

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, 2019

Commission file number: 000-28508

**AVADEL PHARMACEUTICALS PLC**  
(Exact name of registrant as specified in its charter)

Ireland State or other jurisdiction of incorporation or organization	98-1341933 (I.R.S. Employer Identification No.)
10 Earlsfort Terrace Dublin 2, Ireland D02 T380 (Address of principal executive offices)	Not Applicable (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 Depositary 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 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 \$97,947,088 based on the closing sale price of the registrant's American Depositary Shares as reported by the Nasdaq Global Market on June 28, 2019. Such market value excludes 3,464,274 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 10, 2020 was 46,404,432.

**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, 2019, are incorporated by reference into Part III of this Form 10-K.

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## 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 product candidate, FT218, the expected completion of the Phase III clinical trial for FT218 and our ability to obtain regulatory approval of and successfully commercialize FT218;
- Our plans and expectations regarding the effectiveness of our restructuring plan announced in February 2019, including our ability to achieve the desired cost savings;
- 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 reliance on a small number of products to generate all or substantially all of our revenue and the competitive pressures that these products face;
- The lack of patent protection for three of our approved products, Bloxiverz, Vazculep and Akovaz;
- Our ability to successfully launch Nouress in the United States;
- Our ability to develop and obtain U.S. Food and Drug Administration (“FDA”), approval for any future potential “unapproved marketed drug” product candidates in the future;
- 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 ability of our product candidates and products to gain market acceptance;
- Our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our products and product candidates;
- Our dependence on a limited number of suppliers for the manufacturing of our products and certain raw materials in our products 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 sizes and market participation potential for our approved or proposed products;
- 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

The Company is the owner of the Avadel, Akovaz, Bloxiverz, Vazculep, Nouress, Micropump, Liquitime, and Medusa trademarks, as well as certain other trademarks, including design versions of some of these trademarks. The symbols <sup>™</sup> and <sup>®</sup> may not be used in connection with the presentation of these trademarks in this report, but the absence of such symbols does not indicate a lack of trademark rights. Certain other trademarks used in this report are the property of third-party trademark owners and may similarly be presented with or without trademark references.

## **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 an emerging biopharmaceutical company. Our lead product candidate, FT218, is an investigational once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness (“EDS”), and cataplexy in narcolepsy patients. FT218, which uses our Micropump drug-delivery technology, is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from EDS and cataplexy. In addition, we have three approved commercial products developed under our “unapproved marketed drug,” or UMD, program, Akovaz, Bloxiverz and Vazculep, and a fourth approved product, Nouress, which are sterile injectable drugs used in the hospital setting.

We are primarily focused on the development and potential U.S. Food and Drug Administration (“FDA”) approval of FT218. In addition, we continue to market and distribute our current approved hospital products portfolio and, pending resolution of the existing patent infringement claim (as described below), we plan to commercialize Nouress. Outside of our product candidate and our existing commercial products, we continue to evaluate opportunities to expand our product portfolio.

#### ***FT218 (Micropump sodium oxybate)***

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 patients 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 Europe and the United States (“U.S.”) as a twice-nightly formulation indicated for the treatment of EDS and cataplexy in patients with narcolepsy.

In December 2019, we completed patient enrollment of our Phase 3 REST-ON clinical trial of FT218 to assess the safety and efficacy of a once-nightly formulation of FT218 for the treatment of EDS and cataplexy in patients suffering from narcolepsy. The REST-ON trial is a randomized, double-blind, placebo-controlled study that has enrolled 212 patients and is being conducted in clinical sites in the U.S., Canada, Western Europe and Australia. Top line data from the REST-ON trial is currently expected in the second quarter of 2020.

In January 2018, the FDA granted FT218 Orphan Drug Designation, which makes the drug eligible for certain development and commercial incentives, including a potential U.S. market exclusivity for up to seven years. Additionally, in April 2019, our first FT218 patent was issued, providing intellectual property protection into 2037. There are additional patent applications currently in development and/or pending at the U.S. Patent and Trademark Office (“USPTO”), as well as foreign patent offices.

We 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 \$1.7 billion.

#### ***Micropump Drug-Delivery Technology***

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

#### ***Unapproved Marketed Drugs Program***

The FDA allows certain unapproved prescription drugs to be marketed if (i) they are relied on by health care professionals to treat serious medical conditions, and (ii) there is no FDA-approved drug to treat such condition or insufficient supply of FDA-approved drugs. In most cases, these prescription drugs pre-date the establishment of the FDA. Although these products are typically not protected by patents or similar intellectual property, FDA guidance states that, if it approves an NDA for any such products via a 505(b)(2) process, the FDA is more likely to seek enforcement action, such as seizure or injunction, against remaining unapproved drugs of the same type, potentially after a grace period provided by the FDA.

## Existing Commercial Products

To date, we have received FDA approvals for three previously unapproved prescription drugs:

- **Bloxiverz (neostigmine methylsulfate injection)** - Bloxiverz was approved by the FDA in May 2013 and was launched in July 2013. Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery. Bloxiverz was the first FDA-approved version of neostigmine methylsulfate. Today, neostigmine is one of the two most frequently used products for the reversal of the effects of other agents used for neuromuscular blocks. There are approximately 2,500 vials of neostigmine sold annually in the U.S.
- **Vazculep (phenylephrine hydrochloride injection)** - Vazculep was approved by the FDA in June 2014 and was launched in October 2014. Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. There are approximately 7,100 vials of *Vazculep* sold annually in the U.S.
- **Akovaz (ephedrine sulfate injection)**. Akovaz, was approved by the FDA in April 2016 and was launched in August 2016. 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. There are approximately 7,500 vials of Akovaz sold annually in the U.S.

## Nouress

In December 2019, we received FDA approval for Nouress (cysteine hydrochloride injection), a sterile injectable product for use in the hospital setting, and currently have two patents covering that product. Several additional patent applications for Nouress are pending with the USPTO. In light of the recently filed patent suit by Exela Pharma Sciences, LLC, (“Exela”) we are currently evaluating the timing and process for a commercial launch of Nouress in the U.S. See *Note 16: Contingent Liabilities and Commitments* in Part II of this Form 10-K for a discussion on the filed patent suit by Exela.

We use the revenue from our UMD products to fund the research and development of FT218. In addition, we believe evaluating opportunities to commercialize other unapproved drugs in markets with a limited number of competitors may provide us with near-term revenue growth and potentially provide cash flows that can also be used to fund research and development initiatives for the development of FT218 and other potential product candidates.

## Corporate Information

We were incorporated on December 1, 2015 as an Irish private limited company, and re-registered as an Irish public limited company (“plc”), on November 21, 2016. 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](http://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](http://www.sec.gov). We do not incorporate the information on or accessible through our website into this Annual Report on Form 10-K.

We currently have five direct wholly-owned subsidiaries: (a) Avadel US Holdings, Inc., (b) Flamel Ireland Limited, which conducts business under the name Avadel Ireland, (c) Avadel Investment Company Limited, (d) Avadel Finance Ireland Designated Activity Company and (e) Avadel France Holding SAS. Avadel US Holdings, Inc., a Delaware corporation, is the holding entity of (i) Avadel Specialty Pharmaceuticals, LLC (currently the subject of a voluntary Chapter 11 bankruptcy proceeding), (ii) Avadel Legacy Pharmaceuticals, LLC, (iii) Avadel Management Corporation, (iv) FSC Holding Company, (v) Avadel Operations Company, Inc. and (vi) Avadel CNS Pharmaceuticals LLC. Avadel Finance Ireland Designated Activity Company is the holding entity of Avadel Finance Cayman Limited. Flamel Ireland Limited (operating under the trade name Avadel Ireland) is an Irish corporation. Avadel France Holding SAS, a French *société par actions simplifiée*, is the holding entity of Avadel Research SAS through which Avadel conducts substantially all of its R&D activities. A complete list of our subsidiaries can be found in Exhibit 21.1 to this Annual Report on Form 10-K.

## Recent Developments

### *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 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<sup>SM</sup> (“the Sales Agreement”), 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.

### *Securities Purchase Agreement*

On February 21, 2020, we announced that we have 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 has resulted in gross proceeds of approximately \$65,000 before deducting placement agent and other offering expenses, and resulting in net proceeds of approximately \$61,000.

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. Proceeds from the private placement will be used to fund continued clinical and program development of FT218, including an 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.

## **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, the overall landscape of the Pharma/Biotech industry has changed, and consolidation has reduced our pool of potential partners and acquisition opportunities within the biopharmaceutical space.

We compete with a number of companies based upon our current marketed products and those in development. Examples of companies with whom Avadel or any of our future partners would compete, given our current products and pipeline, include Jazz Pharmaceuticals, Fresenius Kabi, Par Pharmaceuticals, Hikma Pharmaceuticals and Ferring.

## Potential competition for FT218

If FT218 receives FDA approval, it will compete with the current approved twice-nightly sodium oxybate formulation, as well as a number of daytime stimulants including lisdexamfetamine, modafinil, armodafinil, solriamfetol and pitolisant, which are widely prescribed, or prescribed concomitantly with sodium oxybate. Sodium oxybate is currently the only product approved for both EDS and cataplexy. In addition, we anticipate that our FT218 product may face competition from manufacturers of generic twice-nightly sodium oxybate formulations, who have reached settlement agreements with the current marketer for entry by 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 low or no sodium versions of sodium oxybate and reboxetine.

## Market Opportunities

Because the pharmaceutical industry is highly competitive, participants seek ways to increase profitability by reducing competition through patent protection. Avadel, combining its existing proprietary drug delivery technologies with the established commercial capability of our unapproved to approved product strategy has evolved into a biopharmaceutical company focusing on re-formulations and requiring shorter product development cycles by using an abbreviated NDA mechanism (505(b)(2)).

In particular, in today's environment, 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 no longer sufficient to gain reimbursement acceptance. Biopharmaceutical companies must now demonstrate, through costly Phase 3 trials, therapeutic efficacy of their new formulations. The FDA has encouraged drug companies developing enhanced formulations to use an abbreviated 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® Technology.** Our Micropump allows for the development of modified and/or controlled 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/controlled 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 extended-/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 were awarded our first FT218-related U.S. patent on April 30, 2019, which is directed to modified release formulations of gamma-hydroxybutyrate ("GHB"), and which expires in 2037. We have a number of additional, FT218-related patent applications pending at the USPTO as well as at non-U.S. patent offices.



- **Nouress Patents.** We have two issued U.S. patents directed to cysteine solutions and methods of using cysteine solutions, both of which are listed in FDA's Orange Book for Nouress, and both of which expire in 2039. Further, we have several Nouress-related patent applications pending at the USPTO.
- **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 delayed and sustained release of an active ingredient and that tend to allow for absorption in the upper part of the intestinal tract (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 sustain a competitive advantage” 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 most of our products, we rely on a limited number of suppliers, and in certain cases only one supplier, for sourcing active pharmaceutical ingredients (“APIs”).

The manufacture of our sterile hospital injectable products marketed by Avadel in the U.S. is outsourced to current good manufacturing practices (“cGMP”) -compliant and FDA-audited contract manufacturing organizations (“CMOs”) pursuant to supply agreements. We will continue to outsource to third-party CMOs, and have no present plans to acquire manufacturing facilities. We believe this outsourcing policy is beneficial to us for products to be marketed in the U.S.

### **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 manufacturing according to stringent 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 Avadel's potential products and commercial prospects or the potential products and commercial prospects of 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 ("IMP") 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<sup>TM</sup> 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 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 to be 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 has several products marketed under this Act and has 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.

### **Employees**

As of December 31, 2019, we had approximately 50 employees, all of which were full-time. Except for employees at our French subsidiaries, none of our other employees is subject to a union or other collective bargaining agreement. Additionally, employees at our French subsidiaries (approximately 19 employees) are represented by a works' council in which employee representatives have the right to be consulted as to certain matters affecting our French subsidiaries. We believe that our relations with our employees are satisfactory.



## **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 Relating to Our 2019 Net Loss and 2019 Restructuring Plan**

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

We reported a net loss of \$33.2 million in 2019 and a loss from operating activities of \$38.3 million. As a result, our cash and marketable securities as of December 31, 2019 totaled \$64.2 million. Our business strategy is to primarily focus on the development and potential FDA approval for FT218 which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from EDS and cataplexy. In addition, we will continue to maximize the value of our current approved hospital products portfolio, including the potential commercialization of our fourth product, Nouress (cysteine hydrochloride injection). The successful pursuit of all components of our strategy will require substantial financial resources, and there can be no assurance that our existing cash and marketable securities assets and the cash generated by our operations will be adequate for these purposes. Failure to implement any component of our strategy may prevent us from achieving profitability in the future or may otherwise have a material adverse effect on our financial condition and results of operation.

***Our restructuring plan announced in February 2019 may not be as effective as anticipated, and we may fail to fully realize the expected cost savings or may experience unintended negative impacts from the restructuring.***

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. In conjunction with the restructuring plan, we also announced the voluntary Chapter 11 bankruptcy filing by our subsidiary, Avadel Specialty Pharmaceuticals, LLC ("Specialty Pharma"), which was responsible solely for the sales, marketing and distribution of our Noctiva product. We refer to the restructuring plan and the Chapter 11 bankruptcy of Specialty Pharma as the 2019 Restructuring. We implemented the restructuring plan in light of disappointing results from the commercial launch of Noctiva, and in order to focus our resources on other product development activities, in particular the ongoing Phase 3 clinical trial of FT218 for the treatment of excessive daytime sleepiness ("EDS"), and cataplexy in narcolepsy patients. The 2019 Restructuring requires the devotion of management attention as well as significant resources, including pre-tax cash charges which were approximately \$12.0 million in 2019, and may pose significant risks. The 2019 Restructuring may not be as effective as we anticipated and may not fully produce the expected cost savings or the effective re-focusing of our efforts toward completing the development of FT218. In addition, the restructuring plan may result in greater implementation costs than we have estimated or may result in unintended negative consequences. For example, because of the speed and magnitude of the workforce reduction that occurred during the 2019 restructuring, it may be difficult in the future to retain certain remaining employees who are critical to our ability to successfully pursue our business plan.

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

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, or the 2023 Notes. For example, the voluntary bankruptcy filing by 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.

***The Chapter 11 bankruptcy filing by Specialty Pharma may have unexpected adverse results.***

As part of the 2019 Restructuring, Avadel US Holdings Inc., Specialty Pharma's immediate parent and our wholly-owned subsidiary, agreed to provide debtor-in-possession financing to Specialty Pharma of up to \$2.7 million. We could face challenges in having

the liquidation plan for Specialty Pharma approved and costs from the restructuring may exceed the amount of financing Avadel US Holdings Inc. has committed to provide. Adverse or unexpected results from the bankruptcy proceeding could impair the success of the 2019 Restructuring.

***A management-directed third-party evaluation of our FT218 development program could result in changes that increase the cost of the program and further delay its completion.***

We recently announced completion of enrollment in the clinical trial for our FT218 product and an estimated completion date for that clinical trial. Management, in conjunction with pharmaceutical industry consulting firms, continues its evaluation of the FT218 program. The results of this on-going evaluation, in addition to the results of our FT218 development program, including our pivotal phase III REST ON study and all other components of an NDA submission, could cause us to modify our development plan with respect to FT218 in ways that could materially increase the ultimate cost of such development or further delay its completion, or could identify unknown risks or problems with the product. Any such cost increases, added delays, risks or problems could have a material adverse effect on our financial condition and results of operation.

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

***We derive a substantial majority of our revenues from a small number of products facing competitive pressures, and from a small number of customers, and the loss of any one of these products or customers could reduce Avadel's revenues significantly.***

In 2019, we derived our \$59.2 million in revenues from sales of our three hospital products, Bloxiverz, Vazculep and Akovaz. Product sales of these three products declined in the aggregate from 2018 to 2019 by \$38.3 million, or 39.2%, from \$97.5 million to \$59.2 million. Our Noctiva product failed to achieve anticipated revenue levels despite a substantial investment of resources toward its commercialization, and these disappointing results led to the voluntary Chapter 11 bankruptcy filing by Specialty Pharma in February 2019. In addition, we depend on a small number of customers for the majority of our revenues from our three hospital products. Three customers accounted for approximately 71% of total revenues from sales of these products in 2019. These three customers comprise a significant portion of the distribution network for pharmaceutical products in the U.S.

Competition for our hospital products in 2019 caused significant downward pricing pressure and loss of market share by us resulting in lower aggregate revenues for these products. Further competition in the future could cause further reductions in prices and market share. The distribution network for pharmaceutical products is continuing to undergo consolidation marked by mergers and acquisitions among wholesale distributors and retail drug store chains. As a result, a small number of large wholesale distributors and large chain drug stores control a significant share of the market. We expect that continuing consolidation in the industry may cause competitive pressures on pharmaceutical companies. The loss of any one of our three hospital products, the termination of our relationship with any of our customers or our failure to broaden our customer base could cause our revenues to further decrease significantly and result in further losses from our operations. Further, we may be unable to negotiate favorable business terms with customers that represent a significant portion of our revenues, and any such inability could have a material adverse effect on our business, results of operations, financial condition and prospects.

Further, as part of our 2013 debt financing transaction with Deerfield, we granted Deerfield a security interest in the intellectual property and product registration rights of certain legacy products. If we default on the terms of the loan agreement with Deerfield, Deerfield could enforce its security interest, which could further impact our revenues.

***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 2019, we spent \$32.9 million on R&D, including on our FT218 product candidate and on Nouress, which was approved by the FDA in December 2019. 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.

***Our products 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, including additional previously unapproved marketed drugs ("UMD") products, and products that utilize our drug delivery technologies. If any of our additional

UMD products or products incorporating our drug delivery technologies fails to reach the commercial market, our future revenues would be adversely affected.

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

- the FDA, the European Medicines Agency (“EMA”), the competent authority of 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 products 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.

***We may rely on collaborations with third parties to commercialize certain of our products in development, particularly products using our drug delivery technologies, 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.

***Our products may not gain market acceptance.***

Our 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 any new UMD product we may successfully pursue, whether and the extent to which the FDA removes competing products from the market;
- in the case of our product candidates that are controlled substances the U.S. Drug Enforcement Administration (“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 products or technologies fails to achieve market acceptance, our ability to generate additional revenue will be limited, which would have a material adverse effect on our business.

***The development of several of our drug delivery technologies and products depends on the services of a single provider and any interruption of operations of such provider could significantly delay or have a material adverse effect on our product pipeline.***

Currently, we use a single source provider for the development, supply of clinical materials and potentially the supply of commercial

batches for several of our products incorporating our drug delivery technologies. Any disruption in the operations of this provider or if this provider fails to supply acceptable quantity and quality materials or services to us for any reason, such disruption or failure could delay our product development and could have a material adverse effect on our business, financial condition and results of operations. In case of a disruption, we may need to establish alternative manufacturing sources for our drug delivery products, and this would likely lead to substantial production delays as we build or locate replacement facilities and seek to satisfy necessary regulatory requirements.

***We depend on a limited number of suppliers for the manufacturing of our products and certain raw materials used in our products 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.***

Currently, we depend on a limited number of contract manufacturing organizations (“CMOs”), for three products, Bloxiverz, Vazculep and Akovaz, from which we derive our revenues. Additionally, we purchase certain raw materials used in our products from a limited number of suppliers, including a single supplier for certain key ingredients. 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 and marketing of certain products 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 products 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.

***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 other 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 products. Among the many experimental therapies being tested in the U.S. and in the EU, there may be some that we do not now know of that may compete with our drug delivery technologies or products in the future. These new biological or chemical products may be safer or may work better than our products.

With respect to our UMD products, the FDA has approved generic versions or previously filed NDAs of our marketed products and may approve additional generic versions in the future.

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

Future prices for our pharmaceutical products and medical devices 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 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. In the U.S., the Trump administration has made public and social media statements causing uncertainty as to future federal U.S. government policies regulating drug prices. Further, the trend toward increased availability of generic products has contributed to overall pricing pressures in the pharmaceutical industry. Additionally, on December 18, 2019, President Trump, the U.S. Department of Health and Human Services, and the FDA issued a notice of proposed rulemaking that, if finalized, would allow for the importation of certain prescription drugs from Canada. FDA also issued a Draft Guidance document outlining a potential

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 foreign country and that was authorized for sale in that foreign country. The regulatory and market implications of the notice of proposed rulemaking and Draft Guidance are unknown at this time, but legislation, regulations or policies allowing the reimportation of drugs, if enacted and implemented, could decrease the price we receive for our products 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 products 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 products. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our products or technologies obsolete or noncompetitive.

***We may fail to effectively execute our business strategy.***

Our business strategy is to continue our UMD program by commercializing our fourth UMD product, Nouress, as well as potentially seek FDA approval for and commercialize additional future UMD product candidates, and to continue to seek FDA approval for FT218, which completed enrollment for its Phase 3 clinical trial and for which we expect topline data in the second quarter of 2020. There can be no assurance that we will be successful in any of these objectives; and a failure in any of these objectives could negatively impact our business and operating results.

***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.

***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;
- the resolution of issues arising from tax audits with various tax authorities;
- 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;
- increases in expenses not deductible for tax purposes, including increases in the fair value of related party payables, write-offs of acquired in-process R&D and impairment of goodwill in connection with acquisitions;
- adjustments to estimated taxes upon finalization of various tax returns;
- the tax effects of purchase accounting for acquisitions that may cause fluctuations between reporting periods.

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, 2019, we had U.S. federal net operating loss carryforwards of approximately \$75.5 million due to prior period losses, some of which, if not utilized, will expire in 2034 and 2035 for federal tax purposes. Approximately \$10.4 million of these net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our profitability. The \$10.4 million of U.S. federal net operating loss carryforwards are subject to an annual limitation as a result of the FSC acquisition under Internal Revenue Code Section 382 and may not be fully utilized before they expire.

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

As of December 31, 2019, we had approximately \$95.8 million 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.

***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.

**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 products 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 products and technologies.

To the extent any of our products 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 products or our business partners’ products. 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 products 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 abroad. 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 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 products, 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 products.***

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

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

***Third parties may claim that our products infringe their rights, and we may incur significant costs resolving these claims.***

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, an Orange Book patent exists related to Exela’s currently marketed cysteine hydrochloride injection product. In this regard, Exela filed a complaint against us and our subsidiary, Avadel Legacy Pharmaceuticals, LLC (“Avadel Legacy”), in the United States District for the District of Delaware in January of 2020 alleging infringement of that Orange Book patent by our recently-approved Nouress product. As another example, approximately 14 Orange Book patents exist related to Jazz Pharmaceuticals’ currently marketed sodium oxybate product, and, in connection with us seeking regulatory approval for FT218, Jazz may allege that FT218 infringes its patents or other intellectual property rights and file suit to prevent us from commercializing FT218. 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 reasonable 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 foreign patents that pose a risk of potential infringement claims.

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 products 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 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 commercialized products that incorporate our drug delivery technologies.

***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 our 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.

***Patent terms may be inadequate to protect our competitive position on our 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 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.



***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(s) or product candidate(s), 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 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.

***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 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 products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in non-U.S. jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign 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 Regulatory and Legal Matters**

***Our products 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 revenues may be adversely affected.***

Our FT218 product, as well as products we may wish to market in the future, may not gain regulatory approval and reach the commercial market for a variety of reasons.

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 products 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 product candidates. If the FDA disagrees with such REMS proposals, it may be more difficult and costly to obtain regulatory approval for our product candidates. 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 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.

***Our products are 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.***

We, on our own, and in conjunction with our pharmaceutical partners will be subject to extensive regulatory requirements for our and the co-developed products and product candidates, even if the products receive regulatory approval. These regulations are wide-ranging and govern, among other things:

- adverse drug experiences and other reporting requirements;
- product promotion and marketing;
- APIs and/or product manufacturing, including cGMP compliance;
- record keeping;
- distribution of drug samples;
- required clinical trials and/or post-marketing studies;
- authorization renewal procedures;
- authorization variation procedures;
- compliance with any required REMS;
- updating safety and efficacy information;
- processing of personal data;
- use of electronic records and signatures; and
- changes to product manufacturing or labeling.

***Clinical development of drugs is costly and time-consuming, and the outcomes are uncertain. A failure to prove that our 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 have made significant investments in our REST-ON Phase 3 clinical trial of FT218. 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. Any failure of our REST-ON Phase 3 clinical trial would prevent or delay the potential approval and commercialization of our sodium oxybate product, which would materially and adversely affect our business, financial condition, results of operations and growth prospects.

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 drug 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 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 products 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.

***If FT218 is approved by the FDA, we may not obtain orphan drug marketing 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 proposed product 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 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 product candidates 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, health-care “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 products and technologies 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 products 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. In particular, it is difficult to predict the effect of health care reform legislation enacted in the U.S. in 2010, certain provisions of which are still subject to regulatory implementation, further legislative change and ongoing judicial review. Any such 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 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 products. 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.

***We and companies to which we have licensed, or will license our products or drug delivery technologies and subcontractors we engage for services related to the development and manufacturing of our products 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 license our 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 domestic regulatory authorities and equivalent foreign 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 receive from our customers.

***We may face product liability claims related to clinical trials for our products or their misuse.***

The testing, including through clinical trials, manufacturing and marketing, and the use of our products 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 and recall 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 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, or 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, 2019, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged from \$1.09 to \$7.70. During the year ended December 31, 2018, the closing sale price of ADSs as reported on the Nasdaq Global Market ranged

from \$1.74 to \$11.70. 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 products or products developed by pharmaceutical and biotechnology company partners that use our drug delivery technologies;
- lack of efficacy of our products;
- litigation;
- decisions by our pharmaceutical and biotechnology company partners relating to the products incorporating 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.

***We incurred a net loss in 2019 and we will likely incur a net loss in 2020, and if we are not able to regain profitability in the future, the value of our shares may fall.***

We reported a net loss of \$33.2 million and \$95.3 million for the years ended December 31, 2019 and 2018, respectively. In addition, in part because we expect sales of our hospital products to suffer further substantial declines during 2020 and we will incur substantial expenses to develop our products, we will likely incur a net loss in 2020 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:

- the demand for our drug delivery technologies and products;
- the level of product and price competition;
- our ability to develop new partnerships and additional commercial applications for our products;
- our ability to control our costs;
- our ability to broaden our customer base;
- the effectiveness of our marketing strategy;
- our effective tax rate;
- the effectiveness of our partners' marketing strategy for products that use our technology; and
- general economic conditions.

***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 choose 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 loss and the resulting decrease in our available liquid assets 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 our 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.

***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, or 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.

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

As of February 25, 2020, RTW Investments LP. owned approximately 10.0% of Avadel's outstanding shares (in the form of ADSs), Avoro Capital Advisors LLC owned approximately 8.4% of our outstanding shares (in the form of ADSs) and Vivo Opportunity, LLC and certain of its affiliates owned approximately 7.6% 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, including change of control transactions.

***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, or 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, 2019 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 2019 taxable year, but that our non-U.S. subsidiaries were CFCs in the 2019 taxable year. We anticipate that our non-U.S. subsidiaries will remain CFCs in the 2020 taxable year, and it is possible that we may become a CFC in the 2020 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.

## 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 \$143.75 million 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 incurred significant net losses in 2019 and we may continue to incur significant losses. 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 (see the discussion under the caption “Recent Developments -- Issuance of Exchangeable Notes” in Item 1 of this Annual Report on Form 10-K). 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.

***Dividends paid by the Parent may be subject to Irish dividend withholding tax***

In certain circumstances, as an Irish tax resident company, Avadel will 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 Avadel's qualifying intermediary or other designated agent (in the case of shares held beneficially), or Avadel or its 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.

**Item 1B. Unresolved Staff Comments.**

Not applicable.

**Item 2. Properties.**

*(Amounts in thousands, except square foot amounts)*

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 still maintain the lease on the former headquarters of FSC Laboratories, Inc. located in Charlotte, North Carolina. This office space consists of 6,300 square feet, and the lease expires in 2020.

Avadel Research SAS, our prior research center, was located in Venissieux, France (a suburb of Lyon) in two adjacent leased facilities totaling approximately 25,600 square feet. One building of approximately 12,800 square feet housed the administrative offices and analytical research laboratories. A second facility comprising approximately 12,800 square feet housed equipment dedicated to our Micropump and LiquiTime platforms. Both leases were terminated during the three months ended December 31, 2019 as part of the 2019 French Restructuring plan. See *Note 18: Restructuring Costs* in Part II, item 8 of this Annual Report on Form 10-K for more information.

We had intellectual property, clinical, quality, regulatory, and supply chain activities located in Dublin, Ireland. The office space consisted of 5,059 square feet and the lease expired in 2025. This lease was surrendered during the three months ended December 31, 2019 as part of the 2019 Corporate Restructuring plan. See *Note 18: Restructuring Costs* in Part II, item 8 of this Annual Report on Form 10-K for more information.

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 three years.

