index that follows the Signatures page of this Form 10-K.

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 (filed herewith)
10.2	Office Lease Agreement by and between Grove II LLC and Eclat Pharmaceuticals LLC dated October 5, 2015, as amended (filed herewith)
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	Master Manufacturing Services Agreement by and between Patheon UK Limited and Éclat Pharmaceuticals L.L.C. dated as of November 8, 2012 (incorporated by reference to Exhibit 10.9 to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 9, 2017)
10.12*	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)

10.13*	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)
10.14*	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)
10.15#	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)
10.16	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)
10.17*#	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)
10.18‡	Avadel Pharmaceuticals plc 2017 Omnibus Incentive Compensation Plan and related equity award agreements (filed herewith)
10.19‡	Avadel Pharmaceuticals plc 2020 Omnibus Incentive Compensation Plan (filed herewith)
14.1	Code of Business Conduct and Ethics (filed herewith)
14.2	Financial Integrity Policy (incorporated by reference to Exhibit 14.2 to the registrant's current report on Form 8-K, filed on March 7, 2017)
21.1	List of Subsidiaries (filed herewith)
23.1	Consent of Deloitte & Touche LLP (filed herewith)
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32.1	Certification of the Chief Executive Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)
32.2	Certification of the Principal Financial Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)
101.INS	XBRL Instant Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* 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 9, 2021

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 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 9, 2021
/s/ Thomas S. McHugh Thomas S. McHugh	Chief Financial Officer and Principal Financial and Accounting Officer	March 9, 2021
/s/ Geoffrey M. Glass Geoffrey M. Glass	Non-Executive Chairman of the Board and Director	March 9, 2021
/s/ Dr. Eric J. Ende Dr. Eric J. Ende	Director	March 9, 2021
/s/ Mark A. McCamish, MD, Ph.D. Mark A. McCamish, MD, Ph.D.	Director	March 9, 2021
/s/ Linda S. Palczuk Linda S. Palczuk	Director	March 9, 2021
/s/ Peter Thornton Peter Thornton	Director	March 9, 2021