### **Item 3. Legal Proceedings.**

#### **Voluntary Chapter 11 Bankruptcy Filing by Specialty Pharma update**

*Note 3: Subsidiary Bankruptcy and Deconsolidation* on Part II, item 8 of this annual report on Form 10-K briefly describes the Chapter 11 bankruptcy case which our subsidiary Specialty Pharma commenced on February 6, 2019, and which on April 26, 2019 resulted in the bankruptcy court-approved sale of all of Specialty Pharma's intangible assets and inventory to an unaffiliated third party. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business. During the pendency of the bankruptcy case, all pending litigation against Specialty Pharma is automatically stayed and any new litigation against Specialty Pharma is precluded unless the bankruptcy court orders otherwise. Below are descriptions of a litigation to which Specialty Pharma is a party and a contract dispute involving Specialty Pharma, both of which matters are subject to the automatic stay during the bankruptcy case.

*Ferring Litigation.* Some of the patents covering the Noctiva product (the "Noctiva Patents") are the subject of litigation initiated by Ferring Pharmaceuticals Inc. and two of its foreign affiliates, who manufacture a competing product known as Nocdurna. Nocdurna was approved by the FDA in June 2018 and commercially launched in the U.S. in November 2018. In this litigation, filed in the United States District Court for the Southern District of New York, Ferring seeks to invalidate and disputes the inventorship of the Noctiva Patents, seeks damages for various alleged breaches of contractual and common law duties, and seeks damages for alleged infringement by Noctiva of Ferring's "Nocdurna" trademark. Specialty Pharma and certain other parties including Serenity Pharmaceuticals, LLC ("Serenity") (the licensor of the Noctiva Patents) have defended this litigation, and have made counterclaims against Ferring, including for infringement of the Noctiva Patents and a declaratory judgment of noninfringement with respect to Ferring's "Nocdurna" trademark. The court dismissed Ferring's inventorship claim and its claims for alleged breaches of contractual and common law duties, although these dismissals may be appealed by Ferring. On February 15, 2019, Specialty Pharma and its co-defendants moved to stay the litigation pending completion of the bankruptcy proceeding of Specialty Pharma. On May 15, 2019, that motion was denied due to a pending settlement of the litigation with respect to just Ferring and Specialty Pharma. On February 25, 2020, Ferring and Specialty Pharma jointly moved for bankruptcy court approval of a settlement agreement with respect to the claims alleged in the litigation. In accordance with the terms of the settlement agreement, promptly following bankruptcy court approval of the settlement agreement, the parties would dismiss with prejudice their respective claims against each other in the litigation. On March 13th, 2020, the bankruptcy court entered an order approving the settlement with Ferring. Pursuant to the terms of the settlement, the parties are to dismiss their respective claims against each other in the District Court litigation in the Southern District of New York, with such dismissals to be effective concurrently. That joint dismissal has not yet been filed with District Court for the Southern District of New York.

*Contract Dispute.* On January 21, 2019, Serenity gave notice to Specialty Pharma of an alleged breach of the parties' Noctiva license agreement. Serenity alleges that Specialty Pharma breached its contractual obligation to devote commercially reasonable efforts to the commercialization of Noctiva and seeks unspecified damages. On January 27, 2019, Specialty Pharma notified Serenity of a claim for \$1.7 million in damages as a result of Serenity's breach of its contractual obligation to pay the costs of the Ferring Litigation. Serenity's notice to Specialty Pharma invoked the dispute resolution provisions of the Noctiva license agreement, which culminate in arbitration, but neither party has yet initiated an arbitration proceeding or filed suit.

*Exela Litigation.* On January 7, 2020, Exela filed a complaint against us and our subsidiary, Avadel Legacy in the United States District for the District of Delaware. The complaint alleges infringement of a certain Exela patent related to its cysteine hydrochloride product. Exela is most notably seeking i) a declaratory judgment that the Nouress product infringes its patent, ii) an injunction (both preliminary and permanent) precluding the launch of Nouress, and iii) monetary damages (including enhanced damages, prejudgment interest and attorneys' fees) in the event Nouress is commercially launched and found to infringe Exela's patent. We have not yet been served with the complaint.

### **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 10, 2020, there were 46,404,432 ordinary shares outstanding, and our closing stock price was \$8.57 per share.

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

	2019 Price Range		2018 Price Range	
	High	Low	High	Low
First quarter	\$ 3.29	\$ 1.44	\$ 11.70	\$ 6.76
Second quarter	3.19	1.09	7.78	5.89
Third quarter	4.47	1.92	7.14	4.08
Fourth quarter	7.70	3.34	4.66	1.74

#### Holder

As of March 10, 2020, there were 79 holders of record of our ordinary shares and 42 accounts registered with The Bank of New York Mellon, the depository 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

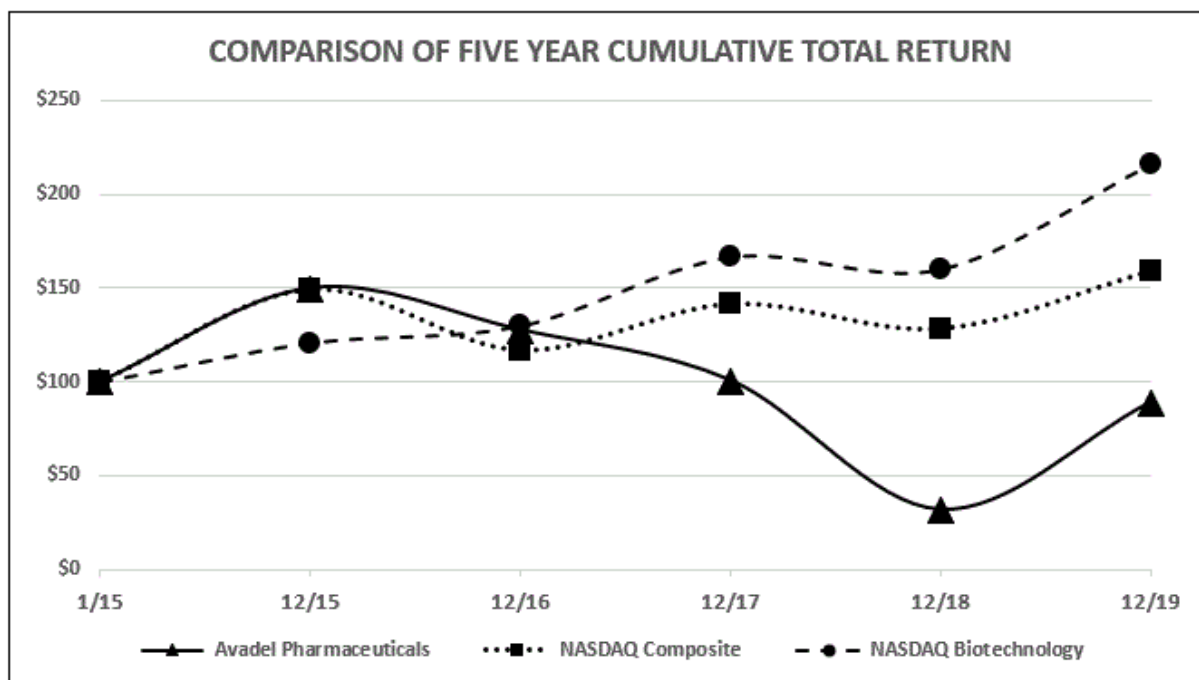
The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

#### Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2019.

## 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, 2013 and our relative performance is tracked through December 31, 2019. 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. Selected Financial Data (in thousands, except per share amounts).****Annual Financial Data:**

The consolidated statements of (loss) income data for fiscal 2019, 2018 and 2017, and the consolidated balance sheet data as of December 31, 2019 and 2018 were derived from our consolidated financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. The consolidated statements of (loss) income for fiscal 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017, 2016 and 2015 were derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K.

The following selected financial data should be read in conjunction with our consolidated financial statements and related notes appearing in Item 8 “Financial Statements and Supplementary Data” and Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Part II of this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results to be expected in any future period.

<b>Statement of (Loss) Income Data:</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>
Total revenues	\$ 59,215	\$ 103,269	\$ 173,245	\$ 150,246	\$ 173,009
Gross profit <sup>(a)</sup>	47,090	85,753	156,944	136,998	161,599
Operating (loss) income <sup>(b)</sup>	(24,112)	(104,926)	89,505	(4,965)	70,758
Net (loss) income	(33,226)	(95,304)	68,271	(41,276)	41,798
Net (loss) income per share - basic	\$ (0.89)	\$ (2.55)	\$ 1.69	\$ (1.00)	\$ 1.03
Net (loss) income per share - diluted	\$ (0.89)	\$ (2.55)	\$ 1.63	\$ (1.00)	\$ 0.96

<b>Balance Sheet Data:</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>
Cash and cash equivalents	\$ 9,774	\$ 9,325	\$ 16,564	\$ 39,215	\$ 65,064
Marketable securities	54,384	90,590	77,511	114,980	79,738
Goodwill	18,491	18,491	18,491	18,491	18,491
Intangible assets, net	813	1,629	92,289	22,837	15,825
Total assets	151,436	190,300	253,277	245,482	215,081
Long-term debt (incl. current portion)	121,686	115,840	267	815	1,118
Long-term related party payable (incl. current portion)	17,327	28,840	98,925	169,347	122,693

<sup>(a)</sup> Gross profit is computed by subtracting cost of products from total revenues.

<sup>(b)</sup> We recorded an impairment charge of \$66,087 during the year ended December 31, 2018.



**Quarterly Financial Data (Unaudited):**

The following tables present certain unaudited consolidated quarterly financial information for each quarter of 2019 and 2018. 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.

<b>2019:</b>	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
Revenues	\$ 16,437	\$ 17,554	\$ 14,229	\$ 10,995
Gross profit <sup>(a)</sup>	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)

<b>2018:</b>	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>
Revenues	\$ 33,293	\$ 29,230	\$ 19,826	\$ 20,920
Gross profit <sup>(a)</sup>	26,701	25,718	16,706	16,628
Operating loss <sup>(b)</sup>	(12,625)	(2,785)	(14,095)	(75,421)
Net loss	(12,236)	(3,438)	(15,771)	(63,859)
Net loss per share - basic	(0.32)	(0.09)	(0.43)	(1.72)
Net loss per share - diluted	(0.32)	(0.09)	(0.43)	(1.72)

<sup>(a)</sup> Gross profit is computed by subtracting cost of products from total revenues.

<sup>(b)</sup> We recorded an impairment charge of \$66,087 during the three months ended December 31, 2018.

## 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 2017 was included in the Company’s Annual Report on Form 10-K for the year-ended December 31, 2018, on pages 42 through 58, 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 15, 2019.

#### **Overview**

##### ***Nature of Operations***

Avadel Pharmaceuticals plc (Nasdaq: AVDL) (“Avadel,” the “Company,” “we,” “our,” or “us”) is an emerging biopharmaceutical company. Our lead product candidate, FT218, is an investigational once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness (“EDS”), and cataplexy in narcolepsy patients. FT218, which uses our Micropump drug-delivery technology, is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from EDS and cataplexy. In addition, we have three approved commercial products developed under our “unapproved marketed drug,” or UMD, program, Akovaz, Bloxiverz and Vazculep, and a fourth approved product, Nouress, which are sterile injectable drugs used in the hospital setting.

We are primarily focused on the development and potential U.S. Food and Drug Administration (“FDA”) approval of FT218. In addition, we continue to market and distribute our current approved hospital products portfolio and, pending resolution of the existing patent infringement claim (as described below), we plan to commercialize Nouress. Outside of our product candidate and our existing commercial products, we continue to evaluate opportunities to expand our product portfolio.

##### ***FT218 (Micropump sodium oxybate)***

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 patients 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 Europe and the United States (“U.S.”) as a twice-nightly formulation indicated for the treatment of EDS and cataplexy in patients with narcolepsy.

In December 2019, we completed patient enrollment of our Phase 3 REST-ON clinical trial of FT218 to assess the safety and efficacy of a once-nightly formulation of FT218 for the treatment of EDS and cataplexy in patients suffering from narcolepsy. The REST-ON trial is a randomized, double-blind, placebo-controlled study that has enrolled 212 patients and is being conducted in clinical sites in the U.S., Canada, Western Europe and Australia. Top line data from the REST-ON trial is currently expected in the second quarter of 2020.

In January 2018, the FDA granted FT218 Orphan Drug Designation, which makes the drug eligible for certain development and commercial incentives, including a potential U.S. market exclusivity for up to seven years. Additionally, in April 2019, our first FT218 patent was issued, providing intellectual property protection into 2037. There are additional patent applications currently in development and/or pending at the USPTO, as well as foreign patent offices.

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 \$1.7 billion.

### ***Micropump Drug-Delivery Technology***

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

### ***Unapproved Marketed Drugs Program***

The FDA allows certain unapproved prescription drugs to be marketed if (i) they are relied on by health care professionals to treat serious medical conditions, and (ii) there is no FDA-approved drug to treat such condition or insufficient supply of FDA-approved drugs. In most cases, these prescription drugs pre-date the establishment of the FDA. Although these products are typically not protected by patents or similar intellectual property, FDA guidance states that, if it approves an NDA for any such products via a 505(b)(2) process, the FDA is more likely to seek enforcement action, such as seizure or injunction, against remaining unapproved drugs of the same type, potentially after a grace period provided by the FDA.

### ***Existing Commercial Products***

To date, we have received FDA approvals for three previously unapproved prescription drugs:

- **Bloxiverz (neostigmine methylsulfate injection)** - Bloxiverz was approved by the FDA in May 2013 and was launched in July 2013. Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery. Bloxiverz was the first FDA-approved version of neostigmine methylsulfate. Today, neostigmine is one of the two most frequently used products for the reversal of the effects of other agents used for neuromuscular blocks.
- **Vazculep (phenylephrine hydrochloride injection)** - Vazculep was approved by the FDA in June 2014 and was launched in October 2014. Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
- **Akovaz (ephedrine sulfate injection)**. Akovaz, was approved by the FDA in April 2016 and was launched in August 2016. 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***

In December 2019, we received FDA approval for Nouress (cysteine hydrochloride injection), a sterile injectable product for use in the hospital setting, and currently have two patents covering that product. Several additional patent applications for Nouress are pending with the USPTO. In light of the recently filed patent suit by Exela Pharma Sciences, LLC, (“Exela”) we are currently evaluating the timing and process for a commercial launch of Nouress in the U.S. See *Note 16: Contingent Liabilities and Commitments* for a discussion on the filed patent suit by Exela Pharma Sciences, LLC.

We use the revenue from our UMD products to fund the research and development of FT218. In addition, we believe evaluating opportunities to commercialize other unapproved drugs in markets with a limited number of competitors may provide us with near-term revenue growth and potentially provide cash flows that can also be used to fund research and development initiatives for the development of FT218 and other potential product candidates.

### ***Corporate Information***

We were incorporated on December 1, 2015 as an Irish private limited company, and re-registered as an Irish public limited company (“plc”), on November 21, 2016. 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](http://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](http://www.sec.gov).

We currently have five direct wholly-owned subsidiaries: (a) Avadel US Holdings, Inc., (b) Flamel Ireland Limited, which conducts business under the name Avadel Ireland, (c) Avadel Investment Company Limited, (d) Avadel Finance Ireland Designated Activity Company and (e) Avadel France Holding SAS. Avadel US Holdings, Inc., a Delaware corporation, is the holding entity of (i) Avadel Specialty Pharmaceuticals, LLC (currently the subject of a voluntary Chapter 11 bankruptcy proceeding), (ii) Avadel Legacy Pharmaceuticals, LLC, (iii) Avadel Management Corporation, (iv) FSC Holding Company, (v) Avadel Operations Company, Inc. and (vi) Avadel CNS Pharmaceuticals LLC. Avadel Finance Ireland Designated Activity Company is the holding entity of Avadel Finance Cayman Limited. Flamel Ireland Limited (operating under the trade name Avadel Ireland) is an Irish corporation. Avadel France Holding SAS, a French *société par actions simplifiée*, is the holding entity of Avadel Research SAS through which Avadel conducts substantially all of its R&D activities. A complete list of our subsidiaries can be found in Exhibit 21.1 to this Annual Report on Form 10-K.

References in these consolidated financial statements and the notes thereto to “Avadel,” the “Company,” “we,” “our,” “us,” and similar terms shall be deemed to be references to Flamel prior to the completion of the Merger, unless the context otherwise requires.

### **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.
- **Possible Net Loss from Operations in 2020:** In part because we expect sales of our hospital products to significantly decline from 2019 and we will incur substantial expenses to further the clinical development of FT218, we likely will incur a net loss in 2020.

### **Recent Developments**

*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 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<sup>SM</sup> (“the Sales Agreement”), 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.

#### *Securities Purchase Agreement*

On February 21, 2020, we announced that we have 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 has resulted in gross proceeds of approximately \$65,000 before deducting placement agent and other offering expenses, and resulting in net proceeds of approximately \$61,000.

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. Proceeds from the private placement will be used to fund continued clinical and program development of FT218, including an 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.

#### **Financial Highlights**

Highlights of our consolidated results for the year ended December 31, 2019 are as follows:

- Revenue was \$59,215 for the year ended December 31, 2019 compared to \$103,269 in the same period last year. This year over year decrease was primarily the result of increased competition driving lower prices as noted above in our discussion of *Key Business Trends and Highlights*. We experienced price and unit volume declines across all our hospital products due to additional competition.
- Operating loss was \$24,112 for the year ended December 31, 2019 compared to an operating loss of \$104,926 for the year ended December 31, 2018. The primary reasons for the decrease in operating loss was due to the 2018 impairment of the Noctiva intangible asset of \$66,087 and lower SG&A and R&D expenses in the current period of \$70,176 and \$6,412, respectively, primarily driven by the exit of Noctiva. These decreases were partially offset by lower total revenues of \$44,054 as discussed above and a decrease of \$23,576 in the gain in fair value of related party contingent consideration recognized during the year ended December 31, 2018 of \$22,731 compared to expense of \$845 recognized during the current year.
- Net loss was \$33,226 for the year ended December 31, 2019 compared to net loss of \$95,304 in the same period last year.
- Diluted net loss per share was \$0.89 for the year ended December 31, 2019 compared to diluted net loss per share of \$2.55 in the same period last year.
- Cash and marketable securities decreased \$35,757 to \$64,158 at December 31, 2019 from \$99,915 at December 31, 2018. This decrease was largely driven from \$38,325 use of cash in operations.

## **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.** Revenue includes sales of pharmaceutical products, licensing fees, and, if any, milestone payments for research and development ("R&D") achievements.

### *Product Sales*

We sell products primarily through wholesalers and considers these wholesalers to be its 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 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, 2019 and 2018, we recognized \$0 and \$1,846 of revenue from license agreements, respectively.

**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.

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

Deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. In evaluating our ability to recover our deferred tax assets in the jurisdiction from which they arise, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income or loss, tax-planning strategies, and results of recent operations. The assumptions about future taxable income or loss require the use of significant judgment and are consistent with the plans and estimates we are using to manage the underlying businesses.

The 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, 2019, we had unremitted earnings of \$3,961 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 has a single reporting unit associated with the development and commercialization of pharmaceutical products. Prior to November 2019, we tested for goodwill impairment using a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then, in the second step, the loss is measured as the excess of recorded goodwill over the implied fair value of the goodwill. Implied fair value of goodwill is the excess of the fair value of the reporting unit as a whole over the fair value of all separately identified assets and liabilities within the reporting unit. As discussed in *Note 2: Effect of New Accounting Standards*, we elected to early adopt Accounting Standards Update (“ASU”) 2017-04 in November 2019, which eliminated step 2 from the goodwill impairment test. 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, 2019 and 2018.

**Long-Lived Assets.** Long-lived assets include fixed assets and intangible assets. Intangible assets consist primarily of purchased licenses and intangible assets recognized as part of the Éclat Pharmaceuticals acquisition. Acquired IPR&D has an indefinite life and is not amortized until completion and development of the project, at which time the IPR&D becomes an amortizable asset, for which amortization of such intangible assets is 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 (see *Note 9: Goodwill and Intangible Assets*). We determined that no impairment existed at December 31, 2019.

**Acquisition-related Contingent Consideration.** 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, are accounted for at fair-value (see *Note 12: Long-Term Related Party Payable* and *Note 17: 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 12: Long-Term Related Party 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 (loss) income and balance sheets. Changes in fair value of these liabilities are recorded in the consolidated statements of (loss) income within operating expenses as changes in fair value of related party contingent consideration.

**Financing-related Royalty Agreements.** We also entered into two royalty agreements with related parties 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, both of whom are related parties (see *Note 12: Long-Term Related Party Payable*). The fair value of financing-related royalty agreements is 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 (loss) income and balance sheets. Changes in the fair value of this liability are recorded in the consolidated statements of (loss) income as other (expense) income - changes in fair value of related party payable.

## **Results of Operations**

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

<b>Comparative Statements of (Loss) Income:</b>	<b>Years Ended December 31,</b>		<b>Increase / (Decrease)</b>	
	<b>2019</b>	<b>2018</b>	<b>\$</b>	<b>%</b>
Product sales	\$ 59,215	\$ 101,423	\$ (42,208)	(41.6)%
License revenue	—	1,846	(1,846)	(100.0)%
Total revenues	59,215	103,269	(44,054)	(42.7)%
<b>Operating expenses:</b>				
Cost of products	12,125	17,516	(5,391)	(30.8)%
Research and development expenses	32,917	39,329	(6,412)	(16.3)%
Selling, general and administrative expenses	30,183	100,359	(70,176)	(69.9)%
Intangible asset amortization	816	6,619	(5,803)	(87.7)%
Changes in fair value of related party contingent consideration	845	(22,731)	23,576	103.7 %
Impairment of intangible asset	—	66,087	(66,087)	(100.0)%
Restructuring costs	6,441	1,016	5,425	534.0 %
Total operating expenses	83,327	208,195	(124,868)	(60.0)%
Operating (loss) income	(24,112)	(104,926)	80,814	77.0 %
Investment and other income, net	1,069	452	617	136.5 %
Interest expense	(12,483)	(10,622)	(1,861)	(17.5)%
Loss on deconsolidation of subsidiary	(2,678)	—	(2,678)	(100.0)%
Other (expense) income - changes in fair value of related party payable	(378)	1,899	(2,277)	(119.9)%
(Loss) income before income taxes	(38,582)	(113,197)	74,615	65.9 %
Income tax (benefit) provision	(5,356)	(17,893)	12,537	70.1 %
Net (loss) income	\$ (33,226)	\$ (95,304)	\$ 62,078	65.1 %
Net (loss) income per share - diluted	\$ (0.89)	\$ (2.55)	\$ 1.66	65.1 %



The revenues for each of our significant products were as follows:

Revenues	Years Ended December 31,		Increase / (Decrease)	
	2019	2018	\$	%
Bloxiverz	\$ 7,479	\$ 20,850	\$ (13,371)	(64.1)%
Vazculep	33,152	42,916	(9,764)	(22.8)%
Akovaz	18,642	33,759	(15,117)	(44.8)%
Other	(58)	3,898	(3,956)	(101.5)%
Product sales	59,215	101,423	(42,208)	(41.6)%
License revenue	—	1,846	(1,846)	(100.0)%
Total revenues	\$ 59,215	\$ 103,269	\$ (44,054)	(42.7)%

Total product sales were \$59,215 for the year ended December 31, 2019, compared to \$101,423 for the same prior year period. Bloxiverz's revenue declined \$13,371 when compared to the same period last year, primarily due to lower net selling prices driven largely by new competitors that entered the market in 2018 and 2019 and continued market penetration from an alternative molecule to neostigmine. Vazculep's revenue decreased by \$9,764 primarily due to a decrease in unit volumes and lower realized net selling prices when compared to the prior year. Akovaz's revenue decreased \$15,117 driven by lower unit volumes and net selling prices due largely to new competitors that entered the market in 2018 and 2019. Other revenues, which includes Noctiva, which was deconsolidated in February 2019, and the pediatric products, which were divested in February 2018, declined when compared to the prior year due to the divestiture of those products as well as an increased returns reserve related to these products during the year ended December 31, 2019.

License and research revenue was \$0 for the year ended December 31, 2019 compared to \$1,846 in the same period last year. 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 during the year ended December 31, 2018, which represented the unsatisfied performance obligations associated with a license agreement.

Cost of Products	Years Ended December 31,		Increase / (Decrease)	
	2019	2018	\$	%
Cost of products	\$ 12,125	\$ 17,516	\$ (5,391)	(30.8)%
Percentage of sales	20.5%	17.0%		

Cost of products decreased \$5,391, or 30.8% during the year ended December 31, 2019 compared to the prior year due to lower sales volumes. As a percentage of total revenue, cost of products sold was higher than the prior year period due to lower net selling prices of our hospital products.

Research and Development Expenses	Years Ended December 31,		Increase / (Decrease)	
	2019	2018	\$	%
Research and development expenses	\$ 32,917	\$ 39,329	\$ (6,412)	(16.3)%
Percentage of sales	55.6%	38.1%		

R&D expenses decreased \$6,412 or 16.3% during the year ended December 31, 2019 as compared to the same period in 2018. This decline was a result of \$2,800 of lower spending associated with the exit of Noctiva, lower payroll, benefits and share-based compensation of \$2,900 related to the 2019 Corporate and French restructuring plans and approximately \$900 of cost reductions at our Lyon, France R&D center. We continue to invest a substantial portion of R&D in our FT218 development program.

Selling, General and Administrative Expenses	Years Ended December 31,		Increase / (Decrease)	
	2019	2018	\$	%
Selling, general and administrative expenses	\$ 30,183	\$ 100,359	\$ (70,176)	(69.9)%
Percentage of sales	51.0%	97.2%		

Selling, general and administrative (“SG&A”) expenses decreased \$70,176 or 69.9% during the year ended December 31, 2019 as compared to the prior year. This decrease was primarily due to a decrease of \$60,100 of sales and marketing costs related to the exit of Noctiva during the first quarter 2019 as well as \$2,700 of decreased costs due to the 2018 divestiture of the pediatric products. Also contributing to the decrease is lower overall payroll and share-based compensation of \$7,200 due to reduced headcount as a result of the 2019 Corporate and French restructuring plans.

Intangibles Asset Amortization	Years Ended December 31,		Increase / (Decrease)	
	2019	2018	\$	%
Intangible asset amortization	\$ 816	\$ 6,619	\$ (5,803)	(87.7)%
Percentage of sales	1.4%	6.4%		

Intangible asset amortization expense decreased \$5,803 or 87.7% during the year ended December 31, 2019 as compared to the prior year driven by the impairment of the intangible asset related to Noctiva at December 31, 2018.

Changes in Fair Value of Related Party Contingent Consideration	Years Ended December 31,		Increase / (Decrease)	
	2019	2018	\$	%
Changes in fair value of related party contingent consideration	\$ 845	\$ (22,731)	\$ 23,576	103.7%
Percentage of sales	1.4%	(22.0)%		

We compute the fair value of the related party 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 can have a material impact on our consolidated statements of loss (income) and balance sheets.

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 \$845 and a gain of \$22,731 and increased/lowered the fair value of the acquisition-related contingent consideration earn-out payments - Éclat for the years ended December 31, 2019 and 2018, respectively. In Item 7 Critical Accounting Estimates, there are numerous assumptions and estimates we use when determining the fair value of the acquisition-related earn-out payments - Éclat. These assumptions include estimates of pricing, market size, the 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 determining the present value of the related cash flows.

For the year ended December 31, 2019, as a result of changes to these estimates when compared to the same estimates at December 31, 2018, we recorded an increase in the fair value of our contingent consideration liabilities. The increase was due to the timing of anticipated market competition when compared to the original estimates.

Impairment of Intangible Asset	Years Ended December 31,		Increase / (Decrease)	
	2019	2018	\$	%
Impairment of intangible asset	\$ —	\$ 66,087	\$ (66,087)	(100.0)%
Percentage of sales	—%	64.0%		

During the fourth quarter of 2018, an impairment charge of \$66,087 was recorded to write-off the remaining carrying value of the acquired developed technology intangible asset related to Noctiva. During the fourth quarter 2018, certain conditions came to light, largely the lack of a meaningful increase in Noctiva prescriptions despite the substantial investment of resources, which indicated that the carrying value of the asset, may not be fully recoverable. As such, we performed an impairment test based on

a comparison of the pretax discounted cash flows expected to be generated by the asset, which is a Level 3 fair value estimate, to the recorded value of the asset and concluded that the associated cash flows did not support any of the carrying value of the intangible asset and we recorded a full impairment charge. The Chapter 11 bankruptcy filing of Avadel Specialty Pharmaceuticals, LLC (“Specialty Pharma”) commenced on February 6, 2019, the subsidiary which marketed, sold and distributed Noctiva, confirmed management’s conclusion on the impairment. There were no such impairment charges during the year ended December 31, 2019.

<b>Restructuring Costs</b>	<b>Years Ended December 31,</b>		<b>Increase / (Decrease)</b>	
	<b>2019</b>	<b>2018</b>	<b>\$</b>	<b>%</b>
Restructuring costs	\$ 6,441	\$ 1,016	\$ 5,425	534.0%
Percentage of sales	10.9%	1.0%		

Restructuring costs increased \$5,425 during the year ended December 31, 2019 as compared to the same prior year period driven by the 2019 French Restructuring and 2019 Corporate Restructuring actions and included severance and legal costs, impairment of certain assets, the reversal of certain retirement indemnity obligations, share-based compensation and the termination payments for vacating the Irish and French office leases during 2019. See *Note 18: Restructuring Costs*.

<b>Investment and Other Income, net</b>	<b>Years Ended December 31,</b>		<b>Increase / (Decrease)</b>	
	<b>2019</b>	<b>2018</b>	<b>\$</b>	<b>%</b>
Investment and other income, net	\$ 1,069	\$ 452	\$ 617	136.5%
Percentage of sales	1.8%	0.4%		

Investment and other income, net increased \$617 during the year ended December 31, 2019 as compared to the same prior year period driven by higher realized and unrealized gains on our marketable securities during the current period when compared to realized and unrealized losses on our marketable securities the prior year period, partially offset by a legal settlement of \$1,750, of which a majority of the settlement is due to a former employee and the remainder to the former employee’s legal counsel. See *Note 16: Contingent Liabilities and Commitments*.

<b>Interest Expense</b>	<b>Years Ended December 31,</b>		<b>Increase / (Decrease)</b>	
	<b>2019</b>	<b>2018</b>	<b>\$</b>	<b>%</b>
Interest expense	\$ 12,483	\$ 10,622	\$ 1,861	17.5%
Percentage of sales	(21.1)%	(10.3)%		

Interest expense increased \$1,861 for the year ended December 31, 2019 when compared to the year ended December 31, 2018 as a result of twelve months of interest recorded in 2019 versus 10.5 months of interest recorded in 2018 due to the 2023 Notes issued in February 2018.

<b>Loss on Deconsolidation of Subsidiary</b>	<b>Years Ended December 31,</b>		<b>Increase / (Decrease)</b>	
	<b>2019</b>	<b>2018</b>	<b>\$</b>	<b>%</b>
Loss on deconsolidation of subsidiary	\$ (2,678)	\$ —	\$ (2,678)	(100.0)%
Percentage of sales	(4.5)%	—%		

As a result of Specialty Pharma’s bankruptcy filing on February 6, 2019, we concluded that we no longer controls its operations and accordingly deconsolidated this subsidiary. We recorded a loss 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.

<b>Other (Expense) Income - Changes in Fair Value of Related Party Payable</b>	<b>Years Ended December 31,</b>		<b>Increase / (Decrease)</b>	
	<b>2019</b>	<b>2018</b>	<b>\$</b>	<b>%</b>
Other (expense) income - changes in fair value of related party payable	\$ (378)	\$ 1,899	\$ (2,277)	(119.9)%
Percentage of sales	(0.6)%	1.8%		

We recorded expense of \$378 to increase the fair value of these liabilities during the year ended December 31, 2019 and income of \$1,899 to reduce the fair value of these liabilities during the year ended December 31, 2018, due to the same reasons associated with the Éclat product sales forecasts as described in the section “Changes in Fair Value of Related Party Contingent Consideration” for these periods. As noted in Item 7 Critical Accounting Estimates, there are a number of assumptions and estimates we use when determining the fair value of the related party payable payments. These estimates include pricing, market size, the market share the related products are forecast to achieve and an appropriate discount rate to use when determining the present value of the related cash flows. These estimates often do change based on changes in current market conditions, competition and other factors.

<b>Income Taxes</b>	<b>Years Ended December 31,</b>		<b>Increase / (Decrease)</b>	
	<b>2019</b>	<b>2018</b>	<b>\$</b>	<b>%</b>
Income tax (benefit) provision	\$ (5,356)	\$ (17,893)	\$ 12,537	70.1%
Percentage of (loss) income before income taxes	13.9%	15.8%		

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.

## **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:

<b>Net Cash (Used In) Provided By</b>	<b>Years Ended December 31,</b>		<b>Increase / (Decrease)</b>	
	<b>2019</b>	<b>2018</b>	<b>\$</b>	<b>%</b>
Operating activities	\$ (38,325)	\$ (82,716)	\$ 44,391	53.7 %
Investing activities	38,723	(36,981)	75,704	204.7 %
Financing activities	(27)	112,659	(112,686)	(100.0)%

### ***Operating Activities***

Net cash used in operating activities of \$38,325 for the year ended December 31, 2019 decreased from net cash used in operating activities of \$82,716 in the prior year. This decrease in cash used in operating activities is driven by lower cash loss (net loss adjusted for non-cash credits and charges) of \$20,858 when compared to the same period last year. This decrease is driven by less cash used in SG&A and R&D expenses in the current year driven by the Specialty Pharma bankruptcy and deconsolidation, partially offset by lower revenue in the current year when compared to the prior year. The decrease in cash used in operating activities was also due to the increase in accounts payable and accrued expenses of \$17,670 and a decrease in the earn-out and royalty payments for related party contingent payable of \$9,570 during the year ended December 31, 2019 compared to the prior year.

### ***Investing Activities***

Cash provided by investing activities was \$38,723 for the year ended December 31, 2019 compared to cash used in investing activities of \$36,981 in the same prior year period. In 2019, we had net proceeds of \$38,598 for the sale of marketable securities compared to our use of \$16,803 cash for the purchase of marketable securities during the year ended December 31, 2018. Additionally, we also had a \$20,000 Noctiva related milestone payment as part of the Exclusive License and Assignment Agreement with Serenity Pharmaceuticals, LLC (“Serenity”) during the year ended December 31, 2018.

### ***Financing Activities***

Cash used in financing activities of \$27 for the year ended December 31, 2019 decreased \$112,686 compared to cash provided by financing activities of \$112,659 for the same prior year period. During the year ended December 31, 2018, \$143,750 of cash was provided by financing activities through the issuance of the 2023 Notes. A portion of the proceeds from the offering of the 2023 Notes was used for share repurchases totaling \$27,637 and to pay direct expenses associated with the issuance of the 2023 Notes of \$6,190 during the first half of 2018.

### ***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, our hospital products revenue stream 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 and to ensure an adequate and robust NDA for filing with the FDA 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. 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.

On February 21, 2020, we announced that we have 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 has resulted in gross proceeds of approximately \$65,000 before deducting placement agent and other offering expenses, and resulting in net proceeds of approximately \$61,000.

## ***Borrowings***

In February 2018, we issued the 2023 Notes. We received net proceeds of approximately \$137,560 from the sale of the 2023 Notes, after deducting fees and expenses of \$6,190.

## ***Share Repurchase Programs***

We fully completed our authorized share buyback program during the year ended December 31, 2018. No share purchases were made during the year ended December 31, 2019.

## **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, 2019 and December 31, 2018, 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.

*Note 3: Subsidiary Bankruptcy and Deconsolidation* briefly describes the Chapter 11 bankruptcy case which our subsidiary Specialty Pharma commenced on February 6, 2019, and which on April 26, 2019 resulted in the bankruptcy court-approved sale of all of Specialty Pharma's intangible assets and inventory to an unaffiliated third party. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business. During the pendency of the bankruptcy case, all pending litigation against Specialty Pharma is automatically stayed and any new litigation against Specialty Pharma is precluded unless the bankruptcy court orders otherwise. Below are descriptions of a litigation to which Specialty Pharma is a party and a contract dispute involving Specialty Pharma, both of which matters are subject to the automatic stay during the bankruptcy case.

*Ferring Litigation.* Some of the patents covering the Noctiva product (the "Noctiva Patents") are the subject of litigation initiated by Ferring Pharmaceuticals Inc. and two of its foreign affiliates, who manufacture a competing product known as Nocdurna. Nocdurna was approved by the FDA in June 2018 and commercially launched in the U.S. in November 2018. In this litigation, filed in the United States District Court for the Southern District of New York, Ferring seeks to invalidate and disputes the inventorship of the Noctiva Patents, seeks damages for various alleged breaches of contractual and common law duties, and seeks damages for alleged infringement by Noctiva of Ferring's "Nocdurna" trademark. Specialty Pharma and certain other parties including Serenity Pharmaceuticals, LLC ("Serenity") (the licensor of the Noctiva Patents) have defended this litigation, and have made counterclaims against Ferring, including for infringement of the Noctiva Patents and a declaratory judgment of noninfringement with respect to Ferring's "Nocdurna" trademark. The court dismissed Ferring's inventorship claim and its claims for alleged breaches of contractual and common law duties, although these dismissals may be appealed by Ferring. On February 15, 2019, Specialty Pharma and its co-defendants moved to stay the litigation pending completion of the bankruptcy proceeding of Specialty Pharma. On May 15, 2019, that motion was denied due to a pending settlement of the litigation with respect to just Ferring and Specialty Pharma. On February 25, 2020, Ferring and Specialty Pharma jointly moved for bankruptcy court approval of a settlement agreement with respect to the claims alleged in the litigation. In accordance with the terms of the settlement agreement, promptly following bankruptcy court approval of the settlement agreement, the parties would dismiss with prejudice their respective claims against each other in the litigation. On March 13th, 2020, the bankruptcy court entered an order approving the settlement with Ferring. Pursuant to the terms of the settlement, the parties are to dismiss their respective claims against each other in the District Court litigation in the Southern District of New York, with such dismissals to be effective concurrently. That joint dismissal has not yet been filed with District Court for the Southern District of New York.

*Contract Dispute.* On January 21, 2019, Serenity gave notice to Specialty Pharma of an alleged breach of the parties' Noctiva license agreement. Serenity alleges that Specialty Pharma breached its contractual obligation to devote commercially reasonable efforts to the commercialization of Noctiva and seeks unspecified damages. On January 27, 2019, Specialty Pharma notified Serenity of a claim for \$1.7 million in damages as a result of Serenity's breach of its contractual obligation to pay the costs of the Ferring Litigation. Serenity's notice to Specialty Pharma invoked the dispute resolution provisions of the Noctiva license agreement, which culminate in arbitration, but neither party has yet initiated an arbitration proceeding or filed suit.

*Exela Litigation.* On January 7, 2020, Exela filed a complaint against us and our subsidiary, Avadel Legacy in the United States District for the District of Delaware. The complaint alleges infringement of a certain Exela patent related to its cysteine hydrochloride product. Exela is most notably seeking i) a declaratory judgment that the Nouress product infringes its patent, ii)

an injunction (both preliminary and permanent) precluding the launch of Nouress, and iii) monetary damages (including enhanced damages, prejudgment interest and attorneys' fees) in the event Nouress is commercially launched and found to infringe Exela's patent. We have not yet been served with the complaint.

*Former employee dispute.* On January 10, 2020, we settled a dispute with a former employee for \$1,750.

### **Material Commitments**

At December 31, 2019, we had various commitments to purchase finished product from customers. Commitments for these arrangements, at maximum quantities and at contractual prices over the remaining life of the contract, and excluding any waived commitments, are as follows for the years ended December 31:

<b>Purchase Commitments:</b>	<b>Balance</b>
2020	\$ 1,434
2021	1,430
2022	1,430
2023	1,430
2024	—
Thereafter	—
Total	\$ 5,724

We also had 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, 2019. Subsequent to the initial build and preparation of the production suite, this commitment also includes annual fees which would commence at the time of FDA approval of the product and continue thereafter for five years. These amounts are not included in the table above, as the start date has not been determined.

We and our subsidiaries lease office facilities under non-cancellable operating leases expiring at various dates. See *Note 10: Leases* for disclosure of these.

Other than the above commitments, there were no other material commitments outside of the normal course of business. Material commitments in the normal course of business include long-term debt and long-term related party payable, which are disclosed in *Item 8. Financial Statements and Supplementary Data, Note 11: Long-Term Debt* and *Note 12: Long-Term Related Party Payable*, respectively.

### **Aggregate Contractual Obligations**

The following table presents our contractual obligations at December 31, 2019:

<b>Contractual Obligations:</b>	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1 to 3 Years</b>	<b>3 to 5 Years</b>	<b>More than 5 Years</b>
Long-term debt and interest	\$ 166,391	\$ 6,469	\$ 12,938	\$ 146,984	\$ —
Long-term related party payable (undiscounted)	29,847	5,554	5,181	4,262	14,850
Purchase commitments	5,724	1,434	2,860	1,430	—
Operating leases	3,368	779	1,167	1,216	206
Total contractual cash obligations	\$ 205,330	\$ 14,236	\$ 22,146	\$ 153,892	\$ 15,056

See *Note 11: Long-Term Debt* and *Note 12: Long-Term Related Party Payable* to our consolidated financial statements contained in *Item 8 – Financial Statements* for obligations with respect to the respective items within the above table.

### **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, 2019 would have had an immaterial impact on net loss for the year ended December 31, 2019.

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 foreign exchange gain (loss) in the consolidated statements of (loss) income. As of December 31, 2019, 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, 2019.



Item 8. Financial Statements and Supplementary Data.

**AVADEL PHARMACEUTICALS PLC**  
**CONSOLIDATED STATEMENTS OF (LOSS) INCOME**

*(In thousands, except per share data)*

	Years ended December 31,		
	2019	2018	2017
<b>Revenues:</b>			
Product sales	\$ 59,215	\$ 101,423	\$ 172,841
License revenue	—	1,846	404
Total revenues	59,215	103,269	173,245
<b>Operating expenses:</b>			
Cost of products	12,125	17,516	16,301
Research and development expenses	32,917	39,329	33,418
Selling, general and administrative expenses	30,183	100,359	58,860
Intangible asset amortization	816	6,619	3,659
Changes in fair value of related party contingent consideration	845	(22,731)	(31,040)
Impairment of intangible asset	—	66,087	—
Restructuring costs	6,441	1,016	2,542
Total operating expenses	83,327	208,195	83,740
Operating (loss) income	(24,112)	(104,926)	89,505
Investment and other income, net	1,069	452	2,136
Interest expense	(12,483)	(10,622)	(1,052)
Loss on deconsolidation of subsidiary	(2,678)	—	—
Other (expense) income - changes in fair value of related party payable	(378)	1,899	2,071
(Loss) income before income taxes	(38,582)	(113,197)	92,660
Income tax (benefit) provision	(5,356)	(17,893)	24,389
Net (loss) income	<u>\$ (33,226)</u>	<u>\$ (95,304)</u>	<u>\$ 68,271</u>
Net (loss) income per share - basic	\$ (0.89)	\$ (2.55)	\$ 1.69
Net (loss) income per share - diluted	\$ (0.89)	\$ (2.55)	\$ 1.63
Weighted average number of shares outstanding - basic	37,403	37,325	40,465
Weighted average number of shares outstanding - diluted	37,403	37,325	41,765

*See accompanying notes to consolidated financial statements.*

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

	Years ended December 31,		
	2019	2018	2017
Net (loss) income	\$ (33,226)	\$ (95,304)	\$ 68,271
Other comprehensive income (loss), net of tax:			
Foreign currency translation (loss) gain	(117)	(419)	134
Net other comprehensive income, net of (\$43), (\$18), \$28 tax, respectively	727	269	165
Total other comprehensive income (loss), net of tax	610	(150)	299
Total comprehensive (loss) income	\$ (32,616)	\$ (95,454)	\$ 68,570

*See accompanying notes to consolidated financial statements.*

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

	December 31,	
	2019	2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,774	\$ 9,325
Marketable securities	54,384	90,590
Accounts receivable	8,281	11,330
Inventories, net	3,570	4,770
Research and development tax credit receivable	2,107	283
Prepaid expenses and other current assets	4,264	8,553
<b>Total current assets</b>	<b>82,380</b>	<b>124,851</b>
Property and equipment, net	544	1,911
Operating lease right-of-use assets	3,612	—
Goodwill	18,491	18,491
Intangible assets, net	813	1,629
Research and development tax credit receivable	6,322	7,272
Other non-current assets	39,274	36,146
<b>Total assets</b>	<b>\$ 151,436</b>	<b>\$ 190,300</b>
<b>LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ —	\$ 106
Current portion of long-term related party payable	5,554	9,439
Current portion of operating lease liability	645	—
Accounts payable	6,100	3,503
Accrued expenses	19,810	21,695
Other current liabilities	3,875	3,640
<b>Total current liabilities</b>	<b>35,984</b>	<b>38,383</b>
Long-term debt, less current portion	121,686	115,734
Long-term related party payable, less current portion	11,773	19,401
Long-term operating lease liability	2,319	—
Other non-current liabilities	8,873	14,002
<b>Total liabilities</b>	<b>180,635</b>	<b>187,520</b>
Shareholders' (deficit) equity:		
Preferred shares, nominal value of \$0.01 per share; 50,000 shares authorized; none issued or outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Ordinary shares, nominal value of \$0.01 per share; 500,000 shares authorized; 42,927 issued and 37,520 outstanding at December 31, 2019, and 42,720 issued and 37,313 outstanding at December 31, 2018	429	427
Treasury shares, at cost, 5,407 shares held at December 31, 2019 and December 31, 2018, respectively	(49,998)	(49,998)
Additional paid-in capital	434,391	433,756
Accumulated deficit	(391,215)	(357,989)
Accumulated other comprehensive loss	(22,806)	(23,416)
<b>Total shareholders' (deficit) equity</b>	<b>(29,199)</b>	<b>2,780</b>
<b>Total liabilities and shareholders' (deficit) equity</b>	<b>\$ 151,436</b>	<b>\$ 190,300</b>

*See accompanying notes to consolidated financial statements.*

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

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Treasury Shares		Total shareholders' (deficit) equity
	Shares	Amount				Shares	Amount	
Balance, December 31, 2016	41,371	\$ 414	\$ 385,020	\$ (319,800)	\$ (23,565)	—	\$ —	\$ 42,069
Net income	—	—	—	68,271	—	—	—	68,271
Other comprehensive income	—	—	—	—	299	—	—	299
Exercise of stock options	69	—	396	—	—	—	—	396
Vesting of restricted shares	23	—	—	—	—	—	—	—
Share-based compensation expense	—	—	8,062	—	—	—	—	8,062
Share repurchases	—	—	—	—	—	2,117	(22,361)	(22,361)
Adjustment to accumulated deficit (see Note 13: <i>Income Taxes</i> )	—	—	—	(11,156)	—	—	—	(11,156)
Balance, December 31, 2017	41,463	414	393,478	(262,685)	(23,266)	2,117	(22,361)	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	433,756	(357,989)	(23,416)	5,407	(49,998)	2,780
Net loss	—	—	—	(33,226)	—	—	—	(33,226)
Other comprehensive income	—	—	—	—	610	—	—	610
Vesting of restricted shares	153	2	(2)	—	—	—	—	—
Employee share purchase plan share issuance	54	—	118	—	—	—	—	118
Share-based compensation expense	—	—	519	—	—	—	—	519
Balance, December 31, 2019	42,927	\$ 429	\$ 434,391	\$ (391,215)	\$ (22,806)	5,407	\$ (49,998)	\$ (29,199)

*See accompanying notes to consolidated financial statements.*

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

	Years ended December 31,		
	2019	2018	2017
<b>Cash flows from operating activities:</b>			
Net (loss) income	\$ (33,226)	\$ (95,304)	\$ 68,271
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization	2,486	7,430	4,883
Impairment of intangible asset	—	66,087	—
Amortization of premiums on marketable securities	41	2,823	732
Remeasurement of related party acquisition-related contingent consideration	845	(22,731)	(31,040)
Remeasurement of related party financing-related contingent consideration	378	(1,899)	(2,071)
Amortization of debt discount and debt issuance costs	5,995	4,830	—
Changes in deferred tax	(6,334)	(19,152)	3,556
Share-based compensation expense	519	7,852	8,072
Loss on deconsolidation of subsidiary	1,750	—	—
Other adjustments	(295)	1,365	(968)
Net changes in assets and liabilities			
Accounts receivable	2,471	3,452	3,054
Inventories, net	1,155	711	(2,899)
Prepaid expenses and other current assets	(1,187)	3,577	(3,741)
Research and development tax credit receivable	(1,014)	(2,545)	(3,141)
Accounts payable & other current liabilities	4,641	(2,032)	595
Deferred revenue	(114)	(1,892)	(216)
Accrued expenses	357	(10,640)	13,187
Accrued income taxes	(30)	(341)	(786)
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(10,988)	(19,468)	(31,636)
Royalty payments for related party payable in excess of original fair value	(1,748)	(2,838)	(4,429)
Other assets and liabilities	(4,027)	(2,001)	(4,761)
Net cash (used in) provided by operating activities	<u>(38,325)</u>	<u>(82,716)</u>	<u>16,662</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(29)	(178)	(591)
Proceeds from disposal of property and equipment	154	—	—
Purchase of intangible assets	—	(20,000)	(53,111)
Proceeds from sales of marketable securities	63,246	359,507	189,009
Purchases of marketable securities	(24,648)	(376,310)	(151,005)
Net cash provided by (used in) investing activities	<u>38,723</u>	<u>(36,981)</u>	<u>(15,698)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from debt issuance	—	143,750	—
Payments for debt issuance costs	—	(6,190)	—
Earn-out payments for related party contingent consideration	—	(645)	(1,246)
Exercise of warrants	—	2,911	—
Proceeds from issuance of ordinary shares	118	577	404
Share repurchases	—	(27,637)	(22,361)
Other financing activities, net	(145)	(107)	(115)
Net cash (used in) provided by financing activities	<u>(27)</u>	<u>112,659</u>	<u>(23,318)</u>
Effect of foreign currency exchange rate changes on cash and cash equivalents	78	(201)	(297)
Net change in cash and cash equivalents	449	(7,239)	(22,651)
Cash and cash equivalents at January 1	9,325	16,564	39,215
Cash and cash equivalents at December 31	<u>\$ 9,774</u>	<u>\$ 9,325</u>	<u>\$ 16,564</u>
<b>Supplemental disclosures of cash flow information:</b>			
Income tax paid	\$ 140	\$ 776	\$ 19,143
Interest paid	6,469	3,359	1,050

*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 an emerging biopharmaceutical company. Our lead product candidate, FT218, is an investigational once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness (“EDS”), and cataplexy in narcolepsy patients. FT218, which uses our Micropump drug-delivery technology, is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from EDS and cataplexy. In addition, we have three approved commercial products developed under our “unapproved marketed drug,” or UMD, program, Akovaz, Bloxiverz and Vazculep, and a fourth approved product, Nouress, which are sterile injectable drugs used in the hospital setting.

We are primarily focused on the development and potential U.S. Food and Drug Administration (“FDA”) approval of FT218. In addition, we continue to market and distribute our current approved hospital products portfolio and, pending resolution of the existing patent infringement claim (as described below), we plan to commercialize Nouress. Outside of our product candidate and our existing commercial products, we continue to evaluate opportunities to expand our product portfolio.

*Current marketed products*

- **Bloxiverz (neostigmine methylsulfate injection)** - Bloxiverz was approved by the FDA in May 2013 and was launched in July 2013. Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery. Bloxiverz was the first FDA-approved version of neostigmine methylsulfate. Today, neostigmine is one of the two most frequently used products for the reversal of the effects of other agents used for neuromuscular blocks.
- **Vazculep (phenylephrine hydrochloride injection)** - Vazculep was approved by the FDA in June 2014 and was launched in October 2014. Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
- **Akovaz (ephedrine sulfate injection).** Akovaz, was approved by the FDA in April 2016 and was launched in August 2016. 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*

In December 2019, we received FDA approval for Nouress (cysteine hydrochloride injection), a sterile injectable product for use in the hospital setting, and currently have two patents covering that product. Several additional patent applications for Nouress are pending with the USPTO. In light of the recently filed patent suit by Exela Pharma Sciences, LLC, we are currently evaluating the timing and process for a commercial launch of Nouress in the U.S. See *Note 16: Contingent Liabilities and Commitments*.

The Company was incorporated in Ireland on December 1, 2015 as a private limited company, and re-registered as an Irish public limited company on November 21, 2016. Our headquarters are in Dublin, Ireland and we have operations in St. Louis, Missouri, U.S., and Lyon, France.

**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.

On February 6, 2019, the Company’s indirect wholly-owned subsidiary, Avadel Specialty Pharmaceuticals, LLC (“Specialty Pharma”), filed a voluntary petition for reorganization under Chapter 11 of the U.S. Code (the “Bankruptcy Code”) in the U.S. District Bankruptcy Court for the District of Delaware (the “Bankruptcy Court”), Case No. 19-10248. Specialty Pharma is operating and managing its business as “debtors-in-possession” under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code and order of the Bankruptcy Court. As a result of Specialty Pharma’s voluntary bankruptcy filing on February 6, 2019, we no longer controlled the operations of Specialty Pharma; therefore, we deconsolidated Specialty Pharma effective with the bankruptcy filing and the Company recorded its investment in Specialty Pharma under the cost method. See *Note 3: Subsidiary Bankruptcy and Deconsolidation*. Our results of operations for the period January 1, 2019

through February 6, 2019 include the results of Specialty Pharma prior to its February 6, 2019 voluntary petition for reorganization under Chapter 11 of the U.S. Bankruptcy Code.

Our results of operations for the period January 1, 2018 through February 16, 2018 and for the year ended December 31, 2017 include the results of FSC Therapeutics and FSC Laboratories, Inc., (collectively "FSC"), prior to its February 16, 2018 disposition date. See *Note 17: Divestiture of the Pediatric Assets*, for additional information.

**Revenue.** Revenue includes 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 4: 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*

We sell products primarily through wholesalers and considers these wholesalers to be its 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 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 4: 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.

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 \$372, \$17,562 and \$2,214 for the years ended December 31, 2019, 2018 and 2017, respectively. The decrease in advertising for the year ended December 31, 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-Scholes 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 (loss) income. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheets.

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

**Marketable Securities.** The Company's marketable securities are considered to be available for sale and are carried at fair value, with unrealized gains and losses, net of taxes, reported as a component of accumulated other comprehensive (loss) income ("AOCI") in shareholders' equity, with the exception of unrealized gains and losses on equity instruments and 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.** Accounts receivable are stated at amounts invoiced net of allowances for doubtful accounts and certain other gross to net variable consideration deductions. The Company makes judgments as to our ability to collect outstanding receivables and provides allowances for the portion of receivables deemed uncollectible. Provision is made based upon a specific review of all significant outstanding invoices. A majority of accounts receivable is due from four significant customers.

**Inventories.** Inventories consist of raw materials and finished products, which are stated at lower of cost or net realizable value, using the first-in, first-out ("FIFO") method. Raw materials used in the production of pre-clinical and clinical products are expensed as R&D costs when consumed. The Company establishes 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:

Laboratory equipment	4-8 years
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 has a single reporting unit associated with the development and commercialization of pharmaceutical products. Prior to November 2019, we tested for goodwill impairment using a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then, in the second step, the loss is measured as the excess of recorded goodwill over the implied fair value of the goodwill. Implied fair value of goodwill is the excess of the fair value of the reporting unit as a whole over the fair value of all separately identified assets and liabilities within the reporting unit. As discussed in *Note 2: Effect of New Accounting Standards*, we elected to early adopt Accounting Standards Update (“ASU”) 2017-04 in November 2019, which eliminated step 2 from the goodwill impairment test. 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, 2019 and 2018.

**Long-Lived Assets.** Long-lived assets include fixed assets and intangible assets. Intangible assets consist primarily of purchased licenses and intangible assets recognized as part of the Éclat Pharmaceuticals acquisition. Acquired IPR&D has an indefinite life and is not amortized until completion and development of the project, at which time the IPR&D becomes an amortizable asset, for which amortization of such intangible assets is 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 (see *Note 9: Goodwill and Intangible Assets*). We determined that no impairment existed at December 31, 2019.

**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 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 (loss) income 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. Nearly all of the Company’s lease contracts do not provide a readily determinable implicit rate. For these contracts, 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.

**Acquisition-related Contingent Consideration.** 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, are accounted for at fair-value (see *Note 12: Long-Term Related Party Payable* and *Note 17: 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 12: Long-Term Related Party 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 (loss) income and balance sheets. Changes in fair value of these liabilities are recorded in the consolidated statements of (loss) income within operating expenses as changes in fair value of related party contingent consideration.

**Financing-related Royalty Agreements.** We also entered into two royalty agreements with related parties 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, both of whom are related parties (see *Note 12: Long-Term Related Party Payable*). The fair value of financing-related royalty agreements is 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 (loss) income and balance sheets. Changes in the fair value of this liability are recorded in the consolidated statements of (loss) income as other (expense) income - changes in fair value of related party payable.

**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 (loss) income and balance sheets. Actual results could differ from those estimates under different assumptions or conditions.

## **NOTE 2: Newly Issued Accounting Standards**

### ***Recently Adopted Accounting Guidance***

In February 2016, the Financial Accounting Standards Board (“FASB”) issued ASU 2016-02, “Leases” which supersedes ASC 840 “Leases” and creates a new topic, ASC 842 “Leases.” This update requires lessees to recognize on their balance sheet a lease liability and a lease asset for all leases, including operating leases, with a term greater than 12 months. The update also expands the required quantitative and qualitative disclosures surrounding leases. This update is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years, with earlier application permitted. In July 2018, the FASB issued ASU 2018-11 “Targeted Improvements”, amending certain aspects of the new leasing standard. The amendment allows an additional optional transition method whereby an entity records a cumulative effect adjustment to opening retained earnings in the year of adoption without restating prior periods, which the Company has elected. The Company adopted this ASU during the first quarter of 2019. See *Note 10: Leases* for more information.

In January 2017, the FASB issued ASU 2017-04, “Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment.” This update eliminates step 2 from the goodwill impairment test, and requires the goodwill impairment test to be performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. This guidance is effective for the Company in the first quarter of 2020. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. In November 2019, the Company elected to early adopt ASU 2017-04, and the adoption had no 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.

In August 2018, the FASB issued 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. The Company is currently evaluating the impact of adopting ASU 2018-13 and does not believe the standard will have a material impact on the consolidated financial statements.

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 are currently evaluating the impact of our adoption of ASU 2016-13 on our condensed consolidated financial statements and currently does not believe the standard will have a material impact on the consolidated financial statements.

### **NOTE 3: Subsidiary Bankruptcy and Deconsolidation**

#### *Bankruptcy Filing and Deconsolidation*

As a result of Specialty Pharma’s bankruptcy filing on February 6, 2019, Avadel has ceded authority for managing the business to the Bankruptcy Court, and Avadel management cannot carry on Specialty Pharma’s activities in the ordinary course of business without Bankruptcy Court approval. Avadel manages the day-to-day operations of Specialty Pharma, but does 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 are subject to review by the Bankruptcy Court. For these reasons, we have concluded that Avadel has lost control of Specialty Pharma, and no longer has 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 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 files 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. Both Specialty Pharma and the Company disagree with the merits of the amended IRS claim and intend to defend their positions vigorously.

#### *Debtor in Possession (“DIP”) Financing – Related Party Relationship*

In connection with the bankruptcy filing, Specialty Pharma entered into a DIP 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. As of December 31, 2019, the Company had funded \$407 under the DIP Credit Agreement. As we have assessed that it is unlikely that Specialty Pharma will pay back the loan to Avadel, the \$407 has been recorded as part of the loss on deconsolidation of subsidiary within the consolidated statements of (loss) income. At December 31, 2019, the fair value of the remaining commitment under the DIP Credit Agreement is not material.

### **NOTE 4: Revenue Recognition**

The Company generates revenue primarily from the sale of pharmaceutical products to customers. From time to time the Company also generates revenue from licensing arrangements whereby the Company provides access to certain of its intellectual property.

## ***Periods prior to January 1, 2018***

### ***Product Sales and Services***

Revenue was generally realized or realizable and earned when persuasive evidence of an arrangement existed, delivery had occurred or services had been rendered, the seller's price to the buyer was fixed or determinable, and collectability was reasonably assured. The Company recorded revenue from product sales when title and risk of ownership transferred to the customer, which was typically upon delivery to the customer and when the selling price was determinable.

### ***Licensing Revenues***

From time to time, the Company enters into licensing agreements for the license of technology used for developing modified controlled release of oral pharmaceutical products. Non-refundable fees where the Company had continuing performance obligations were deferred and recognized ratably over the projected performance period. Milestone payments, which were typically related to regulatory, commercial or other achievements by the Company or their licensees and distributors, were recognized as revenues when the milestone was accomplished and collection was reasonably assured.

## ***Periods commencing January 1, 2018***

### ***Product Sales and Services***

Effective January 1, 2018, the Company implemented ASC 606, *Revenue From Contracts With Customers*. The Company sells products primarily through wholesalers and considers these wholesalers to be its customers. Under ASC 606, revenue from product sales is recognized when the customer obtains control of the Company's product and the Company's performance obligations are met, which occurs typically upon receipt of delivery to the customer. As is customary in the pharmaceutical industry, the Company's gross product sales are subject to a variety of price deductions in arriving at reported net product sales. These adjustments include estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated when the product is delivered based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

### ***Reserves to reduce Gross Revenues to Net Revenues***

Revenues from product sales are recorded at the net selling price, which includes 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 are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable if the amount is payable to the customer, 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 net 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 net product revenue and 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 estimates 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 currently estimates 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 year ended December 31, 2019.

### ***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 is 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 22: 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, 2019 and 2018.

### ***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 2019 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, 2019, the deferred revenue balance related to this obligation is \$0.

We have 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 5: 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:

Fair Value Measurements:	As of December 31, 2019			As of December 31, 2018		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Marketable securities (see Note 6)						
Equity securities	\$ 4,404	\$ —	\$ —	\$ 9,145	\$ —	\$ —
Money market funds	38,799	—	—	52,996	—	—
Corporate bonds	—	4,098	—	—	6,339	—
Government securities - U.S.	—	5,446	—	—	12,701	—
Other fixed-income securities	—	1,637	—	—	9,409	—
Total assets	<u>\$ 43,203</u>	<u>\$ 11,181</u>	<u>\$ —</u>	<u>\$ 62,141</u>	<u>\$ 28,449</u>	<u>\$ —</u>
Related party payable (see Note 12)	—	—	17,327	—	—	28,840
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 17,327</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 28,840</u>

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, 2019, there were no transfers in and out of Level 1, 2, or 3. During the twelve months ended December 31, 2019, 2018 and 2017, 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, 2019 is \$107,692 compared to a book value of \$121,686.

See Note 11: Long-Term Debt for additional information regarding our debt obligations.

**NOTE 6: Marketable Securities**

We have investments in available-for-sale marketable securities which are recorded at fair market value. Prior to January 1, 2018, unrealized gains and losses on all securities are recorded as other comprehensive income (loss) in shareholders' equity, net of income tax effects.

On January 1, 2018, the Company adopted ASU 2016-01, which requires the change in the fair value of available-for-sale equity investments to be recognized in our consolidated statements of (loss) income rather than as a component of our consolidated statement of comprehensive (loss) income. For the years ended December 31, 2019 and 2018, the net unrealized loss on our available-for-sale equity investments, recorded as a component of investment income in the accompanying consolidated statements of (loss) income, was income of \$170 and a loss of \$956, respectively. The net unrealized gain on our available-for-sale equity investments was immaterial for the year ended December 31, 2017 and was recorded as other comprehensive income in shareholders' equity, net of income tax effects.

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, 2019 and 2018, respectively:

Marketable Securities:	2019			
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value
Equity securities	\$ 4,234	\$ 170	\$ —	\$ 4,404
Money market 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

Marketable Securities:	2018			
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value
Equity securities	\$ 10,101	\$ —	\$ (956)	\$ 9,145
Money market funds	52,733	316	(53)	52,996
Corporate bonds	6,411	7	(79)	6,339
Government securities - U.S.	12,714	66	(79)	12,701
Other fixed-income securities	9,400	22	(13)	9,409
Total	\$ 91,359	\$ 411	\$ (1,180)	\$ 90,590

We determine realized gains or losses on the sale of marketable securities on a specific identification method. We recognized gross realized gains of \$483, \$317, and \$1,677 for the twelve months ended December 31, 2019, 2018, and 2017, respectively. These realized gains were offset by realized losses of \$151, \$565, and \$1,390 for the twelve-months ended December 31, 2019, 2018, and 2017, respectively. We reflect these gains and losses as a component of investment income in the accompanying consolidated statements of (loss) income.

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, 2019:

Marketable Debt Securities:	Maturities				Total
	Less than 1 Year	1-5 Years	5-10 Years	Greater than 10 Years	
Corporate bonds	\$ 293	\$ 3,464	\$ 341	\$ —	\$ 4,098
Government securities - U.S.	—	4,744	315	387	5,446
Other fixed-income securities	—	1,637	—	—	1,637
Total	\$ 293	\$ 9,845	\$ 656	\$ 387	\$ 11,181



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.

#### NOTE 7: Inventories

The principal categories of inventories, net of reserves of \$914 and \$4,757 at December 31, 2019 and 2018, respectively, are comprised of the following:

Inventory:	2019	2018
Finished goods	\$ 3,020	\$ 4,270
Raw materials	550	500
Total	<u>\$ 3,570</u>	<u>\$ 4,770</u>

Total net reserves decreased by \$3,843 during the year ended December 31, 2019 driven largely by the deconsolidation of Specialty Pharma.

#### NOTE 8: Property and Equipment, net

The principal categories of property and equipment, net at December 31, 2019 and 2018, respectively, are as follows:

Property and Equipment, net:	2019	2018
Laboratory equipment	\$ —	\$ 8,864
Software, office and computer equipment	1,258	2,487
Furniture, fixtures and fittings	300	3,715
Less - accumulated depreciation	(1,014)	(13,155)
Total	<u>\$ 544</u>	<u>\$ 1,911</u>

The decrease in the principal categories of property and equipment, net during the year ended December 31, 2019, is a result of the restructuring efforts discussed in *Note 18: Restructuring Costs*.

Depreciation expense for the years ended December 31, 2019, 2018 and 2017 was \$459, \$811 and \$1,224, respectively.

#### NOTE 9: Goodwill and Intangible Assets

The Company's amortizable and unamortizable intangible assets at December 31, 2019 and 2018, respectively, are as follows:

Goodwill and Intangible Assets:	2019			2018			
	Gross Value	Accumulated Amortization	Net Carrying Amount	Gross Value	Accumulated Amortization	Impairment	Net Carrying Amount
Amortizable intangible assets:							
Acquired developed technology - Noctiva	\$ —	\$ —	\$ —	\$ 73,111	\$ (7,024)	\$ (66,087)	\$ —
Acquired developed technology - Vazculep	1,629	(816)	813	12,061	(10,432)	—	1,629
Total amortizable intangible assets	<u>\$ 1,629</u>	<u>\$ (816)</u>	<u>\$ 813</u>	<u>\$ 85,172</u>	<u>\$ (17,456)</u>	<u>\$ (66,087)</u>	<u>\$ 1,629</u>
Unamortizable intangible assets -							
Goodwill	\$ 18,491	\$ —	\$ 18,491	\$ 18,491	\$ —	\$ —	\$ 18,491

The Company recorded amortization expense related to amortizable intangible assets of \$816, \$6,619 and \$3,659 for the years ended December 31, 2019, 2018 and 2017, respectively.

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

During the fourth quarter 2018, certain conditions came to light, largely the lack of a meaningful increase in Noctiva prescriptions despite the substantial investment of resources, which indicated that the carrying value of the asset, may not be fully recoverable. As such, we performed an impairment test based on a comparison of the pretax discounted cash flows expected to be generated by the asset, which is a Level 3 fair value estimate, to the recorded value of the asset and concluded that the associated cash flows did not support any of the carrying value of the intangible asset and we recorded a full impairment charge of \$66,087 at December 31, 2018 related to the acquired developed technology associated with Noctiva. The Chapter 11 bankruptcy filing of Specialty Pharma commenced on February 6, 2019, the subsidiary which marketed, sold and distributed Noctiva, confirmed management's conclusion on the impairment. This impairment charge is included in the line "Impairment of intangible asset" in the consolidated statements of (loss) income.

Amortizable intangible assets are amortized over their estimated useful lives, which range from three to fifteen years, using the straight-line method. At December 31, 2019, total amortization of intangible assets for the year ended December 31, 2020 is \$813. There is no estimated amortization during the years ended December 31, 2021-2024 as the acquired developed technology - Vazculep will be fully amortized at December 31, 2020.

#### NOTE 10: Leases

On January 1, 2019, the Company adopted the ASU 842 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. The adoption resulted in the initial recognition of operating lease right-of-use assets of \$5,046 and operating lease liabilities of \$5,131. At December 31, 2019, the balances of the operating lease right-of-use asset and total operating lease liability were \$3,612 and \$2,964, respectively, of which \$645 of the operating lease liability is classified as a current liability.

The Company leases certain office facilities, comprising approximately 81% of the total lease population at December 31, 2019. 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 to break out separately.

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

Lease cost:	2019
Operating lease costs <sup>(1)</sup>	\$ 1,515
Sublease income <sup>(2)</sup>	(276)
Total lease cost	<u>\$ 1,239</u>

<sup>(1)</sup> Variable lease costs were immaterial for the year ended December 31, 2019.

<sup>(2)</sup> Represents sublease income received for the vacated office facility in Charlotte, North Carolina, which was acquired with the FSC acquisition in February 2016. The lease and sublease agreements terminate in December 2020. The Company also vacated portions of its office facility in St. Louis, Missouri during May 2019 and August 2019 and started receiving sublease income starting in May 2019 and August 2019 from two different tenants. The lease agreement ends in April 2025 and the sublease agreement that started in May 2019 ends in May 2021 and the sublease agreement that started in August 2019 ends in July 2020 and can continue thereafter on a month-to-month basis.

During the year ended December 31, 2019, the Company reduced its operating lease liabilities by \$1,480 for cash paid. The remainder of the decrease is related to the exit of certain leases discussed below. In addition, during the year ended December 31, 2019, one new operating lease commenced resulting in the recognition of an operating lease right-of-use asset and liability of \$1,000 and \$0, respectively, as the entire lease payment was paid on March 31, 2019. As of December 31, 2019, 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.

In connection with the 2019 Corporate Restructuring plan discussed in *Note 18: Restructuring Costs*, during the year ended December 31, 2019, the Company came to an agreement with the landlord of the leased office space in Ireland, to surrender the lease by December 31, 2019 with an early termination payment of approximately \$288. This amount was recorded as a restructuring cost in the consolidated statements of (loss) income.

In connection with the 2019 French Restructuring plan discussed in *Note 18: Restructuring Costs*, during the year ended December 31, 2019, the Company came to an agreement with the landlord of the leased office space in France, to surrender the lease by December 31, 2019 with an early termination payment of approximately \$820. The Company accounted for this change in the lease term as a modification of the original lease. As a result of this modification, the right-of-use asset and liability related to the French office lease was remeasured, and the asset was subsequently tested for impairment as the fair value was less than the book value. Since the fair value was determined to be less than the book value, the Company recorded an impairment to the right of use asset of \$826, which is recorded as a restructuring cost in the consolidated statements of loss.

As of December 31, 2019, our operating leases have a weighted-average remaining lease term of 5.0 years and a weighted-average discount rate of 5.3%. Nearly all of Avadel's lease contracts do not provide a readily determinable implicit rate. For these contracts, 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:

<b>Maturities:</b>	<b>Operating Leases</b>
2020	\$ 779
2021	578
2022	590
2023	602
2024	614
Thereafter	201
<b>Total lease payments</b>	<b>3,364</b>
Less: interest	400
<b>Present value of lease liabilities</b>	<b>\$ 2,964</b>

Under the prior lease guidance, minimum rental commitments for non-cancelable leases as of December 31, 2019 were:

<b>Lease Commitment:</b>	<b>Operating Leases</b>
2020	\$ 779
2021	578
2022	590
2023	602
2024	614
Thereafter	201
<b>Total minimum lease payments</b>	<b>\$ 3,364</b>

**NOTE 11: Long-Term Debt**

Long-Term debt is summarized as follows:

	December 31, 2019	December 31, 2018
Principal amount of 4.50% exchangeable senior notes due 2023	\$ 143,750	\$ 143,750
Less: debt discount and issuance costs, net	(22,064)	(28,059)
Net carrying amount of liability component	121,686	115,691
Other debt	—	149
Subtotal	121,686	115,840
Less: current maturities	—	(106)
Long-term debt	\$ 121,686	\$ 115,734

**Equity component:**

Equity component of exchangeable notes, net of issuance costs	\$ (26,699)	\$ (26,699)
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*Issuance of Debt Securities*

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 Company pays 4.50% cash interest per year on the principal amount of the 2023 Notes, payable semi-annually in arrears on February 1 and August 1 of each year, beginning on August 1, 2018, to holders of record at the close of business on the preceding January 15 or July 15, respectively. Interest accrues on the principal amount of the 2023 Notes from and including the date the 2023 Notes were issued or from, and including, the last date in respect of which interest has been paid or provided for, as the case may be, to, but excluding, the next interest payment date. The 2023 Notes are general, unsecured obligations of the Issuer, and are fully and unconditionally guaranteed by the Company on a senior unsecured basis. There are no financial debt covenants associated with the 2023 Notes.

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.

In connection with the issuance of the 2023 Notes, we incurred approximately \$6,190 of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total \$6,190 of debt issuance costs, \$1,201 were allocated to the equity component and recorded as a reduction to additional paid-in capital and \$4,989 were allocated to the liability component and recorded as a reduction to debt on our consolidated balance sheets. The portion allocated to the liability component is amortized to interest expense using the effective interest method over the same five-year term as the related 2023 Notes.

## NOTE 12: Long-Term Related Party Payable

Long-term related party payable and related activity are reported at fair value and consist of the following at December 31, 2019 and 2018, respectively:

	Balance, December 31, 2018	Activity during the Twelve Months Ended December 31, 2019			Balance, December 31, 2019
		Payments to Related Parties	Changes in Fair Value of Related Party Payable		
			Operating Expense	Other Expense	
Acquisition-related contingent consideration:					
Earn-out payments - Éclat Pharmaceuticals <sup>(a)</sup>	\$ 25,615	\$ (10,988)	\$ 845	\$ —	\$ 15,472
Financing-related:					
Royalty agreement - Deerfield <sup>(b)</sup>	2,184	(1,183)	—	250	1,251
Royalty agreement - Broadfin <sup>(c)</sup>	1,041	(565)	—	128	604
Total related party payable	28,840	\$ (12,736)	\$ 845	\$ 378	17,327
Less: Current portion	(9,439)				(5,554)
Total long-term related party payable	\$ 19,401				\$ 11,773

Each of the above items is associated with related parties as further described in *Note 23: Related Party Transactions*.

- (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 certain 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.
- (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.
- (c) As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund, a related party and current 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.

At December 31, 2019, the fair value of each related party 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 related party payables, resulting primarily from management’s revision of key assumptions, will be recorded in the consolidated statements of (loss) income in the line items entitled “Changes in fair value of related party contingent consideration” for items noted in (b) above and in “Other (expense) income - changes in fair value of related party 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.

We have chosen 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 are 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) income – changes in fair value of related party payable” on the consolidated statements of (loss) income.

The following table summarizes changes to the related party payables, a recurring Level 3 measurement, for the twelve-month periods ended December 31, 2019, 2018 and 2017:

<b>Related Party Payable:</b>	<b>Balance</b>
Balance at December 31, 2016	\$ 169,347
Payments of related party payable	(37,311)
Fair value adjustments <sup>(1)</sup>	(33,111)
Balance at December 31, 2017	98,925
Payments of related party payable	(22,951)
Fair value adjustments <sup>(1)</sup>	(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

<sup>(1)</sup> Fair value adjustments are reported as “Changes in fair value of related party contingent consideration” and “Other (expense) income - changes in fair value of related party payable” in the consolidated statements of (loss) income.

### NOTE 13: Income Taxes

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

<b>(Loss) Income Before Income Taxes:</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Ireland	\$ (50,134)	\$ (42,604)	\$ (3,123)
U.S.	10,401	(70,340)	92,754
France	1,151	(253)	3,029
Total (loss) income before income taxes	\$ (38,582)	\$ (113,197)	\$ 92,660

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

<b>Income Tax (Benefit) Provision:</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
<b>Current:</b>			
U.S. - Federal	\$ —	\$ —	\$ 18,064
U.S. - State	97	330	331
France	—	—	265
Total current	97	330	18,660
<b>Deferred:</b>			
Ireland	(1,256)	—	—
U.S. - Federal	(4,093)	(19,503)	4,686
U.S. - State	(104)	1,280	1,043
Total deferred	(5,453)	(18,223)	5,729
Income tax (benefit) provision	\$ (5,356)	\$ (17,893)	\$ 24,389

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

<b>Reconciliation to Effective Income Tax Rate:</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Statutory tax rate	12.5 %	12.5 %	12.5 %
Differences in international tax rates	3.2 %	8.0 %	22.2 %
Nondeductible changes in fair value of contingent consideration	(0.3)%	4.0 %	(11.6)%
Intercompany asset transfer	21.2 %	— %	— %
Change in valuation allowances	(19.1)%	(5.3)%	(0.7)%
Nondeductible stock-based compensation	(2.7)%	(1.3)%	(0.4)%
Cross border merger	— %	— %	0.3 %
Unrealized tax benefits	0.7 %	(1.3)%	1.4 %
State and local taxes (net of federal)	— %	(0.3)%	0.3 %
Change in U.S. tax law	— %	(0.2)%	3.8 %
Nondeductible interest expense	(2.5)%	(1.1)%	— %
Other	0.9 %	0.7 %	(1.5)%
<b>Effective income tax rate</b>	<b>13.9 %</b>	<b>15.7 %</b>	<b>26.3 %</b>
Income tax (benefit) provision - at statutory tax rate	\$ (4,823)	\$ (14,149)	\$ 11,582
Differences in international tax rates	(1,218)	(9,039)	20,557
Nondeductible changes in fair value of contingent consideration	121	(4,559)	(10,779)
Intercompany asset transfer	(8,190)	—	—
Change in valuation allowances	7,379	5,998	(610)
Nondeductible stock-based compensation	1,039	1,499	(375)
Cross-border merger	—	—	265
Unrecognized tax benefits	(261)	1,440	1,296
State and local taxes (net of federal)	(7)	299	252
Change in U.S. tax law	—	274	3,513
Nondeductible interest expense	982	1,269	—
Other	(378)	(925)	(1,312)
<b>Income tax (benefit) provision - at effective income tax rate</b>	<b>\$ (5,356)</b>	<b>\$ (17,893)</b>	<b>\$ 24,389</b>

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.

In 2018, the income tax provision decreased by \$42,282 when compared to the same period in 2017, resulting in an income tax benefit. The decrease in the income tax provision was primarily driven by a significant reduction in the amount of taxable income recorded in the U.S. and Ireland in 2018, when compared to 2017. There was also a significant increase in valuation allowance in 2018, when compared to the same period in 2017 as a result of this. In 2018, there was a significant decrease in amounts related to change in U.S. tax law due to the 2017 U.S. Tax Cuts and Jobs Act.

#### **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 2015. The Internal Revenue Service (IRS) commenced an examination of the Company's U.S. income tax return for 2015 in the 4th quarter of 2016. In the second



quarter of 2019, the IRS added the 2016 and 2017 U.S. income tax return to the ongoing 2015 audit. The French tax authority commenced an examination of the Company's French tax return for 2017 in the first quarter of 2019.

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

Unrecognized Tax Benefit Activity	2019	2018	2017
Balance at January 1:	\$ 5,315	\$ 3,954	\$ 1,686
Additions based on tax positions related to the current year	—	1,087	2,268
Increases (decreases) for tax positions of prior years	2,416	274	—
Statute of limitations expiration	(1,266)	—	—
Balance at December 31:	<u>\$ 6,465</u>	<u>\$ 5,315</u>	<u>\$ 3,954</u>

We expect that within the next twelve months the unrecognized tax benefits could decrease by \$2,000 - \$3,000. Additionally, interest could increase by up to \$400.

At December 31, 2019, 2018, and 2017, there are \$3,806, \$4,597, and \$3,349 of unrecognized tax benefits that if recognized would affect the annual effective tax rate.

We recognize interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2019, 2018, and 2017, we recognized approximately \$555, \$725, and \$304 in interest and penalties. We had approximately \$1,612, and \$1,057 for the payment of interest and penalties accrued at December 31, 2019, and 2018, 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, 2019 and 2018 resulted from the following temporary differences:

Net Deferred Tax Assets and Liabilities:	2019	2018
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 30,275	\$ 19,510
Amortization	11,602	6,830
Stock based compensation	3,577	4,587
Accounts receivable	53	—
Fair value contingent consideration	264	384
Restructuring costs (Noctiva)	—	13,812
Other	901	479
Gross deferred tax assets	<u>46,672</u>	<u>45,602</u>
<b>Deferred tax liabilities:</b>		
Amortization	(172)	(308)
Accounts receivable	—	(661)
Prepaid expenses	(35)	(405)
Gross deferred tax liabilities	<u>(207)</u>	<u>(1,374)</u>
Less: valuation allowances	(17,038)	(21,199)
Net deferred tax assets	<u>\$ 29,427</u>	<u>\$ 23,029</u>

At December 31, 2019, we had \$95,771 of net operating losses in Ireland that do not have an expiration date and \$75,537 of net operating loss in the U.S. Of the \$75,537 of net operating loss in the U.S., \$10,365 were acquired due to the acquisition of FSC and \$65,172 is due to the losses at US Holdings. The portion due to the acquisition of FSC will expire in 2034 through 2035. A valuation allowance is recorded if, based on the weight of available evidence, it is more likely than not that a deferred tax asset

will not be realized. This assessment is based on an evaluation of the level of historical taxable income and projections for future taxable income. For the year ended December 31, 2019 we recorded \$13,320 of valuation allowances related to Irish net operating losses and \$309 of valuation allowances related to the U.S. 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 as of December 31, 2019, and all of our net operating losses in Ireland and France as of December 31, 2018. 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, we 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 18: Restructuring Costs*.

While we believe it is more likely than not that it will be able to realize the deferred tax assets in the U.S., we continue to monitor changes in the U.S. hospital products market as unfavorable changes could ultimately impact our assessment of the realizability of our U.S. deferred tax assets. If we experience 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, 2019, we have unremitted earnings of \$3,961 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.

#### ***Research and Development 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, 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. As of December 31, 2018, our net Research tax credit receivable amounts to \$7,555 and represents a French gross research tax credit of \$6,922 and an Irish gross research tax credit of \$633.

#### ***Income Tax Deferred Charge***

On December 16, 2014, we transferred all of our intangible intellectual property from our French entity to our Irish entity as part of a global reorganization. The intellectual property includes patents on drug delivery platforms, clinical data sets and other intangible assets related to the pipeline of proprietary products in development. This intra-entity transaction resulted in a charge of \$14,088 of related taxes to the French government in December 2014. As this represents an intra-entity transaction, no deferred tax asset was originally recognized, but rather was recorded as \$986 of prepaid expenses and \$13,102 of a long-term income tax deferred charge asset in accordance with ASC 740-10-25-3 (e). This income tax deferred charge asset is amortized over the tax life of the asset at a rate of 7% per year and will result in tax relief in Ireland of \$8,500 from 2016 to 2029, subject to the ability to realize tax benefits for additional deductions. At December 31, 2016, the balance of these respective accounts was classified as prepaid expenses of \$814 and income tax deferred charge asset of \$10,342. In 2017, we adopted the provisions of ASU 2016-16, related to Intra-Entity Transfers of Assets Other Than Inventory. Adoption of ASU 2016-16 eliminated the \$11,156 income tax deferred charge recorded within the consolidated balance sheet as of December 31, 2016. In addition to the elimination of the income tax deferred charge, we recorded a deferred tax asset of \$7,954 related to the remaining unamortized tax basis of the intangible intellectual property. A full valuation allowance was recorded against the deferred tax asset as sufficient evidence does not exist at this time that we will be able to utilize these benefits.

#### ***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 Act being signed into law, we recognized a provisional charge of \$274 and \$3,513 in 2018 and 2017, respectively, 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 14: Post-Retirement Benefit Plans****Post-Retirement Benefit Contributions to French Government Agencies**

The Company is required by French law for our French employees to deduct specific monthly payroll amounts to support post-retirement benefit programs sponsored by the relevant government agencies in France. As the ultimate obligation is maintained by the French government agencies, there is no additional liability recorded by the Company in connection with this plan. Expenses recognized for this plan were \$288 in 2019, \$356 in 2018, and \$606 in 2017.

**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 (loss) income 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 during the year ended December 31, 2019. See *Note 18: Restructuring Costs*.

The benefit obligation is calculated as the present value of estimated future benefits to be paid, using the following assumptions for the years ended December 31:

<b>Retirement Benefit Obligation Assumptions:</b>	<b>2018</b>	<b>2017</b>
Compensation rate increase	2.75%	3.00%
Discount rate	1.50%	1.25%
Employee turn-over	Actuarial standard and average of the last 5 years	
Average age of retirement	60 to 65 years actuarial standard based on age and professional status	

Certain actuarial assumptions, such as discount rate, have a significant effect on the amounts reported for net periodic benefit cost and accrued retirement indemnity benefit obligation amounts. The discount rate is determined annually by benchmarking a published long-term bond index using the iBoxx € Corporates AA 10+ index.

Changes in the funded status of the retirement indemnity benefit plans were as follows for the years ended December 31:

<b>Retirement Benefit Obligation Activity:</b>	<b>2019</b>		<b>2018</b>	
Retirement indemnity benefit obligation, beginning of year	\$	1,024	\$	1,303
Service cost		—		93
Interest cost		—		17
Plan amendment		—		—
Benefits paid		—		(12)
Curtailement gain		(1,000)		(148)
Actuarial loss		—		(178)
Exchange rate changes		(24)		(51)
Retirement indemnity benefit obligation, end of year	\$	—	\$	1,024

The lump sum retirement indemnity was accrued at December 31, 2018 on the Company's consolidated balance sheets within non-current other liabilities, excluding the current portion. As these are not funded benefit plans, there are no respective assets recorded.

Due to the 2019 French Restructuring plan, at December 31, 2019 there are no future expected retirement indemnity benefits to be paid. See *Note 18: Restructuring Costs*.

**NOTE 15: Other Assets and Liabilities**

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

<b>Prepaid Expenses and Other Current Assets:</b>	<b>2019</b>	<b>2018</b>
Valued-added tax recoverable	\$ 1,051	\$ 1,378
Prepaid and other expenses	2,116	2,145
Guarantee from Armistice (see Note 17)	454	534
Income tax receivable	536	921
Short-term deposit	—	3,350
Other	107	225
<b>Total</b>	<b>\$ 4,264</b>	<b>\$ 8,553</b>

<b>Other Non-Current Assets:</b>	<b>2019</b>	<b>2018</b>
Deferred tax assets	\$ 29,427	\$ 23,029
Long-term deposits	1,477	1,477
Guarantee from Armistice (see Note 17)	1,367	5,697
Right of use assets at contract manufacturing organizations	6,428	5,894
Other	575	49
<b>Total</b>	<b>\$ 39,274</b>	<b>\$ 36,146</b>

<b>Accrued Expenses:</b>	<b>2019</b>	<b>2018</b>
Accrued compensation	\$ 3,944	\$ 3,971
Accrued social charges	592	1,009
Accrued restructuring (see Note 18)	2,949	879
Customer allowances	6,470	6,541
Accrued contract research organization charges	2,098	1,000
Accrued contract manufacturing organization costs	735	2,028
Accrued contract sales organization and marketing costs	—	3,469
Other	3,022	2,798
<b>Total</b>	<b>\$ 19,810</b>	<b>\$ 21,695</b>

<b>Other Non-Current Liabilities:</b>	<b>2019</b>	<b>2018</b>
Provision for retirement indemnity	\$ —	\$ 1,024
Customer allowances	981	1,352
Unrecognized tax benefits	6,465	5,315
Guarantee to Deerfield (see Note 17)	1,372	5,717
Other	55	594
<b>Total</b>	<b>\$ 8,873</b>	<b>\$ 14,002</b>

**NOTE 16: 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, 2019 and December 31, 2018, 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.

*Note 3: Subsidiary Bankruptcy and Deconsolidation* briefly describes the Chapter 11 bankruptcy case which our subsidiary Specialty Pharma commenced on February 6, 2019, and which on April 26, 2019 resulted in the bankruptcy court-approved sale of all of Specialty Pharma's intangible assets and inventory to an unaffiliated third party. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business. During the pendency of the bankruptcy case, all pending litigation against Specialty Pharma is automatically stayed and any new litigation against Specialty Pharma is precluded unless the bankruptcy court orders otherwise. Below are descriptions of a litigation to which Specialty Pharma is a party and a contract dispute involving Specialty Pharma, both of which matters are subject to the automatic stay during the bankruptcy case.

*Ferring Litigation.* Some of the patents covering the Noctiva product (the "Noctiva Patents") are the subject of litigation initiated by Ferring Pharmaceuticals Inc. and two of its foreign affiliates, who manufacture a competing product known as Nocdurna. Nocdurna was approved by the FDA in June 2018 and commercially launched in the U.S. in November 2018. In this litigation, filed in the United States District Court for the Southern District of New York, Ferring seeks to invalidate and disputes the inventorship of the Noctiva Patents, seeks damages for various alleged breaches of contractual and common law duties, and seeks damages for alleged infringement by Noctiva of Ferring's "Nocdurna" trademark. Specialty Pharma and certain other parties including Serenity Pharmaceuticals, LLC ("Serenity") (the licensor of the Noctiva Patents) have defended this litigation, and have made counterclaims against Ferring, including for infringement of the Noctiva Patents and a declaratory judgment of noninfringement with respect to Ferring's "Nocdurna" trademark. The court dismissed Ferring's inventorship claim and its claims for alleged breaches of contractual and common law duties, although these dismissals may be appealed by Ferring. On February 15, 2019, Specialty Pharma and its co-defendants moved to stay the litigation pending completion of the bankruptcy proceeding of Specialty Pharma. On May 15, 2019, that motion was denied due to a pending settlement of the litigation with respect to just Ferring and Specialty Pharma. On February 25, 2020, Ferring and Specialty Pharma jointly moved for bankruptcy court approval of a settlement agreement with respect to the claims alleged in the litigation. In accordance with the terms of the settlement agreement, promptly following bankruptcy court approval of the settlement agreement, the parties would dismiss with prejudice their respective claims against each other in the litigation. On March 13th, 2020, the bankruptcy court entered an order approving the settlement with Ferring. Pursuant to the terms of the settlement, the parties are to dismiss their respective claims against each other in the District Court litigation in the Southern District of New York, with such dismissals to be effective concurrently. That joint dismissal has not yet been filed with District Court for the Southern District of New York.

*Contract Dispute.* On January 21, 2019, Serenity gave notice to Specialty Pharma of an alleged breach of the parties' Noctiva license agreement. Serenity alleges that Specialty Pharma breached its contractual obligation to devote commercially reasonable efforts to the commercialization of Noctiva and seeks unspecified damages. On January 27, 2019, Specialty Pharma notified Serenity of a claim for \$1.7 million in damages as a result of Serenity's breach of its contractual obligation to pay the costs of the Ferring Litigation. Serenity's notice to Specialty Pharma invoked the dispute resolution provisions of the Noctiva license agreement, which culminate in arbitration, but neither party has yet initiated an arbitration proceeding or filed suit.

*Exela Litigation.* On January 7, 2020, Exela filed a complaint against us and our subsidiary, Avadel Legacy in the United States District for the District of Delaware. The complaint alleges infringement of a certain Exela patent related to its cysteine hydrochloride product. Exela is most notably seeking i) a declaratory judgment that the Nouress product infringes its patent, ii) an injunction (both preliminary and permanent) precluding the launch of Nouress, and iii) monetary damages (including enhanced damages, prejudgment interest and attorneys' fees) in the event Nouress is commercially launched and found to infringe Exela's patent. We have not yet been served with the complaint.

*Former employee dispute.* On January 10, 2020, we settled a dispute with a former employee for \$1,750.

### Material Commitments

At December 31, 2019, we have various commitments to purchase finished product from customers. For the year ended December 31, 2019, the Company paid \$7,400 related to the below purchase commitments. Commitments for these arrangements, at maximum quantities and at contractual prices over the remaining life of the contract, and excluding any waived commitments, are as follows for the years ended December 31:

<b>Purchase Commitments:</b>		<b>Balance</b>
2020	\$	1,434
2021		1,430
2022		1,430
2023		1,430
2024		—
Thereafter		—
<b>Total</b>	<b>\$</b>	<b>5,724</b>

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, 2019. Subsequent to the initial build and preparation of the production suite, this commitment also includes annual fees which would commence at the time of FDA approval of the product and continue thereafter for five years. These amounts are not included in the table above, as the start date has not been determined.

### Leases

The Company and our subsidiaries lease office facilities under non-cancellable operating leases expiring at various dates. See *Note 10: Leases* for disclosure of these.

Other than the above commitments, there were no other material commitments outside of the normal course of business. Material commitments in the normal course of business include long-term debt and long-term related party payable, which are disclosed in *Note 11: Long-Term Debt* and *Note 12: Long-Term Related Party Payable*, respectively.

### Contractual Obligations

The following table presents contractual obligations of the Company at December 31, 2019:

<b>Contractual Obligations:</b>	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1 to 3 Years</b>	<b>3 to 5 Years</b>	<b>More than 5 Years</b>
Long-term debt and interest	\$ 166,391	\$ 6,469	\$ 12,938	\$ 146,984	\$ —
Long-term related party payable (undiscounted)	29,847	5,554	5,181	4,262	14,850
Purchase commitments	5,724	1,434	2,860	1,430	—
Operating leases	3,368	779	1,167	1,216	206
<b>Total contractual cash obligations</b>	<b>\$ 205,330</b>	<b>\$ 14,236</b>	<b>\$ 22,146</b>	<b>\$ 153,892</b>	<b>\$ 15,056</b>

### NOTE 17: 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*

Also, in connection with the closing under the Purchase Agreement, Flamel Ireland Limited, an Irish private limited company operating under the trade name of Avadel Ireland (“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*

In connection with the closing under the Purchase Agreement, 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 will be amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

### Armistice Guarantee

In connection with the closing under the Purchase Agreement, 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 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 period January 1, 2018 through February 16, 2018 and for the years ended December 31, 2018 and 2017 include 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 (loss) income.

### NOTE 18: 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 is an effort to align the Company's cost structure with our ongoing and future planned projects. The reduction in workforce is substantially complete at December 31, 2019. Restructuring charges associated with this plan of \$4,855 were recognized during the year ended December 31, 2019. Included in the 2019 French Restructuring charges of \$4,855 were charges for employee severance, benefits and other costs of \$4,339, charges related to fixed asset impairment of \$629, charges related to the early termination penalty related to the office and copier lease terminations of \$887 (see Note 10: Leases), 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 year ended December 31, 2019:

2019 French Restructuring Obligation:	2019
Balance of restructuring accrual at January 1,	\$ —
Charges for employee severance, benefits and other costs	4,339
Payments	(2,441)
Foreign currency impact	24
Balance of restructuring accrual at December 31,	<u>\$ 1,922</u>

The 2019 French Restructuring liabilities of \$1,849, \$42 and \$31 are included in the consolidated balance sheet in accrued expenses, other long-term liabilities and accounts payable at December 31, 2019, respectively.

#### 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 is substantially complete at December 31, 2019. The restructuring charges associated with this plan of \$1,755 were recognized during the year ended December 31, 2019, respectively. 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 year ended December 31, 2019:

<b>2019 Corporate Restructuring Obligation:</b>	<b>2019</b>
Balance of restructuring accrual at January 1,	\$ —
Charges for employee severance, benefits and other costs	3,406
Payments	(2,326)
Balance of restructuring accrual at December 31,	<u>\$ 1,080</u>

The restructuring accrual at December 31, 2019 is included in the consolidated balance sheet in accrued expenses.

#### *2017 French Restructuring*

During the first quarter of 2017, the Company announced a plan to reduce its workforce at our Venissieux, France site by approximately 50% (the "2017 French Restructuring"). This reduction was an effort to align the Company's cost structure with our ongoing and future planned projects. In July 2017, the Company completed negotiations with the works council for our French operations and received approval from the French Labor Commission (DIRECCTE) to implement the plan. The reduction was substantially complete at December 31, 2019. The 2017 French Restructuring benefit for the year ended December 31, 2019 was \$169 and the 2017 French Restructuring expense for the year ended December 31, 2018 was \$1,164.

The following table sets forth activities for the Company's cost reduction plan obligations for the years ended December 31, 2019 and 2018:

<b>2017 French Restructuring Obligation:</b>	<b>2019</b>	<b>2018</b>
Balance of restructuring accrual at January 1,	\$ 879	\$ 1,000
Charges for employee severance, benefits and other	(169)	1,164
Payments	(673)	(1,261)
Foreign currency impact	(9)	(24)
Balance of restructuring accrual at December 31,	<u>\$ 28</u>	<u>\$ 879</u>

The restructuring accrual at December 31, 2019 and 2018 is included the consolidated balance sheets in accrued expenses and other long-term liabilities.

#### **NOTE 19: Equity Instruments and Share-Based Compensation**

##### ***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, 2019, we had 42,927 and 37,520 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, none of which is currently issued and outstanding.

##### ***Share Repurchases***

In March 2017, the Board of Directors approved an authorization to repurchase up to \$25,000 of Avadel ordinary shares represented by ADSs. Under this authorization, which has an indefinite duration, share repurchases may be made in the open market, in block transactions on or off the exchange, in privately negotiated transactions, or through other means as determined by the Board of Directors and in accordance with the regulations of the Securities and Exchange Commission. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our shares, cash resources, alternative investment opportunities, corporate and regulatory requirements and market conditions. This share repurchase program may be modified, suspended or discontinued at any time without prior notice. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. Additionally, on

February 12, 2018, the Board of Directors approved an authorization to repurchase up to \$18,000 of Avadel ordinary shares represented by American Depository Shares in connection with our Convertible Notes Offering completed on February 16, 2018. See *Note 11: Long-Term Debt*. In March 2018, the Board of Directors approved an authorization to repurchase up to \$7,000 of Avadel ordinary shares represented by American Depository Shares, bring the total authorization to \$50,000. There were no share repurchases during the year ended December 31, 2019. As of December 31, 2019, the Company had repurchased 5,407 ordinary shares for \$49,998.

### Share-Based Compensation

Compensation expense included in the Company's consolidated statements of (loss) income for all share-based compensation arrangements was as follows for the periods ended December 31, 2019, 2018 and 2017, respectively:

Share-based Compensation Expense:	2019	2018	2017
Research and development	\$ 429	\$ 880	\$ 672
Selling, general and administrative	2,154	6,972	7,400
Restructuring costs	(2,064)	—	—
Total share-based compensation expense	<u>\$ 519</u>	<u>\$ 7,852</u>	<u>\$ 8,072</u>

As of December 31, 2019, the Company expects \$2,695 of unrecognized expense related to granted, but non-vested share-based compensation arrangements to be incurred in future periods. This expense is expected to be recognized over a weighted average period of 2.4 years.

The excess tax benefit related to share-based compensation recorded by the Company was not material for the years ended December 31, 2019, 2018 and 2017.

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

At December 31, 2019, there were 565,716 shares authorized for stock option grants, warrant grants and restricted share 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. Prior to 2017, warrants were typically issued to the Company's Board of Directors as compensation for services rendered and generally become exercisable within one year following the grant date, and expire four years after the grant date. Beginning in 2017, the Company issues stock options to our Board of Directors as compensation for services rendered and generally become exercisable within one year following the grant date, and expire four years after the grant date.

The weighted-average assumptions under the Black-Scholes option-pricing model for stock option grants as of December 31, 2019, 2018 and 2017, are as follows:

Stock Option Assumptions:	2019	2018	2017
Stock option grants:			
Expected term (years)	6.25	6.25	6.25
Expected volatility	56.48%	56.59%	58.82%
Risk-free interest rate	2.52%	2.68%	2.20%
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 and the grant of stock options to a limited population, 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 has no plan to distribute dividends in the foreseeable future.

### Stock Options

A summary of the combined stock option activity and other data for the Company's stock option plans for the year ended December 31, 2019 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, 2019	4,601	\$ 11.39		
Granted	2,631	2.24		
Exercised	—	—		
Forfeited	(1,333)	7.37		
Expired	(778)	12.91		
Stock options outstanding, December 31, 2019	5,121	\$ 7.51	7.43 years	\$ 12,119
Stock options exercisable, December 31, 2019	2,636	\$ 11.63	5.73 years	\$ 572

The aggregate intrinsic value of options exercisable at December 31, 2019, 2018 and 2017 was \$572, \$0, and \$1,161, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2019, 2018 and 2017 was \$1.24, \$3.60 and \$5.20 per share, respectively.

### Warrants

A summary of the combined warrant activity and other data for the year ended December 31, 2019 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, 2019	596	\$ 17.72		
Granted	—	—		
Exercised	—	—		
Forfeited	—	—		
Expired	(305)	21.67		
Warrants outstanding, December 31, 2019	291	\$ 13.59	0.61 years	\$ —
Warrants exercisable, December 31, 2019	291	\$ 13.59	0.61 years	\$ —

Each of the above warrants is convertible into one ordinary share. There was no aggregate intrinsic value of warrants exercised during the years ended December 31, 2019, 2018 and 2017.

There were no warrants granted during the years ended December 31, 2019, 2018 and 2017.

At January 1, 2018, an additional 3,300 warrants were outstanding and exercisable relative to consideration paid for the Company's acquisition of Éclat Pharmaceuticals on March 13, 2012. These warrants are not considered share-based compensation and are therefore excluded from the above tables, and instead are addressed within *Note 12: Long-Term Related Party Payable*. On February 23, 2018, the related party exercised in full the warrant to purchase 2,200 ordinary shares. On March 12, 2018 the remaining warrants to purchase 1,100 ordinary shares expired.

### 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. Beginning in 2018, the Company issues 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, 2019, 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, 2019	491	\$ 7.20
Granted	251	2.47
Vested	(153)	7.50
Forfeited	(242)	5.65
Non-vested restricted share awards outstanding, December 31, 2019	347	\$ 4.73

The weighted average grant date fair value of restricted share awards granted during the years ended December 31, 2019, 2018 and 2017 was \$2.47, \$5.87 and \$8.95, respectively.

#### ***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, 2019 and 2018, the Company issued 54 and 25 ordinary shares to employees, respectively. Expense related to the ESPP for the years ended December 31, 2019 and 2018 was immaterial.

#### **NOTE 20: Net (Loss) Income Per Share**

Basic net (loss) income per share is calculated by dividing net (loss) income by the weighted average number of shares outstanding during each period. Diluted net (loss) income per share is calculated by dividing net (loss) income by the diluted number of shares outstanding during each period. Except where the result would be anti-dilutive to net (loss) income, diluted net (loss) income per share would be calculated assuming the impact of the conversion of the 2023 Notes, the exercise of outstanding equity compensation awards, ordinary shares expected to be issued under our ESPP and the exercise of contingent consideration warrants, all of which have been exercised or have expired during the first quarter of 2018.

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, RSU's and ordinary shares expected to be issued under our ESPP has been calculated using the treasury stock method.

A reconciliation of basic and diluted net (loss) income per share, together with the related shares outstanding in thousands for the years ended December 31, 2019, 2018 and 2017, is as follows:

<b>Net (Loss) Income Per Share:</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Net (loss) income	\$ (33,226)	\$ (95,304)	\$ 68,271
Weighted average shares:			
Basic shares	37,403	37,325	40,465
Effect of dilutive securities—employee and director equity awards outstanding and 2023 Notes	—	—	1,300
Diluted shares	<u>37,403</u>	<u>37,325</u>	<u>41,765</u>
Net (loss) income per share - basic	\$ (0.89)	\$ (2.55)	\$ 1.69
Net (loss) income per share - diluted	\$ (0.89)	\$ (2.55)	\$ 1.63

Potential ordinary shares of 16,740, 17,529, and 6,368 were excluded from the calculation of weighted average shares for the years ended December 31, 2019, 2018 and 2017, respectively, because their effect was considered to be anti-dilutive. For the years ended December 31, 2019 and 2018, the effects of dilutive securities were entirely excluded from the calculation of net (loss) income per share as a net loss was reported in these periods.

#### **NOTE 21: Comprehensive (Loss) Income**

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

<b>Accumulated Other Comprehensive (Loss) Income:</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Foreign currency translation adjustment:			
Beginning balance	\$ (23,621)	\$ (23,202)	\$ (23,336)
Net other comprehensive (loss) income	(117)	(419)	134
Balance at December 31,	<u>(23,738)</u>	<u>(23,621)</u>	<u>(23,202)</u>
Unrealized gain (loss) on marketable securities, net			
Beginning balance	205	(64)	(229)
Net other comprehensive income, net of (\$43), (\$18), \$28, tax, respectively	727	269	165
Balance at December 31,	<u>932</u>	<u>205</u>	<u>(64)</u>
Accumulated other comprehensive loss at December 31,	<u>\$ (22,806)</u>	<u>\$ (23,416)</u>	<u>\$ (23,266)</u>

**NOTE 22: 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, 2019, 2018, and 2017:

<b>Revenue by Product:</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Bloxiverz	\$ 7,479	\$ 20,850	\$ 45,596
Vazculep	33,152	42,916	38,187
Akovaz	18,642	33,759	80,617
Other	(58)	3,898	8,441
Product sales	59,215	101,423	172,841
License revenue	—	1,846	404
Total revenues	\$ 59,215	\$ 103,269	\$ 173,245

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, 2019, 2018, and 2017:

<b>Revenue by Significant Customer:</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Cardinal Health	\$ 15,088	\$ 25,413	\$ 37,965
McKesson Corporation	14,900	26,794	44,762
AmerisourceBergen	12,059	18,620	25,691
Others	17,168	30,596	64,423
Product sales	59,215	101,423	172,841
License revenue	—	1,846	404
Total revenues	\$ 59,215	\$ 103,269	\$ 173,245

In 2017, 31% of product sales was sold to PharMedium. In 2018 and 2019, product sales to PharMedium was less than 10%.

As of December 31, 2019, the Company had three customers, each of which are substantial wholesale distributors, and accounted for 10% or more of the accounts receivable balance. One customer accounted for 40%, or \$3,346, a second customer accounted for 29% or \$2,416, and a third customer accounted for 11% or \$949. As of December 31, 2019, the Company had no significant past due account receivable balances.

The following table summarizes revenues by geographic region for the twelve months ended December 31, 2019, 2018, and 2017:

<b>Revenue by Geographic Region:</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
U.S.	\$ 59,215	\$ 101,423	\$ 172,841
Ireland	—	1,846	404
Total revenues	\$ 59,215	\$ 103,269	\$ 173,245

Currently, we depend on a single contract manufacturing organization for the manufacture of Bloxiverz and Vazculep and two contract manufacturing organizations for the manufacture of Akovaz, from which we derive a majority of our revenues. Additionally,

we purchase certain raw materials used in our products 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 and intangible assets. The following table summarizes non-monetary long-lived assets by geographic region as of December 31, 2019, 2018, and 2017:

<b>Long-lived Assets by Geographic Region:</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
U.S.	\$ 22,254	\$ 27,761	\$ 116,536
France	196	1,365	2,257
Ireland	7,244	6,028	1,360
Total	<u>\$ 29,694</u>	<u>\$ 35,154</u>	<u>\$ 120,153</u>

### **NOTE 23: Related Party Transactions**

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 Capital L.P (“Deerfield”), a significant shareholder of the Company. During the three months ended December 31, 2019, Deerfield sold all of their shares. At December 31, 2019, the remaining consideration obligation for this transaction consisted of commitments to make earnout payments to Breaking Stick of 20% of any gross profit generated by certain Éclat products (the “Products”). Breaking Stick is majority owned by Deerfield, with a minority interest owned by certain current and former employees. The Company entered into a Security Agreement dated March 13, 2012 with Breaking Stick, whereby Breaking Stick was granted a security interest in various tangible and intangible assets related to the Products to secure the obligations of Éclat and Avadel US Holdings, Inc., including the full and prompt payment of royalties to Breaking Stick under the Royalty Agreement.

As part of a February 2013 debt financing transaction conducted with Deerfield Management, Éclat entered into a Royalty Agreement with Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P., both affiliates of the Deerfield Entities (together, “Deerfield PDF/Horizon”). The Royalty Agreement provides for the Company to pay Deerfield PDF/Horizon 1.75% of the net sales of the Products sold by the Company and any of our affiliates until December 31, 2024, with royalty payments paid in arrears for each calendar quarter during the term of the Royalty Agreement. The Company has also entered into a Security Agreement dated February 4, 2013 with Deerfield PDF/Horizon, whereby Deerfield PDF/Horizon was granted a security interest in the various tangible and intangible assets related to the Products to secure the obligations of Éclat and Avadel US Holdings, Inc., including the full and prompt payment of royalties to Deerfield PDF/Horizon under the Royalty Agreement.

As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund (“Broadfin”), the Company also entered into a Royalty Agreement with Broadfin, a significant shareholder of the Company, dated as of December 3, 2013 (the “Broadfin Royalty Agreement”). During the three months ended December 31, 2019, Broadfin sold a majority of their shares and was not a significant shareholder at December 31, 2019. Pursuant to the Broadfin Royalty Agreement, the Company is required to pay a royalty of 0.834% on the net sales of certain products sold by the Company and any of our affiliates until December 31, 2024 with royalty payments paid in arrears for each calendar quarter during the term of the Royalty Agreement. We also entered into a Security Agreement dated December 3, 2013 with Broadfin, whereby Broadfin was granted a security interest in the various tangible and intangible assets related to the Products to secure the obligations of Éclat and Avadel US Holdings, Inc., including the full and prompt payment of royalties to Broadfin under the Royalty Agreement.

The Company entered into an agreement dated February 5, 2016 to acquire FSC Holdings, LLC (“FSC”), a specialty pharmaceutical company dedicated to providing innovative solutions to unmet medical needs for pediatric patients, from Deerfield CSF, LLC, a Deerfield Management company (“Deerfield”), a related party. Under the terms of the acquisition, 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 will 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. In connection with the divestiture, the Company provided its guarantee in favor of Deerfield and in return, Armistice Capital Master Fund, Inc., the majority shareholder of Cerecor, guaranteed to the Company the payment by Cerecor of the Assumed Obligations mentioned in *Note 17: Divestiture of the Pediatric Assets*. 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 discussed in *Note 17*. 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, another 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. See *Note 17* for further discussion around the divestiture.

#### **NOTE 24: Subsequent Events**

##### *Exela Litigation*

On January 7, 2020, Exela filed a complaint against the Company and its subsidiary, Avadel Legacy in the United States District for the District of Delaware. The complaint alleges infringement of a certain Exela patent by Avadel's NOURESS™ product, which has not yet been commercially launched in the U.S. Exela is most notably seeking i) a declaratory judgment that the NOURESS™ product infringes its patent, ii) an injunction (both preliminary and permanent) precluding the launch of NOURESS™, and iii) monetary damages (including enhanced damages, prejudgment interest and attorneys' fees) in the event NOURESS™ is commercially launched and found to infringe Exela's patent. The Company and Avadel Legacy have not yet been served with the complaint.

##### *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 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<sup>SM</sup> ("the Sales Agreement"), 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.

##### *Securities Purchase Agreement (dollars and shares in thousands)*

On February 21, 2020, we announced that we have 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 has resulted in gross proceeds of approximately \$65,000 before deducting placement agent and other offering expenses, and resulting in net proceeds of approximately \$61,000.

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. Proceeds from the private placement will be used to fund continued clinical and program development of FT218, including an 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. If this transaction would have happened prior to December 31, 2019, ordinary shares issued and outstanding would have been 51,927 and 46,200, respectively.



## 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, 2019 and 2018, the related consolidated statements of (loss) income, comprehensive (loss) income, shareholders' (deficit) equity, and cash flows, for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2020, 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.

/s/ Deloitte and Touche LLP

St. Louis, Missouri

March 16, 2020

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, 2019, 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, 2019, 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, 2019, of the Company and our report dated March 16, 2020, 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 16, 2020

**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, 2019. 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, 2019, the Company's internal control over financial reporting is effective based on those criteria.

**Changes in Internal Control Over Financial Reporting**

During the year ended December 31, 2019 as part of our restructuring initiatives described in this Annual Report under Item 8 "Financial Statements and Supplementary Data - Note 18 (Restructuring Costs)" and Item 7 "Management Discussion and Analysis of Results of Operations and Financial Condition - Results of Operation," we moved all of our Irish and a portion of our French accounting operations to St. Louis, Missouri. Further, as part of these restructuring initiatives, the Company completed the outsourcing of a majority of its Information Technology resources to a third party. These moves were made in order to consolidate our accounting systems, gain efficiencies of scale, reduce costs and make internal control over financial reporting more consistent across our various entities. These moves were not made in response to any identified deficiency or weakness in the Company's internal control over financial reporting. Other than these changes, there has been no change in our internal control over financial reporting during the quarter or year ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**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 2019 annual general meeting of shareholders pursuant to Regulation 14A of the Securities Exchange Act of 1934 (our "Definitive 2019 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 2019 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 2020 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2019.

#### **Item 11. Executive Compensation.**

Information regarding Executive Compensation is hereby incorporated by reference to our Definitive 2020 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2019.

#### **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 2020 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2019.

#### **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 2020 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2019.

#### **Item 14. Principal Accountant Fees and Services.**

Information regarding Principal Accountant Fees and Services is hereby incorporated by reference to our Definitive 2020 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2019.

**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)*

<b>Deferred Tax Asset Valuation Allowance:</b>	<b>Balance, Beginning of Period</b>	<b>Additions (a)</b>	<b>Deductions (b)</b>	<b>Other Changes (c)</b>	<b>Balance, End of Period</b>
2019	\$ 21,199	\$ 6,496	\$ (4,762)	\$ (5,896)	\$ 17,037
2018	\$ 15,354	\$ 6,089	\$ (75)	\$ (169)	\$ 21,199
2017	\$ 7,599	\$ 391	\$ (664)	\$ 8,028	\$ 15,354

- 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**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
3.1	<a href="#"><u>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).</u></a>
3.2	<a href="#"><u>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).</u></a>
4.1	<a href="#"><u>Guaranty dated January 1, 2017 by Avadel Pharmaceuticals plc in favor of Breaking Stick Holdings, LLC (f/k/a Éclat Holdings, LLC) with respect to obligations under the Note Agreement filed as Exhibit 4.1 (incorporated by reference to Exhibit 4.1 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 28, 2017).</u></a>

- 4.2 [Warrant to purchase 1,100,000 American Depositary Shares, each representing one ordinary share of Avadel Pharmaceuticals plc \(incorporated by reference to Exhibit 4.1 to the registrant's Post-Effective Amendment No. 2 to Form F-3 registration statement \(No. 333-183961\) on Form S-3, filed on January 6, 2017\).](#)
- 4.3 [Warrant to purchase 2,200,000 American Depositary Shares, each representing one ordinary share of Avadel Pharmaceuticals plc \(incorporated by reference to Exhibit 4.2 to the registrant's Post-Effective Amendment No. 2 to Form F-3 registration statement \(No. 333-183961\) on Form S-3, filed on January 6, 2017\).](#)
- 4.4 [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 \(including an as exhibit the Form of 4.50% Exchangeable Senior Note due 2023\) \(incorporated by reference to Exhibit 4.1 to the registrant's current report on Form 8-K, filed on February 16, 2018\).](#)
- 4.5 [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 \(incorporated by reference to Exhibit 4.1 to the registrant's current report on Form 8-K, filed on February 7, 2019\).](#)
- 4.6 [Description of Securities \(filed herewith\)](#)
- 10.1 [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 \(including as an exhibit the form of American Depositary Receipt\) \(incorporated by reference to Exhibit 1.1 to the registrant's current report on Form 8-K12B, filed on January 4, 2017 and amended January 6, 2017\).](#)
- 10.2\* [Royalty Agreement among Éclat Pharmaceuticals LLC, Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P. dated December 31, 2012 \(incorporated by reference to Exhibit 4.8 to the registrant's annual report on Form 20-F for the year ended December 31, 2012, filed on April 30, 2013\).](#)
- 10.3\* [Security Agreement between Éclat Pharmaceuticals, LLC and Deerfield Private Design Fund II, L.P. and Horizon Santé FLML, Sarl dated February 4, 2013 \(incorporated by reference to Exhibit 4.9 to the registrant's annual report on Form 20-F for the year ended December 31, 2012, filed on April 30, 2013\).](#)
- 10.4 [Broadfin Facility Agreement effective as of December 3, 2013 \(incorporated by reference to Exhibit 4.9 to the registrant's annual report on Form 20-F for the year ended December 31, 2013, filed on April 30, 2014\).](#)
- 10.5\* [Broadfin Royalty Agreement dated as of December 3, 2013 \(incorporated by reference to Exhibit 4.10 to the registrant's annual report on Form 20-F for the year ended December 31, 2013, filed on April 30, 2014\).](#)
- 10.6 [Asset Purchase Agreement by and among Flamel Technologies S.A. and Recipharm Pessac dated November 26, 2014 \(incorporated by reference to Exhibit 4.11 to the registrant's annual report on Form 20-F for the year ended December 31, 2014, filed on April 30, 2015\).](#)
- 10.7 [Master Agreement on Supply of Services and Products by and between Avadel Technologies S.A. and Recipharm Pessac dated December 1, 2014 \(incorporated by reference to Exhibit 4.12 to the registrant's annual report on Form 20-F for the year ended December 31, 2014, filed on April 30, 2015\).](#)
- 10.8 [Service Agreement by and between Flamel Technologies S.A. and Recipharm Pessac dated December 1, 2014 \(incorporated by reference to Exhibit 4.13 to the registrant's annual report on Form 20-F for the year ended December 31, 2014, filed on April 30, 2015\).](#)
- 10.9 [Supply Agreement by and between Flamel Technologies S.A. and Recipharm Pessac dated December 1, 2014 \(incorporated by reference to Exhibit 4.14 to the registrant's annual report on Form 20-F for the year ended December 31, 2014, filed on April 30, 2015\).](#)

- 10.10\* [Membership Interest Purchase Agreement by and among Éclat Holdings LLC, Éclat Pharmaceuticals LLC, Flamel Technologies S.A. and Flamel US Holdings Inc. dated March 13, 2012 \(incorporated by reference to Exhibit 4.15 to the registrant's annual report on Form 20-F for the year ended December 31, 2014, filed on April 30, 2015\)](#)
- 10.11\* [Exclusive License Agreement by and between Elan Pharma International Limited and Flamel Ireland Limited dated September 30, 2015 \(incorporated by reference to Exhibit 10.14 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016\)](#)
- 10.12 [Lease Agreement by and between Grove II LLC and Eclat Pharmaceuticals LLC dated October 5, 2015 \(incorporated by reference to Exhibit 10.16 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016\)](#)
- 10.13 [Membership Interest Purchase Agreement dated as of February 5, 2016 by and among James Flynn, Peter Steelman, Deerfield CSF, LLC, FSC Holding Company, LLC, FSC Therapeutics, LLC, FSC Laboratories, Inc., Flamel Technologies SA, and Flamel US Holdings, Inc. \(incorporated by reference to Exhibit 10.20 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016\)](#)
- 10.14‡ [Rules Governing the Free Share Plan - December 2014 \(incorporated by reference to Exhibit 10.21 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016\)](#)
- 10.15‡ [Rules Governing the Free Share Plan - December 2014 \(incorporated by reference to Exhibit 10.22 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016\)](#)
- 10.16‡ [June 2015 Stock Warrant Rules \(incorporated by reference to Exhibit 10.23 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016\)](#)
- 10.17‡ [Subscription Form of Stock Warrant \(incorporated by reference to Exhibit 10.24 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016\)](#)
- 10.18‡ [December 2015 Stock Option Rules \(incorporated by reference to Exhibit 10.25 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016\)](#)
- 10.19‡ [Form of Stock Option Grant Letter \(incorporated by reference to Exhibit 10.26 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016\)](#)
- 10.20‡ [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\)](#)
- 10.21‡ [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\)](#)
- 10.22‡ [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\)](#)
- 10.23‡ [Form of stock option grant letter for 2016 Stock Option Rules \(incorporated by reference to Exhibit 10.31 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 28, 2017\)](#)
- 10.24‡ [Employment Agreement by and between Avadel Management Corporation and Phillandas T. Thompson dated August 15, 2017 \(incorporated by reference to Exhibit 10.5 to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 9, 2017\)](#)

- 10.25‡ [Amended Employment Agreement dated as of June 3, 2019 between Avadel Management Corporation and Gregory J. Divis \(incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K, filed on June 5, 2019\)](#)
- 10.26‡ [Employment Agreement dated as of June 5, 2019 between Avadel Management Corporation and Jordan Dubow \(incorporated by reference to Exhibit 10.2 to the registrant's current report on Form 8-K, filed on June 5, 2019\)](#)
- 10.28\* [Exclusive Right of Negotiation Agreement by and between Avadel Specialty Pharmaceuticals, LLC and Serenity Pharmaceuticals, LLC dated as of August 11, 2017 \(incorporated by reference to Exhibit 10.6 to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 9, 2017\)](#)
- 10.29\* [Exclusive License and Assignments Agreement by and between Avadel Specialty Pharmaceuticals, LLC and Serenity Pharmaceuticals, LLC dated as of September 1, 2017 \(incorporated by reference to Exhibit 10.7 to the registrant's Quarterly Report on Form 10-Q/A for the quarter ended September 30, 2017, filed on November 17, 2017\)](#)
- 10.30 [Renaissance Agreements Assignment and Assumption Agreement by and between Avadel Specialty Pharmaceuticals, LLC and Serenity Pharmaceuticals, LLC dated as of September 1, 2017 \(incorporated by reference to Exhibit 10.8B to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 9, 2017\)](#)
- 10.31 [Master Manufacturing Services Agreement by and between Patheon UK Limited and Éclat Pharmaceuticals L.L.C. dated as of November 8, 2012 \(incorporated by reference to Exhibit 10.9 to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 9, 2017\)](#)
- 10.32\* [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 \(incorporated by reference to Exhibit 10.43 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 16, 2018\)](#)
- 10.33\* [License and Development Agreement by and between Cerecor, Inc. and Flamel Ireland Limited operating under the trade name of Avadel Ireland dated as of February 16, 2018 \(incorporated by reference to Exhibit 10.44 to the registrant's Annual Report on Form 10-K/A for the year ended December 31, 2017, filed on April 30, 2018\)](#)
- 10.34\* [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 \(incorporated by reference to Exhibit 10.45 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 16, 2018\)](#)
- 10.35\* [Guarantee by Armistice Capital Master Fund, Ltd. in favor of Avadel US Holdings, Inc. dated as of February 16, 2018 \(incorporated by reference to Exhibit 10.46 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2017, filed on March 16, 2018\)](#)
- 10.36 [Letter Agreement, dated February 22, 2018, between Breaking Stick Holdings, LLC and Avadel Pharmaceuticals plc \(incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K, filed on February 22, 2018\)](#)
- 10.37‡ [Employment Agreement Termination and Release Agreement, dated December 30, 2018, between Avadel Management Corporation, Avadel Pharmaceuticals plc and Michael S. Anderson \(incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K, filed on January 3, 2019\)](#)



<b>10.38</b>	<a href="#"><u>Binding Term Sheet between Avadel US Holdings, Inc. and Avadel Specialty Pharmaceuticals LLC (incorporated by reference to Exhibit 10.1 to the registrant's current report on Form 8-K, filed on February 14, 2019).</u></a>
<b>10.39#</b>	<a href="#"><u>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).</u></a>
<b>10.40</b>	<a href="#"><u>Registration Rights Agreement, dated February 25, 2020, by and among Avadel Pharmaceuticals plc and the Investors named therein (filed herewith).</u></a>
<b>14.1</b>	<a href="#"><u>Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 to the registrant's current report on Form 8-K, filed on March 7, 2017).</u></a>
<b>14.2</b>	<a href="#"><u>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).</u></a>
<b>21.1</b>	<a href="#"><u>List of Subsidiaries (filed herewith)</u></a>
<b>23.1</b>	<a href="#"><u>Consent of Deloitte &amp; Touche, LLP (filed herewith)</u></a>
<b>31.1</b>	<a href="#"><u>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).</u></a>
<b>31.2</b>	<a href="#"><u>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).</u></a>
<b>32.1</b>	<a href="#"><u>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).(1)</u></a>
<b>32.2</b>	<a href="#"><u>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).(1)</u></a>
<b>101.INS</b>	XBRL Instant Document
<b>101.SCH</b>	XBRL Taxonomy Extension Schema Document
<b>101.CAL</b>	XBRL Taxonomy Extension Calculation Linkbase Document
<b>101.DEF</b>	XBRL Taxonomy Extension Definition Linkbase Document
<b>101.LAB</b>	XBRL Taxonomy Extension Labels Linkbase Document
<b>101.PRE</b>	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 16, 2020

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 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 Phillandas T. Thompson, 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Gregory J. Divis</u> Gregory J. Divis	Director, Chief Executive Officer and Principal Executive Officer	March 16, 2020
<u>/s/ Thomas S. McHugh</u> Thomas S. McHugh	Chief Financial Officer and Principal Financial and Accounting Officer	March 16, 2020
<u>/s/ Geoffrey M. Glass</u> Geoffrey M. Glass	Non-Executive Chairman of the Board and Director	March 16, 2020
<u>/s/ Dr. Eric J. Ende</u> Dr. Eric J. Ende	Director	March 16, 2020
<u>/s/ Mark A. McCamish, MD, Ph.D.</u> Mark A. McCamish, MD, Ph.D.	Director	March 16, 2020
<u>/s/ Linda S. Palczuk</u> Linda S. Palczuk	Director	March 16, 2020
<u>/s/ Peter Thornton</u> Peter Thornton	Director	March 16, 2020

**Description of the Registrant’s Securities Registered Pursuant to  
Section 12 of the Securities Exchange Act of 1934, as amended**

*The following description of the registered securities of Avadel Pharmaceuticals plc (“Avadel,” “we” or “our”) summarizes the material terms and provisions of our ordinary shares, which may be represented by American Depositary Shares, or ADSs, and preferred shares. The following description of our share capital does not purport to be complete and is subject to, and qualified in its entirety by, our memorandum and articles of association (the “Avadel Constitution”), which is incorporated by reference as Exhibit 3.1 to this Form 10-K, and by applicable law.*

*The following description includes comparisons of certain provisions of the Avadel Constitution and Irish law applicable to us and the Delaware General Corporation Law, or the DGCL, the law under which many publicly listed companies in the United States are incorporated. Because such statements are summaries, they do not address all aspects of Irish law that may be relevant to us and our shareholders or all aspects of Delaware law which may differ from Irish law, and they are not intended to be a complete discussion of the respective rights.*

**General**

Our authorized share capital is \$5,500,000 divided into 500,000,000 ordinary shares with a nominal value of \$0.01 each and 50,000,000 preferred shares with a nominal value of \$0.01 each, plus €25,000 divided into 25,000 deferred ordinary shares with a nominal value of €1.00 each.

**Ordinary Shares**

The holders of ordinary shares are entitled to one vote for each share held of record on all matters submitted to a vote of the shareholders.

Our ordinary shares are not for trading and only registered in connection with the listing of American Depositary Shares (“ADSs”) on the Nasdaq Global Select Market under the trading symbol “AVDL.”

The transfer agent and registrar for our ordinary shares is Computershare Ireland.

**Preferred Shares**

The Avadel Constitution empowers our Board of Directors, without action by our shareholders, to issue up to 50,000,000 preferred shares from time to time in one or more classes or series. Our Board of Directors is authorized, without obtaining any vote or consent of the holders of any class or series of shares, unless expressly provided by the terms of that class or series of shares, to provide from time to time for the issuance of other classes or series of shares and to establish the characteristics of each class or series, including the number of shares, designations, relative voting rights, dividend rights, liquidation and other rights, redemption, repurchase or exchange rights and any other preferences and relative, participating, optional or other rights and limitations not inconsistent with applicable law.

**Warrants**

We may issue warrants for the purchase of our ordinary shares, preferred shares or debt securities or any combination thereof. Warrants may be issued independently or together with our ordinary shares, preferred shares or debt securities and may be attached to or separate from any offered securities. To the extent warrants that we issue are to be publicly-traded, each series of such warrants will be issued under a separate warrant agreement to be entered into between us and a bank or trust company, as warrant agent. The warrant agent will act solely as our agent in connection with such warrants. The warrant agent will not have any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants. This summary of certain provisions of the warrants is not complete. For the terms of a particular series of warrants, you should refer to the prospectus supplement for that series of warrants and the warrant agreement for that particular series.

**Registration Rights**

On February 20, 2020, we entered into a Securities Purchase Agreement with purchasers named therein (the “Investors”) for the sale of an aggregate of 8,680,225 ordinary shares in the form of ADSs and 487,614 Series A Non-Voting Convertible Preferred Shares. In connection with the Purchase Agreement, we entered into a Registration Rights Agreement with the Investors on February 25, 2020 (the “Closing Date”). Pursuant to the Registration Rights Agreement, we agreed to prepare and

file a registration statement with the Securities and Exchange Commission (the “SEC”) within the later of 30 calendar days following the Closing Date or the fifth trading day following the filing of the our 2020 definitive Proxy Statement with the SEC.

## **Anti-Takeover Provisions of Irish Law**

### ***Business Combinations with Interested Shareholders***

The Avadel Constitution includes a provision similar to Section 203 of the Delaware General Corporation Law, which generally prohibits us from engaging in a business combination with an interested shareholder for a period of three years following the date the person became an interested shareholder, unless, in general:

- our Board of Directors approved the transaction which resulted in the shareholder becoming an interested shareholder;
- upon consummation of the transaction which resulted in the shareholder becoming an interested shareholder, the shareholder owned at least 85% of the voting shares outstanding at the time of commencement of such transaction, excluding for purposes of determining the number of voting shares outstanding (but not the outstanding voting shares owned by the interested shareholder), voting shares owned by persons who are directors and also officers and by certain employee share plans; or
- the business combination is approved by our Board of Directors and authorized at an annual or extraordinary general meeting of shareholders by the affirmative vote of the holders of at least 75% of the outstanding voting shares that are not owned by the interested shareholder.

A “business combination” is generally defined as a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested shareholder. An “interested shareholder” is generally defined as a person who, together with affiliates and associates, owns or, within three years prior to the date in question, owned 15% or more of our outstanding voting shares.

### ***Irish Takeover Rules and Substantial Acquisition Rules***

A transaction in which a third party seeks to acquire 30% or more of our voting rights and any other acquisitions of our securities will be governed by the Irish Takeover Panel Act 1997 and the Irish Takeover Rules made thereunder, the Irish Takeover Panel Act, 1997, Takeover Rules, 2013 (the “Irish Takeover Rules”), and will be regulated by the Irish Takeover Panel. The “General Principles” of the Irish Takeover Rules and certain important aspects of the Irish Takeover Rules are described below.

#### ***General Principles***

The Irish Takeover Rules are built on the following General Principles which will apply to any transaction regulated by the Irish Takeover Panel:

- in the event of an offer, all holders of securities of the target company must be afforded equivalent treatment and, if a person acquires control of a company, the other holders of securities must be protected;
- the holders of securities in the target company must have sufficient time and information to enable them to reach a properly informed decision on the offer; where it advises the holders of securities, the Board of Directors of the target company must give its views on the effects of the implementation of the offer on employment, employment conditions and the locations of the target company’s place of business;
- a target company’s Board of Directors must act in the interests of that company as a whole and must not deny the holders of securities the opportunity to decide on the merits of the offer;
- false markets must not be created in the securities of the target company, the bidder or any other company concerned by the offer in such a way that the rise or fall of the prices of the securities becomes artificial and the normal functioning of the markets is distorted;

- a bidder can only announce an offer after ensuring that he or she can fulfill in full the consideration offered, if such is offered, and after taking all reasonable measures to secure the implementation of any other type of consideration;
- a target company may not be hindered in the conduct of its affairs longer than is reasonable by an offer for its securities; and
- a “substantial acquisition” of securities, whether such acquisition is to be effected by one transaction or a series of transactions, shall take place only at an acceptable speed and shall be subject to adequate and timely disclosure.

### ***Mandatory Bid***

Under certain circumstances, a person who acquires shares, or other voting securities, of a company may be required under the Irish Takeover Rules to make a mandatory cash offer for the remaining outstanding voting securities in that company at a price not less than the highest price paid for the securities by the acquiror, or any parties acting in concert with the acquiror, during the previous 12 months. This mandatory bid requirement is triggered if an acquisition of securities would increase the aggregate holding of an acquiror, including the holdings of any parties acting in concert with the acquiror, to securities representing 30% or more of the voting rights in a company, unless the Irish Takeover Panel otherwise consents. An acquisition of securities by a person holding, together with its concert parties, securities representing between 30% and 50% of the voting rights in a company would also trigger the mandatory bid requirement if, after giving effect to the acquisition, the percentage of the voting rights held by that person, together with its concert parties, would increase by 0.05% within a 12-month period. Any person, excluding any parties acting in concert with the holder, holding securities representing more than 50% of the voting rights of a company is not subject to these mandatory offer requirements in purchasing additional securities.

### ***Voluntary Bid; Requirements to Make a Cash Offer and Minimum Price Requirement***

If a person makes a voluntary offer to acquire our outstanding ordinary shares, the offer price must not be less than the highest price paid for our ordinary shares by the bidder or its concert parties during the three-month period prior to the commencement of the offer period. The Irish Takeover Panel has the power to extend the “look back” period to 12 months if the Irish Takeover Panel, taking into account the General Principles, believes it is appropriate to do so.

If the bidder or any of its concert parties has acquired our ordinary shares (1) during the 12-month period prior to the commencement of the offer period that represent more than 10% of our total ordinary shares or (2) at any time after the commencement of the offer period, the offer must be in cash or accompanied by a full cash alternative and the price per ordinary share must not be less than the highest price paid by the bidder or its concert parties during, in the case of clause (1), the 12-month period prior to the commencement of the offer period or, in the case of (2), the offer period. The Irish Takeover Panel may apply this Rule to a bidder who, together with its concert parties, has acquired less than 10% of our total ordinary shares in the 12-month period prior to the commencement of the offer period if the Irish Takeover Panel, taking into account the General Principles, considers it just and proper to do so.

An offer period will generally commence from the date of the first announcement of the offer or proposed offer.

### ***Substantial Acquisition Rules***

The Irish Takeover Rules also contain rules governing substantial acquisitions of shares and other voting securities which restrict the speed at which a person may increase his or her holding of shares and rights over shares to an aggregate of between 15% and 30% of the voting rights of the company. Except in certain circumstances, an acquisition or series of acquisitions of shares or rights over shares representing 10% or more of the voting rights of the company is prohibited, if such acquisition(s), when aggregated with shares or rights already held, would result in the acquirer holding 15% or more but less than 30% of the voting rights of the company and such acquisitions are made within a period of seven days. These rules also require accelerated disclosure of acquisitions of shares or rights over shares relating to such holdings.

### ***Frustrating Action***

Under the Irish Takeover Rules, our Board of Directors is not permitted to take any action that might frustrate an offer for our shares once our Board of Directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as 1) the issue of shares, options,

restricted share units or convertible securities, (2) material acquisitions or disposals, (3) entering into contracts other than in the ordinary course of business or (4) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our Board of Directors has reason to believe an offer is or may be imminent. Exceptions to this prohibition are available where:

- (a) the action is approved by our shareholders at a general meeting; or
- (b) the Irish Takeover Panel has given its consent, where:
  - (i) it is satisfied the action would not constitute frustrating action;
  - (ii) our shareholders holding more than 50% of the voting rights state in writing that they approve the proposed action and would vote in favor of it at a general meeting;
  - (iii) the action is taken in accordance with a contract entered into prior to the announcement of the offer, or any earlier time at which our Board of Directors considered the offer to be imminent; or
  - (iv) the decision to take such action was made before the announcement of the offer and either has been at least partially implemented or is in the ordinary course of business.

### ***Shareholders' Rights Plan***

Irish law does not expressly authorize or prohibit companies from issuing share purchase rights or adopting a shareholder rights plan as an anti-takeover measure. However, there is no directly relevant case law on the validity of such plans under Irish law. In addition, such a plan would be subject to the Irish Takeover Rules and the General Principles underlying the Irish Takeover Rules. The Avadel Constitution allows our Board of Directors to adopt a shareholder rights plan upon such terms and conditions as our Board of Directors deems expedient and in the best interests of us, subject to applicable law.

Subject to the Irish Takeover Rules, our Board of Directors also has power to issue any of our authorized and unissued shares on such terms and conditions as it may determine and any such action should be taken in our best interests. It is possible, however, that the terms and conditions of any issue of preference shares could discourage a takeover or other transaction that holders of some or a majority of the ordinary shares believe to be in their best interests or in which holders might receive a premium for their shares over the then-market price of the shares.

### ***Disclosure of Interests in Shares***

Under the Irish Companies Act, our shareholders must notify us if, as a result of a transaction, the shareholder will become interested in three percent or more of our voting shares, or if as a result of a transaction a shareholder who was interested in three percent or more of our voting shares ceases to be so interested. Where a shareholder is interested in three percent or more of our voting shares, the shareholder must notify us of any alteration of his or her interest that brings his or her total holding through the nearest whole percentage number, whether an increase or a reduction. The relevant percentage figure is calculated by reference to the aggregate nominal value of the voting shares in which the shareholder is interested as a proportion of the entire nominal value of our issued share capital (or any such class of share capital in issue). Where the percentage level of the shareholder's interest does not amount to a whole percentage, this figure may be rounded down to the next whole number. We must be notified within five business days of the transaction or alteration of the shareholder's interests that gave rise to the notification requirement. If a shareholder fails to comply with these notification requirements, the shareholder's rights in respect of any of our shares it holds will not be enforceable, either directly or indirectly. However, such person may apply to the court to have the rights attaching to such shares reinstated.

In addition to these disclosure requirements, we, under the Irish Companies Act, may, by notice in writing, require a person whom we know or have reasonable cause to believe to be, or at any time during the three years immediately preceding the date on which such notice is issued to have been, interested in shares comprised in our relevant share capital to (i) indicate whether or not it is the case and (ii) where such person holds or has during that time held an interest in our shares, to provide additional information, including the person's own past or present interests in our shares. If the recipient of the notice fails to respond within the reasonable time period specified in the notice, we may apply to the Irish court for an order directing that the affected shares be subject to certain restrictions, as prescribed by the Irish Companies Act, as follows:

- any transfer of those shares or, in the case of unissued shares, any transfer of the right to be issued with shares and any issue of shares, shall be void;
- no voting rights shall be exercisable in respect of those shares;
- no further shares shall be issued in right of those shares or in pursuance of any offer made to the holder of those shares; and
- no payment shall be made of any sums due from us on those shares, whether in respect of capital or otherwise.

The court may also order that shares subject to any of these restrictions be sold with the restrictions terminating upon the completion of the sale.

In the event we are in an offer period pursuant to the Irish Takeover Rules, accelerated disclosure provisions apply for persons holding an interest in our securities of one percent or more.

### Differences in Corporate Law

As a public limited company incorporated under the laws of Ireland, the rights of our shareholders are governed by applicable Irish law, including the Irish Companies Act, and not by the law of any U.S. state. As a result, our directors and shareholders are subject to different responsibilities, rights and privileges than are applicable to directors and shareholders of U.S. corporations. The applicable provisions of the Irish Companies Act differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the Irish Companies Act applicable to us and the General Corporation Law of the State of Delaware relating to shareholders' rights and protections. The applicable provisions in respect of the Company under the Avadel Constitution is also set out where relevant. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and Irish law. You are also urged to carefully read the relevant provisions of the Delaware General Corporation Law and the Irish Companies Act for a more complete understanding of the differences between Delaware and Irish law.

	<b>Ireland</b>	<b>Delaware</b>
Number of Directors	The Irish Companies Act provides for a minimum of two directors. The Avadel Constitution provides for a minimum of two directors and a maximum of 13. Our shareholders may from time to time increase or reduce the maximum number, or increase the minimum number, of directors by ordinary resolution. Our Board of Directors determines the number of directors within the range of two to 13.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.



## Removal of Directors

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Under the Irish Companies Act, the shareholders may, by ordinary resolution, remove a director from office before the expiration of his or her term, at a meeting held no less than 28 days' notice and at which the director is entitled to be heard. Because of this provision of the Irish Companies Act, a director may be so removed before the expiration of his or her period of office.

The power of removal is without prejudice to any claim for damages for breach of contract (e.g., employment contract) that the director may have against the Company in respect of his or her removal.

The Avadel Constitution also provides that the office of a director will also be vacated if the director is restricted or disqualified to act as a director under the Irish Companies Act; resigns his or her office by notice in writing to us or in writing offers to resign and the directors resolve to accept such offer; or is requested to resign in writing by not less than 75% of the other directors.

Under Delaware law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, stockholders may effect such removal only for cause, or (ii) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

## Vacancies on the Board of Directors

Any vacancy on our Board of Directors, including a vacancy resulting from an increase in the number of directors or from the death, resignation, retirement, disqualification or removal of a director, shall be deemed a casual vacancy. Subject to the terms of any one or more classes or series of preferred shares, any casual vacancy shall only be filled by the decision of a majority of our Board of Directors then in office, provided that a quorum is present and provided that the appointment does not cause the number of directors to exceed any number fixed by or in accordance with the Avadel Constitution as the maximum number of directors.

Any director of a class of directors elected to fill a vacancy resulting from an increase in the number of directors of such class shall hold office for the remaining term of that class. Any director elected to fill a vacancy not resulting from an increase in the number of directors shall have the same remaining term as that of his predecessor. A director retiring at a meeting shall retain office until the close or adjournment of the meeting.

Under Delaware law, vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) or by a sole remaining director unless (i) otherwise provided in the certificate of incorporation or bylaws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

## Annual General Meeting

We are required to hold annual general meetings at intervals of no more than fifteen months after the previous annual general meeting, provided that an annual general meeting is held in each calendar year following our first annual general meeting, no more than nine months after our fiscal year-end.

The only matters which must, as a matter of Irish company law, be transacted at an annual general meeting are the consideration of the Irish statutory financial statements, the report of the directors, the report of the auditors on those statements and that report and a review by the members of our affairs. If no resolution is made in respect of the reappointment of an auditor at an annual general meeting, the previous auditor will be deemed to have continued in office.

Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.

## General Meeting

Our extraordinary general meetings may be convened by (i) our Board of Directors, (ii) on requisition of shareholders holding not less than 10% of our paid up share capital carrying voting rights or (iii) on requisition of our auditors. Extraordinary general meetings are generally held for the purposes of approving shareholder resolutions as may be required from time to time.

If our directors become aware that our net assets are half or less of the amount of our called-up share capital, our directors must convene an extraordinary general meeting of our shareholders not later than 28 days from the date that they learn of this fact. This meeting must be convened for the purposes of considering whether any, and if so what, measures should be taken to address the situation.

Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.

## Notice of General Meetings

Notice of a general meeting must be given to all our shareholders and to our auditors. The Avadel Constitution provides that the maximum notice period is 60 days. The minimum notice periods are 21 days' notice in writing for an annual general meeting or an extraordinary general meeting to approve a special resolution and 14 days' notice in writing for any other extraordinary general meeting. General meetings may be called by shorter notice, but only with the consent of our auditors and all of our shareholders entitled to attend and vote thereat. Because of the 21-day and 14-day requirements described in this paragraph, the Avadel Constitution includes provisions reflecting these requirements of Irish law.

In the case of an extraordinary general meeting convened by our shareholders, the proposed purpose of the meeting must be set out in the requisition notice. Upon receipt of this requisition notice, our Board of Directors has 21 days to convene a meeting of our shareholders to vote on the matters set out in the requisition notice. This meeting must be held within two months of the receipt of the requisition notice. If our Board of Directors does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of the receipt of the requisition notice.

Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour and purpose or purposes of the meeting.

## Quorum

The presence, in person or by proxy, of five or more persons holding or representing by proxy at least a majority in nominal value of the class or, at any adjourned meeting of such holders, one holder holding or representing by proxy at least a majority in nominal value of the issued shares of the class constitutes a quorum for the conduct of business. No business may take place at a general meeting if a quorum is not present in person or by proxy. Our Board of Directors has no authority to waive quorum requirements stipulated in the Avadel Constitution. Abstentions and broker non-votes will be counted as present for purposes of determining whether there is a quorum in respect of the proposals.

The certificate of incorporation or bylaws may specify the number of shares, the holders of which shall be present or represented by proxy at any meeting in order to constitute a quorum, but in no event shall a quorum consist of less than one third of the shares entitled to vote at the meeting. In the absence of such specification in the certificate of incorporation or bylaws, a majority of the shares entitled to vote, present in person or represented by proxy, shall constitute a quorum at a meeting of stockholders.

## Proxy

Under Irish law, a shareholder may designate another person to attend, speak and vote at a general meeting of the company on their behalf by proxy, which proxy need not be a shareholder.

Where interests in shares are held by a nominee trust company, this company may exercise the rights of the beneficial holders on their behalf as their proxy.

Voting rights may be exercised by shareholders registered in the share register as of the record date for the meeting or by a duly appointed proxy of such a registered shareholder, which proxy need not be a shareholder. Where interests in shares are held by a nominee trust company, this company may exercise the rights of the beneficial holders on their behalf as their proxy. All proxies must be appointed in accordance with the Avadel Constitution. The Avadel Constitution permits the appointment of proxies by our shareholders to be notified to us electronically, when permitted by our directors.

Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

## Issue of New Shares

Under the Avadel Constitution, we may issue shares subject to the maximum authorized share capital contained in the Avadel Constitution. The authorized share capital may be increased or reduced by a resolution approved by a simple majority of the votes cast at a general meeting of our shareholders, referred to under Irish law as an "ordinary resolution." As a matter of Irish law, the directors of a company may issue new ordinary or preferred shares without shareholder approval once authorized to do so by its constitution or by an ordinary resolution adopted by our shareholders at a general meeting. The authorization may be granted for a maximum period of five years, at which point it may be renewed by shareholders by an ordinary resolution. Accordingly, the Avadel Constitution authorizes our Board of Directors to issue new ordinary or preferred shares without shareholder approval for a period of five years from the date of the adoption of the Avadel Constitution. The authority to issue preferred shares provides us with the flexibility to consider and respond to future business needs and opportunities as they arise from time to time, including in connection with capital raising, financing and acquisition transactions or opportunities.

Under the Avadel Constitution, our Board of Directors will be authorized to issue preferred shares on a non-pre-emptive basis, with discretion as to the terms attaching to the preferred shares, including as to voting, dividend and conversion rights and priority relative to other classes of shares with respect to dividends and upon a liquidation. As described in the preceding paragraph, this authority extends until five years from the date of the adoption of the Avadel Constitution, at which time it will expire unless renewed by our shareholders.

Notwithstanding this authority, under the Irish Takeover Rules our Board of Directors would not be permitted to issue any of our shares, including preferred shares, during a period when an offer has been made for us or is believed to be imminent unless the issue is (i) approved by our shareholders at a general meeting; (ii) consented to by the Irish Takeover Panel on the basis it would not constitute action frustrating the offer;

Under Delaware law, if the company's certificate of incorporation so provides, the directors have the power to authorize the issuance of additional stock. The directors may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the company or any combination thereof.

(iii) consented to by the Irish Takeover Panel and approved by the holders of more than 50% of our shares carrying voting rights;

(iv) consented to by the Irish Takeover Panel in circumstances where a contract for the issue of the shares had been entered into prior to that period; or (v) consented to by the Irish Takeover Panel in circumstances where the issue of the shares was decided by our directors prior to that period and either action has been taken to implement the issuance (whether in part or in full) prior to such period or the issuance was otherwise in the ordinary course of business.

## Preemptive Rights

Under Irish law, unless otherwise authorized, when an Irish public limited company issues shares for cash to new shareholders, it is required first to offer those shares on the same or more favorable terms to existing shareholders of the company on a pro rata basis, commonly referred to as the statutory preemption right. However, we have opted out of these preemption rights in the Avadel Constitution as permitted under Irish law. Because Irish law permits this opt-out to last for a maximum of five years, the Avadel Constitution provides that this opt-out will lapse five years after the adoption of the Avadel Constitution. Such opt-out may be renewed by a special resolution of the shareholders. A special resolution requires not less than 75% of the votes cast at a general meeting of our shareholders. If the opt-out is not renewed, shares issued for cash must be offered to pre-existing shareholders of Avadel plc pro rata to their existing shareholding before the shares can be issued to any new shareholders. The statutory preemption rights do not apply where shares are issued for non-cash consideration and do not apply to the issue of non-equity shares (that is, shares that have the right to participate only up to a specified amount in any income or capital distribution).

Under Delaware law, shareholders have no preemptive rights to subscribe to additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.



## Authority to Allot

Under the Avadel Constitution, we may issue shares subject to the maximum authorized share capital contained in the Avadel Constitution. The authorized share capital may be increased or reduced by a resolution approved by a simple majority of the votes cast at a general meeting of our shareholders, referred to under Irish law as an "ordinary resolution." Our authorized share capital may be divided into shares of such nominal value as the resolution shall prescribe. As a matter of Irish law, the directors of a company may issue new ordinary or preferred shares without shareholder approval once authorized to do so by its constitution or by an ordinary resolution adopted by our shareholders at a general meeting. The authorization may be granted for a maximum period of five years, at which point it may be renewed by shareholders by an ordinary resolution. Accordingly, the Avadel Constitution authorizes our Board of Directors to issue new ordinary or preferred shares without shareholder approval for a period of five years from the date of the adoption of the Avadel Constitution. The authority to issue preferred shares provides us with the flexibility to consider and respond to future business needs and opportunities as they arise from time to time, including in connection with capital raising, financing and acquisition transactions or opportunities.

Under Delaware law, if the corporation's charter or certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. The board may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.

## Liability of Directors and Officers

To the fullest extent permitted by Irish law, the Avadel Constitution contains indemnification for the benefit of our directors, company secretary and executive officers. However, as to our directors and company secretary, this indemnity is limited by the Irish Companies Act, which prescribes that an advance commitment to indemnify only permits a company to pay the costs or discharge the liability of a director or company secretary where judgment is given in favor of the director or company secretary in any civil or criminal action in respect of such costs or liability, or where an Irish court grants relief because the director or company secretary acted honestly and reasonably and ought fairly to be excused. Any provision whereby an Irish company seeks to commit in advance to indemnify its directors or company secretary over and above the limitations imposed by the Irish Companies Act will be void, whether contained in its articles of association or any contract between the company and the director or company secretary. This restriction does not apply to our executive officers who are not directors, our company secretary or other persons who would be considered “officers” within the meaning of the Irish Companies Act.

We are permitted under the Avadel Constitution and the Irish Companies Act to take out directors' and officers' liability insurance, as well as other types of insurance, for our directors, officers, employees and agents. In order to attract and retain qualified directors and officers, we expect to purchase and maintain customary directors' and officers' liability insurance and other types of comparable insurance.

## Voting Rights

Under the Avadel Constitution, each holder of our ordinary shares is entitled to one vote for each ordinary share that he or she holds as of the record date for the meeting. The holder of our deferred ordinary shares is not entitled to a vote. We may not exercise any voting rights in respect of any shares held as treasury shares. Any shares held by our subsidiaries will count as treasury shares for this purpose, and such subsidiaries cannot therefore exercise any voting rights in respect of those shares.

Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or
- any transaction from which the director derives an improper personal benefit.

## Shareholder Vote on Certain Transactions

Pursuant to Irish law, shareholder approval in connection with a transaction involving the Company would be required under the following circumstances:

in connection with a scheme of arrangement, both a court order from the Irish High Court and the approval of a majority in number representing 75% in value of the shareholders present and voting in person or by proxy at a meeting called to approve such a scheme would be required;

in connection with an acquisition of the Company by way of a merger with an EU company under the EU Cross-Border Mergers Directive 2005/56/EC, (as replaced by Directive (EU) 2017/1132 of 14 June 2017), approval by a special resolution of the shareholders would be required; and

in connection with a merger with an Irish company under the Irish Companies Act, approval by a special resolution of shareholders would be required.

Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires:

the approval of the board of directors; and the approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of the corporation entitled to vote on the matter.

## Standard of Conduct for Directors

The directors of the Company have certain statutory and fiduciary duties as a matter of Irish law. All of the directors have equal and overall responsibility for the management of the Company (although directors who also serve as employees may have additional responsibilities and duties arising under their employment agreements (if applicable), and it is likely that more will be expected of them in compliance with their duties than non-executive directors). The Irish Companies Act provides specifically for certain fiduciary duties of the directors of Irish companies, including duties:

to act in good faith and in the best interests of the company;

to act honestly and responsibly in relation to the company's affairs;

to act in accordance with the company's constitution and to exercise powers only for lawful purposes;

not to misuse the company's property, information and/or opportunity;

not to fetter their independent judgment;

to avoid conflicts of interest;

to exercise care, skill and diligence; and

to have regard for the interests of the company's shareholders.

Other statutory duties of directors include ensuring the maintenance of proper books of account, having annual accounts prepared, having an annual audit performed, maintaining certain registers, making certain filings and disclosing personal interests. Directors of public limited companies such as Avadel will have a specific duty to ensure that the company secretary is a person with the requisite knowledge and experience to discharge the role. Directors may rely on information, opinions, reports or statements, including financial statements and other financial data, prepared or presented by

Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

Directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its shareholders. The duty of care generally requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation.

In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the shareholders.

(1) other directors, officers or employees of the company whom the director reasonably believes to be reliable and competent in the matters prepared or presented, (2) legal counsel, public accountants or other persons as to matters the director reasonably believes to be within their professional or expert competence, or (3) a committee of the board of which the director does not serve as to matters within its designated authority, which committee the director reasonably believed to merit confidence.

## Shareholder Suits

In Ireland, the decision to institute proceedings is generally taken by a company's board of directors, who will usually be empowered to manage the company's business. In certain limited circumstances, a shareholder may be entitled to bring a derivative action on behalf of the company.

The central question at issue in deciding whether a minority shareholder may be permitted to bring a derivative action is whether, unless the action is brought, a wrong committed against the company would otherwise go un-redressed.

The principal case law in Ireland indicates that to bring a derivative action a person must first establish a prima facie case (i) that the company is entitled to the relief claimed and (ii) that the action

falls within one of the five exceptions derived from case law, as follows:

- (1) where an ultra vires or illegal act is perpetrated;
- (2) where more than a bare majority is required to ratify the "wrong" complained of;
- (3) where the shareholders' personal rights are infringed;
- (4) where a fraud has been perpetrated upon a minority by those in control; or
- (5) where the justice of the case requires a minority to be permitted to institute proceedings.

Shareholders may also bring proceedings against the company where the affairs of the company are being conducted, or the powers of the directors are being exercised, in a manner oppressive to the shareholders or in disregard of their interests. Oppression connotes conduct that is burdensome, harsh or wrong.

Conduct must relate to the internal management of the company. This is an Irish statutory remedy and the court can grant any order it sees fit, usually providing for the purchase or transfer of the shares of any shareholder.

Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:

state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and

allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action; or state the reasons for not making the effort.

Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

## American Depositary Shares

The Bank of New York Mellon, as depositary, registers and delivers our ADSs. Each ADS represents one share (or a right to receive one share) deposited with The Bank of New York Mellon, acting through an office located in the United Kingdom, as custodian for the depositary. Each ADS also represents any other securities, cash or other property which may be held by the depositary. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

ADSs may be held either (A) directly (i) by having an American Depositary Receipt (an "ADR"), which is a certificate evidencing a specific number of ADSs, registered in the name of the holder, or (ii) by having uncertificated ADSs registered in the name of the holder, or (B) indirectly by holding a security entitlement in ADSs through a broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. This description assumes you are an ADS holder, which is the case if the ADS is directly held. If the ADSs are indirectly held, holders must rely on the procedures of their broker or other financial institution to assert the rights of ADS holders described in this section. We encourage all holders to consult with their broker or financial institution to find out what those procedures are.

ADS holders are not treated as one of our shareholders and do not have shareholder rights. Irish law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. This summary the depositary agreement does not purport to be complete and is not intended to be a complete discussion of the respective rights.

### **Dividends and Other Distributions**

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. These distributions are to be made in proportion to the number of shares the ADSs represent.

**Cash.** The depositary will (if necessary) convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted.

The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, some value of the distribution may be lost.*

**Shares.** The depositary may distribute additional ADSs representing any shares we distribute as a dividend or fee distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

**Rights to purchase additional shares.** If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse and no value will be distributed. The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs

representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

**Other Distributions.** The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders.

### **Deposit, Withdrawal and Cancellation**

The depositary will deliver ADSs if the holder or broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the requested names and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

ADSs may be surrendered for the purpose of withdrawal at the depositary's office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. The depositary may charge a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

An ADR may be surrendered to the depositary for the purpose of exchanging an ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

### **Voting Rights**

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit voting instructions (and we are not required to do so), the depositary will notify ADS holders of a shareholders' meeting and send or make voting materials available. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of Ireland and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit voting instructions, ADS holders can still send voting instructions, and, in that case, the depositary may try to vote as instructed, but it is not required to do so.

*Except by instructing the depositary as described above, ADS holders will not be able to exercise voting rights unless they surrender their ADSs and withdraw the shares. However, there may not be enough advance notice of a meeting to withdraw the shares in time.* In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If we asked the depositary to solicit voting instructions at least 30 days before the meeting date but the depositary does not receive voting instructions from an ADS holder by the specified date, this will be considered authorization and direction to give a discretionary proxy to a person designated by us to vote that number of deposited securities. The depositary will give a discretionary proxy in those circumstances to vote on all questions at to be voted upon unless we notify the depositary that:



- we do not wish to receive a discretionary proxy;
- there is substantial shareholder opposition to the particular question; or
- the particular question would have an adverse impact on our shareholders.

We are required to notify the depositary if one of the conditions specified above exists.

We cannot assure that ADS holders will receive the voting materials in time to ensure that they can instruct the depositary to vote their shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions.

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to Deposited Securities, if we request the Depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

### Fees and Expenses

<i>Persons depositing or withdrawing shares or ADS holders must pay:</i>	<i>For:</i>
\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property  Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
\$0.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
\$0.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement)  converting foreign currency to U.S. dollars  As necessary
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of

establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depository or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depository may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depository and that may earn or share fees, spreads or commissions.

The depository may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depository or its affiliate receives when buying or selling foreign currency for its own account. The depository makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depository's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

#### **Payment of Taxes**

ADS holders are responsible for any taxes or other governmental charges payable on their ADSs or on the deposited securities represented by any of their ADSs. The depository may refuse to register any transfer of ADSs or withdrawal requests of the deposited securities represented by ADSs until those taxes or other charges are paid. It may apply payments owed to the ADS holder or sell deposited securities represented by the holder's ADSs to pay any taxes owed and the holder will remain liable for any deficiency. If the depository sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

#### **Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities**

The depository will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depository may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depository as a holder of deposited securities, the depository will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depository receives new securities in exchange for or in lieu of the old deposited securities, the depository will hold those replacement securities as deposited securities under the deposit agreement. However, if the depository decides it would not be lawful and to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depository may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depository will continue to hold the replacement securities, the depository may distribute new ADSs representing the new deposited securities or request the surrender of outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depository may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

#### **Amendment and Termination**

We may agree with the depository to amend the deposit agreement and the ADRs without ADS holders' consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depository for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depository notifies ADS holders of the amendment. *At the time an amendment becomes effective, ADS holders, by continuing to hold ADSs, are considered to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

The depository will initiate termination of the deposit agreement if we instruct it to do so. The depository may initiate

termination of the deposit agreement if

- 60 days have passed since the depository told us it wants to resign but a successor depository has not been appointed and accepted its appointment;
- we delist the ADSs from an exchange on which they were listed and do not list the ADSs on another exchange;
- we appear to be insolvent or enter insolvency proceedings
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depository will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depository may sell the deposited securities. After that, the depository will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depository will sell as soon as practicable after the termination date.

After the termination date and before the depository sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depository may refuse to accept a surrender for the purpose of withdrawing deposited securities if it would interfere with the selling process. The depository may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depository will continue to collect distributions on deposited securities, but, after the termination date, the depository is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

#### **Limitations on Obligations and Liability**

##### ***Limits on our Obligations and the Obligations of the Depository; Limits on Liability to Holders of ADSs***

The deposit agreement expressly limits our obligations and the obligations of the depository. It also limits our liability and the liability of the depository. We and the depository:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if we are or it is prevented or delayed by law or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;

- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on the ADS holder's behalf or on behalf of any other person;
- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

### **Requirements for Depositary Actions**

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

### **Right to Receive the Shares Underlying ADSs**

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;
- when the ADS holder owes money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

### **Direct Registration System**

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf

of a registered holder of uncertificated ADSs, to direct the depository to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depository of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depository will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depository's reliance on and compliance with instructions received by the depository through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depository.

#### **Shareholder communications; inspection of register of holders of ADSs**

The depository will make available for inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depository will send copies of those communications or otherwise make those communications available to ADS holders if we ask it to. ADS holders have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

#### **Jury Trial Waiver**

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depository arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. If we or the depository opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law.

ADS holders will not, by agreeing to the terms of the deposit agreement, be deemed to have waived our or the depository's compliance with U.S. Securities Act of 1933 or the rules and regulations promulgated thereunder.

## REGISTRATION RIGHTS AGREEMENT

This Registration Rights Agreement (this “*Agreement*”) is made and entered into as of February 25, 2020, by and among Avadel Pharmaceuticals plc, an Irish public limited company (the “*Company*”), and the several purchasers signatory hereto (each a “*Purchaser*” and collectively, the “*Purchasers*”).

This Agreement is made pursuant to the Securities Purchase Agreement, dated as of the February 20, 2020, between the Company and each Purchaser (the “*Purchase Agreement*”).

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and each of the Purchasers agree as follows:

1. **Definitions.** Capitalized terms used and not otherwise defined herein that are defined in the Purchase Agreement shall have the meanings given such terms in the Purchase Agreement. As used in this Agreement, the following terms shall have the following meanings:

“*Advice*” has the meaning set forth in Section 6(d).

“*Affiliate*” means, with respect to any person, any other person which directly or indirectly controls, is controlled by, or is under common control with, such person.

“*Agreement*” has the meaning set forth in the Preamble.

“*Business Day*” means a day, other than a Saturday or Sunday, on which banks in New York City are open for the general transaction of business.

“*Closing*” has the meaning set forth in the Purchase Agreement.

“*Closing Date*” has the meaning set forth in the Purchase Agreement.

“*Commission*” means the Securities and Exchange Commission.

“*Company*” has the meaning set forth in the Preamble.

“*Effective Date*” means the date that the Registration Statement filed pursuant to Section 2(a) is first declared effective by the Commission.

“*Effectiveness Deadline*” means, with respect to the Initial Registration Statement or the New Registration Statement, the thirtieth (30<sup>th</sup>) calendar day following the Filing Deadline (or, in the event the Commission reviews and has written comments to the Initial Registration Statement or the New Registration Statement, the sixtieth (60<sup>th</sup>) calendar day following the Filing Deadline); *provided, however*, that if the Company is notified by the Commission that the Initial Registration Statement or the New Registration Statement will not be reviewed or is no longer subject to further review and comments, the Effectiveness Deadline as to such Registration Statement shall be the fifth (5<sup>th</sup>) Trading Day following the date on which the Company is so notified if such date precedes the dates otherwise required above; *provided, further*, that if the Effectiveness Deadline falls on a Saturday, Sunday or other day that the Commission is closed for business, the Effectiveness Deadline shall be extended to the next Business Day on which the Commission is open for business.

“*Effectiveness Period*” has the meaning set forth in Section 2(b).

“*Exchange Act*” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“*Filing Deadline*” means, with respect to the Initial Registration Statement required to be filed pursuant to Section 2(a), the later of (i) the thirtieth (30<sup>th</sup>) calendar day following the Closing Date or (ii) the fifth (5<sup>th</sup>) Trading Day following the filing of the Company’s 2020 Definitive Proxy Statement with the Commission, *provided, however*, that if the Filing Deadline falls on a Saturday, Sunday or other day that the Commission is closed for business, the Filing Deadline shall be extended to the next business day on which the Commission is open for business.

“*Holder*” or “*Holders*” means the holder or holders, as the case may be, from time to time of Registrable Securities.

“*Indemnified Party*” has the meaning set forth in Section 5(c).

“*Indemnifying Party*” has the meaning set forth in Section 5(c).

“*Initial Registration Statement*” means the initial Registration Statement filed pursuant to Section 2(a) of this Agreement.

“*Losses*” has the meaning set forth in Section 5(a).

“*New Registration Statement*” has the meaning set forth in Section 2(a).

“*Ordinary Shares*” means the ordinary shares, nominal value \$0.01 per share, of the Company, in the form of American Depositary Shares (the “*ADSs*”), and any securities into which such ordinary shares may hereinafter be reclassified.

“*Person*” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“*Principal Market*” means the Trading Market on which the ADSs are primarily listed on and quoted for trading, which, as of the Closing Date, shall be the Nasdaq Global Market.

“*Proceeding*” means an action, claim, suit, investigation or proceeding (including, without limitation, an investigation or partial proceeding, such as a deposition), whether commenced or threatened.

“*Prospectus*” means the prospectus included in a Registration Statement (including, without limitation, a prospectus that includes any information previously omitted from a prospectus filed as part of an effective registration statement in reliance upon Rule 430B promulgated under the Securities Act), as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Securities covered by a Registration Statement, and all other amendments and supplements to the Prospectus, including post-effective amendments, and all material incorporated by reference or deemed to be incorporated by reference in such Prospectus.

“*Purchase Agreement*” has the meaning set forth in the Recitals.

“*Purchaser*” or “*Purchasers*” has the meaning set forth in the Preamble.

“*Registrable Securities*” means all of (i) the Shares and (ii) any securities issued or issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to the foregoing, *provided*, that the Holder has completed and delivered to the Company a Selling Shareholder Questionnaire; and *provided, further*, that with respect to a particular Holder, such Holder’s Shares shall cease to be Registrable Securities upon the earliest to occur of the following: (A) a sale pursuant to a Registration Statement or Rule 144 under the Securities Act (in which case, only such security sold by the Holder shall cease to be a Registrable Security); (B) becoming eligible for resale by the Holder under Rule 144 without the requirement for the Company to be in compliance with the current public information required thereunder and without volume or manner-of-sale restrictions, pursuant to a written opinion letter of counsel for the Company to such effect, addressed, delivered and acceptable to the Transfer Agent; or (C) the expiration of twelve months from the Closing Date.

“*Registration Statements*” means any one or more registration statements of the Company filed under the Securities Act that covers the resale of any of the Registrable Securities pursuant to the provisions of this Agreement (including without limitation the Initial Registration Statement, the New Registration Statement and any Remainder Registration Statements), amendments and supplements to such Registration Statements, including post-effective amendments, all exhibits and all material incorporated by reference or deemed to be incorporated by reference in such Registration Statements.

“*Remainder Registration Statement*” has the meaning set forth in Section 2(a).

“*Rule 144*” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

“*Rule 415*” means Rule 415 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

“*Rule 424*” means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

“*SEC Guidance*” means (i) any publicly-available written or oral guidance, comments, requirements or requests of the Commission staff; provided, that any such oral guidance, comments, requirements or requests are reduced to writing by the Commission and (ii) the Securities Act.

“*Securities Act*” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“*Selling Shareholder Questionnaire*” means a questionnaire in the form attached as Annex B hereto, or such other form of questionnaire as may reasonably be adopted by the Company from time to time.

“*Series A Preferred Shares*” means the Series A Non-Voting Convertible Preferred Shares, nominal value \$0.01 per share, of the Company.

“*Shares*” means the Ordinary Shares in the form of ADSs issued or issuable to the Purchasers pursuant to the Purchase Agreement, including those Ordinary Shares in the form of ADSs which may be issued upon conversion of the Series A Preferred Shares as designated by the Board of Directors of the Company on February 20, 2020.

“*Trading Day*” means any day on which the ADSs are traded on the Principal Trading Market; provided that “*Trading Day*” shall not include any day on which the ADSs are scheduled to trade on such exchange or market for less than 4.5 hours or any day that the ADSs suspended from trading during the final hour of trading on such exchange or market (or if such exchange or market does not designate in advance the closing time of trading on such exchange or market, then during the hour ending at 4:00 p.m., New York time).

“*Trading Market*” means whichever of the New York Stock Exchange, the NYSE American (formerly the American Stock Exchange), the Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market or OTC Bulletin Board on which the ADSs are listed or quoted for trading on the date in question.

2. Registration.

(a) On or prior to the Filing Deadline, the Company shall prepare and file with the Commission a Registration Statement covering the resale of all of the Registrable Securities not then registered on an existing and effective Registration Statement for an offering to be made on a continuous basis pursuant to Rule 415 or, if Rule 415 is not available for offers and sales of the Registrable Securities, by such other means of distribution of Registrable Securities as the Holders may reasonably specify (the “*Initial Registration*”).



Statement”). The Initial Registration Statement shall be on Form S-3 (except if the Company is then ineligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on such other form available to register for resale the Registrable Securities as a secondary offering) subject to the provisions of Section 2(d) and shall contain (except if otherwise required pursuant to written comments received from the Commission upon a review of such Registration Statement) the “Plan of Distribution” section substantially in the form attached hereto as Annex A (which may be modified to respond to comments, if any, provided by the Commission). Notwithstanding the registration obligations set forth in this Section 2, in the event the Commission informs the Company that all of the Registrable Securities cannot, as a result of the application of Rule 415, be registered for resale as a secondary offering on a single registration statement, the Company agrees to promptly (i) inform each of the Holders thereof and use its reasonable best efforts to file amendments to the Initial Registration Statement as required by the Commission and/or (ii) withdraw the Initial Registration Statement and file a new registration statement (a “New Registration Statement”), in either case covering the maximum number of Registrable Securities permitted to be registered by the Commission, on Form S-3 or, if the Company is ineligible to register the Registrable Securities on Form S-3, such other form available to register for resale the Registrable Securities as a secondary offering; *provided, however*, that prior to filing such amendment or New Registration Statement, the Company shall be obligated to use its reasonable best efforts to advocate with the Commission for the registration of all of the Registrable Securities in accordance with the SEC Guidance, including without limitation, the Securities Act Rules Compliance and Disclosure Interpretations Question 612.09. Each Purchaser shall have the right to comment or have their counsel comment on any written submission made to the staff of Commission (the “Staff”) with respect to any disclosure specifically relating to such Purchaser. No such written submission shall be made to the Staff containing disclosure specifically relating to such Purchaser to which such Purchaser's counsel reasonably objects. Notwithstanding any other provision of this Agreement, if any SEC Guidance sets forth a limitation of the number of Registrable Securities permitted to be registered on a particular Registration Statement as a secondary offering (and notwithstanding that the Company used reasonable best efforts to advocate with the Commission for the registration of all or a greater number of Registrable Securities), unless otherwise directed in writing by a Holder as to its Registrable Securities, the number of Registrable Securities to be registered on such Registration Statement will first be reduced by Registrable Securities not acquired pursuant to the Purchase Agreement (whether pursuant to registration rights or otherwise), and second by Registrable Securities represented by Shares (applied, in the case that some Shares may be registered, to the Holders on a pro rata basis based on the total number of unregistered Shares held by such Holders, subject to a determination by the Commission that certain Holders must be reduced first based on the number of Shares held by such Holders). In the event the Company amends the Initial Registration Statement or files a New Registration Statement, as the case may be, under clauses (i) or (ii) above, the Company will use its reasonable best efforts to file with the Commission, as promptly as allowed by Commission or SEC Guidance provided to the Company or to registrants of securities in general, one or more registration statements on Form S-3 or such other form available to register for resale those Registrable Securities that were not registered for resale on the Initial Registration Statement, as amended, or the New Registration Statement (the “Remainder Registration Statements”).

(b) The Company shall use its reasonable best efforts to cause each Registration Statement to be declared effective by the Commission as soon as practicable and, with respect to the Initial Registration Statement or the New Registration Statement, as applicable, no later than the Effectiveness Deadline (including filing with the Commission a request for acceleration of effectiveness in accordance with Rule 461 promulgated under the Securities Act), and shall use its reasonable best efforts to keep each Registration Statement continuously effective under the Securities Act for so long as the securities registered for resale thereunder retain their character as Registrable Securities (the “Effectiveness Period”). The Company shall request effectiveness of a Registration Statement as of 4:00 P.M. New York City time on a Trading Day. The Company shall promptly notify the Holders via e-mail of the effectiveness of a Registration Statement or any post-effective amendment thereto on the same Trading Day that the Company telephonically confirms effectiveness with the Commission, which date of confirmation shall initially be the date

requested for effectiveness of such Registration Statement. The Company shall, by 9:30 A.M. New York City time on the first Trading Day after the Effective Date, file a final Prospectus with the Commission, as required by Rule 424(b).

(c) Each Holder agrees to furnish to the Company a completed Selling Shareholder Questionnaire not more than five (5) Trading Days following the date of this Agreement. At least ten (10) Trading Days prior to the first anticipated filing date of a Registration Statement for any registration under this Agreement, the Company will notify each Holder of the information the Company requires from that Holder other than the information contained in the Selling Shareholder Questionnaire, if any, which shall be completed and delivered to the Company promptly upon request and, in any event, within three (3) Trading Days prior to the applicable anticipated filing date. Each Holder further agrees that it shall not be entitled to be named as a selling securityholder in the Registration Statement or use the Prospectus for offers and resales of Registrable Securities at any time, unless such Holder has returned to the Company a completed and signed Selling Shareholder Questionnaire and a response to any reasonable requests for further information as described in the previous sentence. If a Holder of Registrable Securities returns a Selling Shareholder Questionnaire or a request for further information, in either case, after its respective deadline, the Company shall use its reasonable best efforts to take such actions as are required to name such Holder as a selling security holder in the Registration Statement or any pre-effective or post-effective amendment thereto and to include (to the extent not theretofore included) in the Registration Statement the Registrable Securities identified in such late Selling Shareholder Questionnaire or request for further information. Each Holder acknowledges and agrees that the information in the Selling Shareholder Questionnaire or request for further information as described in this Section 2(d) will be used by the Company in the preparation of the Registration Statement and hereby consents to the inclusion of such information in the Registration Statement.

(d) In the event that Form S-3 is not available for the registration of the resale of Registrable Securities hereunder, the Company shall (i) register the resale of the Registrable Securities on another appropriate form reasonably acceptable to the Holders and (ii) undertake to register the Registrable Securities on Form S-3 promptly after such form is available, *provided* that the Company shall maintain the effectiveness of the Registration Statement then in effect until such time as a Registration Statement on Form S-3 covering the Registrable Securities has been declared effective by the Commission.

### 3. Registration Procedures

In connection with the Company's registration obligations hereunder, the Company shall:

(a) Not less than five (5) Trading Days prior to the filing of each Registration Statement and not less than one (1) Trading Day prior to the filing of any related Prospectus or any amendment or supplement thereto (except for Annual Reports on Form 10-K, and Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and any similar or successor reports), (i) furnish to each Holder copies of such Registration Statement, Prospectus or amendment or supplement thereto, as proposed to be filed, which documents will be subject to the review of such Holder (it being acknowledged and agreed that if a Holder does not object to or comment on the aforementioned documents within such five (5) Trading Day or one (1) Trading Day period, as the case may be, then the Holder shall be deemed to have consented to and approved the use of such documents) and (ii) use reasonable best efforts to cause its officers and directors, counsel and independent registered public accountants to respond to such inquiries as shall be necessary, in the reasonable opinion of respective counsel to each Holder, to conduct a reasonable investigation within the meaning of the Securities Act. The Company shall not file any Registration Statement or amendment or supplement thereto in a form to which a Holder reasonably objects in good faith, provided that, the Company is notified of such objection in writing within the five (5) Trading Day or one (1) Trading Day period described above, as applicable.

(b) (i) Prepare and file with the Commission such amendments (including post-effective amendments) and supplements, to each Registration Statement and the Prospectus used in connection therewith as may be necessary to keep such Registration Statement continuously effective as to the applicable Registrable Securities for its Effectiveness Period; (ii) cause the related Prospectus to be amended or supplemented by any required Prospectus supplement (subject to the terms of this Agreement), and, as so supplemented or amended, to be filed pursuant to Rule 424; (iii) respond as promptly as reasonably possible to any comments received from the Commission with respect to each Registration Statement or any amendment thereto and, as promptly as reasonably possible, notify the Holders of such comments and provide the Holders true and complete copies of all correspondence from and to the Commission relating to such Registration Statement that pertains to the Holders as "Selling Stockholders" but not any comments

that would result in the disclosure to the Holders of material and non-public information concerning the Company; and (iv) comply with the provisions of the Securities Act and the Exchange Act with respect to the disposition of all Registrable Securities covered by a Registration Statement until such time as all of such Registrable Securities shall have been disposed of (subject to the terms of this Agreement) in accordance with the intended methods of disposition by the Holders thereof as set forth in such Registration Statement as so amended or in such Prospectus as so supplemented; *provided, however*, that each Purchaser shall be responsible for the delivery of the Prospectus to the Persons to whom such Purchaser sells any of the Shares (including in accordance with Rule 172 under the Securities Act), and each Purchaser agrees to dispose of Registrable Securities in compliance with the “Plan of Distribution” described in the Registration Statement and otherwise in compliance with applicable federal and state securities laws. In the case of amendments and supplements to a Registration Statement which are required to be filed pursuant to this Agreement (including pursuant to this Section 3(b)) by reason of the Company filing a report on Form 10-K, Form 10-Q or Form 8-K or any analogous report under the Exchange Act, the Company shall have incorporated such report by reference into such Registration Statement, if applicable, or shall file such amendments or supplements with the Commission on the same day on which the Exchange Act report which created the requirement for the Company to amend or supplement such Registration Statement was filed.

(c) Notify the Holders (which notice shall, pursuant to clauses (iii) through (vi) hereof, be accompanied by an instruction to suspend the use of the Prospectus until the requisite changes have been made) as promptly as reasonably possible (and, in the case of (i)(A) below, not less than one (1) Trading Day prior to such filing) and confirm such notice in writing no later than one (1) Trading Day following the day: (i)(A) when a Prospectus or any Prospectus supplement or post-effective amendment to a Registration Statement is proposed to be filed; (B) when the Commission notifies the Company whether there will be a “review” of such Registration Statement and whenever the Commission comments in writing on any Registration Statement (in which case the Company shall provide to each of the Holders true and complete copies of all comments that pertain to the Holders as a “Selling Stockholder” or to the “Plan of Distribution” and all written responses thereto, but not information that the Company believes would constitute material and non-public information); and (C) with respect to each Registration Statement or any post-effective amendment, when the same has become effective; (ii) of any request by the Commission or any other Federal or state governmental authority for amendments or supplements to a Registration Statement or Prospectus or for additional information that pertains to the Holders as “Selling Stockholders” or the “Plan of Distribution”; (iii) of the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of a Registration Statement covering any or all of the Registrable Securities or the initiation of any Proceedings for that purpose; (iv) of the receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Registrable Securities for sale in any jurisdiction, or the initiation or threatening of any Proceeding for such purpose; (v) of the occurrence of any event or passage of time that makes the financial statements included or incorporated by reference in a Registration Statement ineligible for inclusion or incorporation by reference therein or any statement made in such Registration Statement or Prospectus or any document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires any revisions to such Registration Statement, Prospectus or other documents so that, in the case of such Registration Statement or the Prospectus, as the case may be, it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus, form of prospectus or supplement thereto, in light of the circumstances under which they were made), not misleading and (vi) of the occurrence or existence of any pending corporate development with respect to the Company that the Company reasonably believes may be material and that, in the good faith determination of the Board of Directors, would be materially detrimental to the Company to allow continued availability of a Registration Statement or Prospectus, *provided* that, any and all such information shall remain confidential to each Holder until such information otherwise becomes public, unless disclosure by a Holder is required by law; and *provided, further*, that notwithstanding each Holder’s agreement to keep such information confidential, each such Holder makes no acknowledgement that any such information is material, non-public information.

(d) Use reasonable best efforts to avoid the issuance of, or, if issued, obtain the withdrawal of (i) any order suspending the effectiveness of a Registration Statement, or (ii) any suspension of the qualification (or exemption from qualification) of any of the Registrable Securities for sale in any jurisdiction, as soon as possible.

(e) Furnish to such Holder, without charge, at least one conformed copy of each Registration Statement and each amendment thereto and all exhibits to the extent requested by such Person (including those previously furnished or incorporated by reference) promptly after the filing of such documents with the Commission;

provided, that the Company shall have no obligation to provide any document pursuant to this clause that is available on the Commission's EDGAR system.

(f) Promptly deliver to the Holders, without charge, as many copies of each Prospectus or Prospectuses (including each form of prospectus) and each amendment or supplement thereto as such Person may reasonably request. The Company hereby consents to the use of such Prospectus and each amendment or supplement thereto by each of the selling Holders in connection with the offering and sale of the Registrable Securities covered by such Prospectus and any amendment or supplement thereto.

(g) Prior to any resale of Registrable Securities by a Holder, use its reasonable best efforts to register or qualify or cooperate with the selling Holders in connection with the registration or qualification (or exemption from the registration or qualification) of such Registrable Securities for the resale by the Holder under the securities or Blue Sky laws of such jurisdictions within the United States as any Holder reasonably requests in writing, to keep each registration or qualification (or exemption therefrom) effective during the Effectiveness Period and to do any and all other acts or things reasonably necessary or advisable to enable the disposition in such jurisdictions of the Registrable Securities covered by each Registration Statement; provided, that the Company shall not be required to qualify generally to do business in any jurisdiction where it is not then so qualified, subject the Company to any material tax in any such jurisdiction where it is not then so subject or file a general consent to service of process in any such jurisdiction.

(h) Cooperate with such Holder to facilitate the timely preparation and delivery of certificates or book entry statements, as applicable, representing Registrable Securities to be delivered to a transferee pursuant to the Registration Statement, which certificates or statements shall be free, to the extent permitted by the Purchase Agreement and under law, of all restrictive legends, and to enable such Registrable Securities to be in such denominations and registered in such names as any such Holders may request.

(i) Following the occurrence of any event contemplated by Section 3(c), as promptly as reasonably possible (taking into account the Company's good faith assessment of any adverse consequences to the Company and its shareholders of the premature disclosure of such event), prepare a supplement or amendment, including a post-effective amendment, to the affected Registration Statements or a supplement to the related Prospectus or any document incorporated or deemed to be incorporated therein by reference, and file any other required document so that, as thereafter delivered, no Registration Statement nor any Prospectus will contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus, form of prospectus or supplement thereto, in light of the circumstances under which they were made), not misleading. If the Company notifies the Holders in accordance with clauses (iii) through (vi) of Section 3(c) above to suspend the use of any Prospectus until the requisite changes to such Prospectus have been made, then the Holders shall suspend use of such Prospectus. The Company will use its reasonable best efforts to ensure that the use of the Prospectus may be resumed as promptly as is practicable. The Company shall be entitled to exercise its right under this Section 3(i) to suspend the availability of a Registration Statement and Prospectus. For the avoidance of doubt, any period of time for which the availability of a Registration Statement and Prospectus are suspended pursuant to Section 2(d) shall be disregarded when determining the time period allotted under this Section 3(i).

(j) The Company may require each selling Holder to furnish to the Company a certified statement as to (i) the number of Ordinary Shares or ADSs beneficially owned by such Holder and any Affiliate thereof, (ii) any Financial Industry Regulatory Authority ("FINRA") affiliations, (iii) any natural persons who have the power to vote or dispose of the Ordinary Shares or ADSs and (iv) any other information as may be requested by the Commission, FINRA or any state securities commission.

(k) The Company shall cooperate with any registered broker through which a Holder proposes to resell its Registrable Securities in effecting a filing with FINRA pursuant to FINRA Rule 5110 as requested by any such Holder and the Company shall pay the filing fee required for the first such filing within two (2) Business Days of the request therefor.

4. Registration Expenses. All fees and expenses incident to the Company's performance of or compliance with its obligations under this Agreement (excluding any underwriting discounts and selling commissions and all legal fees and expenses of legal counsel for any Holder) shall be borne by the Company whether or not any Registrable Securities are sold pursuant to a Registration Statement. The fees and expenses referred to in the foregoing sentence shall include, without limitation, (i) all registration and filing fees (including, without limitation, fees and expenses (A) with respect to filings required to be made with any Trading Market on which the ADSs are then listed for trading, (B) with respect to compliance with applicable state securities or Blue Sky laws (including, without limitation, fees and disbursements of counsel for the Company in connection with Blue Sky qualifications or exemptions of the

Registrable Securities and determination of the eligibility of the Registrable Securities for investment under the laws of such jurisdictions as requested by the Holders) and (C) if not previously paid by the Company in connection with Section 3(j) above, with respect to any filing that may be required to be made by any broker through which a Holder intends to make sales of Registrable Securities with FINRA pursuant to the FINRA Rule 5110, so long as the broker is receiving no more than a customary brokerage commission in connection with such sale, (ii) printing expenses (including, without limitation, expenses of printing certificates for Registrable Securities and of printing prospectuses if the printing of prospectuses is reasonably requested by the Holders of a majority of the Registrable Securities included in the Registration Statement), (iii) messenger, telephone and delivery expenses, (iv) fees and disbursements of counsel for the Company, (v) Securities Act liability insurance, if the Company so desires such insurance, and (vi) fees and expenses of all other Persons retained by the Company in connection with the consummation of the transactions contemplated by this Agreement. In addition, the Company shall be responsible for all of its internal expenses incurred in connection with the consummation of the transactions contemplated by this Agreement (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), the expense of any annual audit and the fees and expenses incurred in connection with the listing of the Registrable Securities on any securities exchange as required hereunder. In no event shall the Company be responsible for any underwriting, broker or similar fees or commissions of any Holder or, except to the extent provided for in the Transaction Documents, any legal fees or other costs of the Holders.

5. Indemnification.

(a) Indemnification by the Company. The Company shall, notwithstanding any termination of this Agreement, indemnify, defend and hold harmless each Holder, the officers, directors, agents, partners, members, managers, stockholders, Affiliates and employees of each of them, each Person who controls any such Holder (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) and the officers, directors, partners, members, managers, stockholders, agents and employees of each such controlling Person, to the fullest extent permitted by applicable law, from and against any and all losses, claims, damages, liabilities, costs (including, without limitation, reasonable costs of preparation and investigation and reasonable attorneys' fees) and expenses (collectively, "Losses"), as incurred, that arise out of or relate to (i) any untrue or alleged untrue statement of a material fact contained in any Registration Statement, any Prospectus or any form of prospectus or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus or form of prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading, or (ii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act or any state securities law or any rule or regulation thereunder, in connection with the performance of its obligations under this Agreement, except to the extent, but only to the extent, that (A) such untrue statements, alleged untrue statements, omissions or alleged omissions are based solely upon information regarding such Holder furnished in writing to the Company by such Holder expressly for use therein, or to the extent that such information relates to such Holder or such Holder's proposed method of distribution of Registrable Securities and was reviewed and approved in writing by such Holder expressly for use in the Registration Statement, such Prospectus or such form of Prospectus or in any amendment or supplement thereto (it being understood that each Holder has approved Annex A hereto for this purpose) or (B) in the case of an occurrence of an event of the type specified in Section 3(c)(iii)-(vi), related to the use by a Holder of an outdated or defective Prospectus after the Company has notified such Holder in writing that the Prospectus is outdated or defective and prior to the receipt by such Holder of the Advice contemplated and defined in Section 6(d) below, to the extent that following the receipt of the Advice the misstatement or omission giving rise to such Loss would have been corrected or (C) to the extent that any such Losses arise out of the Purchaser's (or any other indemnified Person's) failure to send or give a copy of the Prospectus or supplement (as then amended or supplemented), if required, pursuant to Rule 172 under the Securities Act (or any successor rule) to the Persons asserting an untrue statement or alleged untrue statement or alleged untrue statement or omission or alleged omission at or prior to the written confirmation of the sale of Registrable Securities to such Person if such statement or omission was corrected in such Prospectus or supplement. The Company shall notify the Holders promptly of the institution, threat or assertion of any Proceeding arising from or in connection with the transactions contemplated by this Agreement of which the Company is aware. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of an Indemnified Party (as defined in Section 5(c)) and shall survive the transfer of the Registrable Securities by the Holders.

(b) Indemnification by Holders. Each Holder shall, severally and not jointly, indemnify and hold harmless the Company, its directors, officers, agents and employees, each Person who controls the Company (within

the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, agents or employees of such controlling Persons, to the fullest extent permitted by applicable law, from and against all Losses, as incurred, arising out of or are based solely upon any untrue or alleged untrue statement of a material fact contained in any Registration Statement, any Prospectus, or any form of prospectus, or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus, or any form of prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading (i) to the extent that such untrue statements or omissions are based solely upon information regarding such Holder furnished in writing to the Company by such Holder expressly for use therein or (ii) to the extent that such information relates to such Holder or such Holder's proposed method of distribution of Registrable Securities and was reviewed and approved in writing by such Holder expressly for use in a Registration Statement (it being understood that the Holder has approved Annex A hereto for this purpose), such Prospectus or such form of Prospectus or in any amendment or supplement thereto or (iii) in the case of an occurrence of an event of the type specified in Section 3(c)(iii)-(vi), to the extent related to the use by such Holder of an outdated or defective Prospectus after the Company has notified such Holder in writing that the Prospectus is outdated or defective and prior to the receipt by such Holder of the Advice contemplated in Section 6(d). In no event shall the liability of any selling Holder hereunder be greater in amount than the dollar amount of the net proceeds received by such Holder upon the sale of the Registrable Securities giving rise to such indemnification obligation.

(c) Conduct of Indemnification Proceedings. If any Proceeding shall be brought or asserted against any Person entitled to indemnity hereunder (an "*Indemnified Party*"), such Indemnified Party shall promptly notify the Person from whom indemnity is sought (the "*Indemnifying Party*") in writing, and the Indemnifying Party shall have the right to assume the defense thereof, including the employment of counsel reasonably satisfactory to the Indemnified Party and the payment of all reasonable fees and expenses incurred in connection with defense thereof; *provided*, that the failure of any Indemnified Party to give such notice shall not relieve the Indemnifying Party of its obligations or liabilities pursuant to this Agreement, except (and only) to the extent that it shall be finally determined by a court of competent jurisdiction (which determination is not subject to appeal or further review) that such failure shall have materially and adversely prejudiced the Indemnifying Party.

An Indemnified Party shall have the right to employ separate counsel in any such Proceeding and to participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnified Party or Parties unless: (1) the Indemnifying Party has agreed in writing to pay such fees and expenses; (2) the Indemnifying Party shall have failed promptly to assume the defense of such Proceeding and to employ counsel reasonably satisfactory to such Indemnified Party in any such Proceeding; or (3) the named parties to any such Proceeding (including any impleaded parties) include both such Indemnified Party and the Indemnifying Party, and such Indemnified Party shall have been advised by counsel that a conflict of interest exists if the same counsel were to represent such Indemnified Party and the Indemnifying Party (in which case, if such Indemnified Party notifies the Indemnifying Party in writing that it elects to employ separate counsel at the expense of the Indemnifying Party, the Indemnifying Party shall not have the right to assume the defense thereof and such counsel shall be at the expense of the Indemnifying Party); *provided*, that the Indemnifying Party shall not be liable for the fees and expenses of more than one separate firm of attorneys at any time for all Indemnified Parties. The Indemnifying Party shall not be liable for any settlement of any such Proceeding effected without its written consent, which consent shall not be unreasonably withheld, delayed or conditioned. No Indemnifying Party shall, without the prior written consent of the Indemnified Party, effect any settlement of any pending Proceeding in respect of which any Indemnified Party is a party, unless such settlement includes an unconditional release of such Indemnified Party from all liability on claims that are the subject matter of such Proceeding.

Subject to the terms of this Agreement, all fees and expenses of the Indemnified Party (including reasonable fees and expenses to the extent incurred in connection with investigating or preparing to defend such Proceeding in a manner not inconsistent with this Section 5) shall be paid to the Indemnified Party, as incurred, within twenty (20) Trading Days of written notice thereof to the Indemnifying Party; *provided*, that the Indemnified Party shall promptly reimburse the Indemnifying Party for that portion of such fees and expenses applicable to such actions for which such Indemnified Party is finally judicially determined to not be entitled to indemnification hereunder). The failure to deliver written notice to the Indemnifying Party within a reasonable time of the commencement of any such

action shall not relieve such Indemnifying Party of any liability to the Indemnified Party under this Section 5, except to the extent that the Indemnifying Party is materially and adversely prejudiced in its ability to defend such action.

(d) Contribution. If a claim for indemnification under Section 5(a) or 5(b) is unavailable to an Indemnified Party or insufficient to hold an Indemnified Party harmless for any Losses, then each Indemnifying Party, in lieu of indemnifying such Indemnified Party, shall contribute to the amount paid or payable by such Indemnified Party as a result of such Losses, in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party and Indemnified Party in connection with the actions, statements or omissions that resulted in such Losses as well as any other relevant equitable considerations. The relative fault of such Indemnifying Party and Indemnified Party shall be determined by reference to, among other things, whether any action in question, including any untrue or alleged untrue statement of a material fact or omission or alleged omission of a material fact, has been taken or made by, or relates to information supplied by, such Indemnifying Party or Indemnified Party, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such action, statement or omission. The amount paid or payable by a party as a result of any Losses shall be deemed to include, subject to the limitations set forth in this Agreement, any reasonable attorneys' or other reasonable fees or expenses incurred by such party in connection with any Proceeding to the extent such party would have been indemnified for such fees or expenses if the indemnification provided for in this Section 5 was available to such party in accordance with its terms.

The parties hereto agree that it would not be just and equitable if contribution pursuant to this Section 5(d) were determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to in the immediately preceding paragraph. Notwithstanding the provisions of this Section 5(d), (A) no Holder shall be required to contribute, in the aggregate, any amount in excess of the amount by which the net proceeds actually received by such Holder from the sale of the Registrable Securities subject to the Proceeding exceeds the amount of any damages that such Holder has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission and (B) **no contribution will be made under circumstances where the maker of such contribution would not have been required to indemnify the Indemnified Party under the fault standards set forth in this Section 5**. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation.

The indemnity and contribution agreements contained in this Section 5 are in addition to any liability that the Indemnifying Parties may have to the Indemnified Parties and are not in diminution or limitation of the indemnification provisions under the Purchase Agreement.

6. Miscellaneous.

(a) Remedies. In the event of a breach by the Company or by a Holder of any of their obligations under this Agreement, each Holder or the Company, as the case may be, in addition to being entitled to exercise all rights granted by law and under this Agreement, including recovery of damages, will be entitled to specific performance of its rights under this Agreement. The Company and each Holder agree that monetary damages would not provide adequate compensation for any losses incurred by reason of a breach by it of any of the provisions of this Agreement and hereby further agrees that, in the event of any action for specific performance in respect of such breach, it shall waive the defense that a remedy at law would be adequate.

(b) No Piggyback on Registrations; Prohibition on Filing Other Registration Statements. Except and to the extent specified in the Purchase Agreement, neither the Company nor any of its security holders (other than the Holders in such capacity pursuant hereto) may include securities of the Company in a Registration Statement other than the Registrable Securities and the Company shall not prior to the Effective Date enter into any agreement providing any such right to any of its security holders.

(c) Compliance. Each Holder covenants and agrees that it will comply with the prospectus delivery requirements of the Securities Act as applicable to it (unless an exemption therefrom is available) in connection with sales of Registrable Securities pursuant to the Registration Statement and shall sell the Registrable Securities only in accordance with a method of distribution described in the Registration Statement

(d) Discontinued Disposition. By its acquisition of Registrable Securities, each Holder agrees that, upon receipt of a notice from the Company of the occurrence of any event of the kind described in Section 3(c)(iii)-(vi), such Holder will forthwith discontinue disposition of such Registrable Securities under a Registration

Statement until it is advised in writing (the “Advice”) by the Company that the use of the applicable Prospectus (as it may have been supplemented or amended) may be resumed. The Company will use its reasonable best efforts to ensure that the use of the Prospectus may be resumed as promptly as is possible.

(e) No Inconsistent Agreements. Neither the Company nor any of its Subsidiaries has entered, as of the date hereof, nor shall the Company or any of its Subsidiaries, on or after the date hereof, enter into any agreement with respect to its securities, that would have the effect of impairing the rights granted to the Holders in this Agreement or otherwise conflicts with the provisions hereof.

(f) Amendments and Waivers. The provisions of this Agreement, including the provisions of this sentence, may not be amended, modified or supplemented, or waived unless the same shall be in writing and signed by the Company and Holders holding no less than a majority of the then outstanding Registrable Securities, provided that any party may give a waiver as to itself. Notwithstanding the foregoing, a waiver or consent to depart from the provisions hereof with respect to a matter that relates exclusively to the rights of Holders and that does not directly or indirectly affect the rights of other Holders may be given by Holders of all of the Registrable Securities to which such waiver or consent relates; *provided, however*, that the provisions of this sentence may not be amended, modified, or supplemented except in accordance with the provisions of the immediately preceding sentence.

(g) Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be delivered as set forth in the Purchase Agreement.

(h) Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the successors and permitted assigns of each of the parties and shall inure to the benefit of each Holder. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. The Company may not assign its rights (except by merger or in connection with another entity acquiring all or substantially all of the Company’s assets) or obligations hereunder without the prior written consent of all the Holders of the then outstanding Registrable Securities. Each Holder may assign its respective rights hereunder in the manner and to the Persons as permitted under the Purchase Agreement; provided in each case that (i) the Holder agrees in writing with the transferee or assignee to assign such rights and related obligations under this Agreement, and for the transferee or assignee to assume such obligations, and a copy of such agreement is furnished to the Company within a reasonable time after such assignment, (ii) the Company is, within a reasonable time after such transfer or assignment, furnished with written notice of the name and address of such transferee or assignee and the securities with respect to which such registration rights are being transferred or assigned, (iii) at or before the time the Company received the written notice contemplated by clause (ii) of this sentence, the transferee or assignee agrees in writing with the Company to be bound by all of the provisions contained herein and (iv) the transferee is an “accredited investor,” as that term is defined in Rule 501 of Regulation D.

(i) Execution and Counterparts. This Agreement may be executed in two or more counterparts, each of which when so executed shall be deemed to be an original and, all of which taken together shall constitute one and the same Agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by e-mail delivery of a “.pdf” format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such “.pdf” signature were the original thereof.

(j) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be determined in accordance with the provisions of the Purchase Agreement.

(k) Cumulative Remedies. The remedies provided herein are cumulative and not exclusive of any other remedies provided by law.

(l) Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their good faith reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.



(m) Headings. The headings in this Agreement are for convenience only and shall not limit or otherwise affect the meaning hereof.

(n) Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under this Agreement are several and not joint with the obligations of any other Purchaser hereunder, and no Purchaser shall be responsible in any way for the performance of the obligations of any other Purchaser hereunder. The decision of each Purchaser to purchase the Securities pursuant to the Transaction Documents has been made independently of any other Purchaser. Nothing contained herein or in any other agreement or document delivered at any closing, and no action taken by any Purchaser pursuant hereto or thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert with respect to such obligations or the transactions contemplated by this Agreement. Each Purchaser acknowledges that no other Purchaser has acted as agent for such Purchaser in connection with making its investment hereunder and that no Purchaser will be acting as agent of such Purchaser in connection with monitoring its investment in the Securities or enforcing its rights under the Transaction Documents. Each Purchaser shall be entitled to protect and enforce its rights, including, without limitation, the rights arising out of this Agreement, and it shall not be necessary for any other Purchaser to be joined as an additional party in any Proceeding for such purpose. The Company acknowledges that each of the Purchasers has been provided with the same Registration Rights Agreement for the purpose of closing a transaction with multiple Purchasers and not because it was required or requested to do so by any Purchaser.

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IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

AVADEL PHARMACEUTICALS PLC

By: /s/ Gregory J. Divis

Name: Gregory J. Divis

Title: Chief Executive Officer

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IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

INVESTOR:

KVP Capital, LP

By: /s/ Caley Castelein  
Name: Caley Castelein  
Title: Managing Director

ADDRESS FOR NOTICE

c/o:

Street: \_\_\_\_\_

City/State/Zip: \_

Attention:

Tel:

Fax:

Email:

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

INVESTOR:

RTW Master Fund, Ltd.

By: /s/ Roderick Wong  
Name: Roderick Wong  
Title: Director

ADDRESS FOR NOTICE

c/o:

Street: \_\_\_\_\_

City/State/Zip: \_

Attention:

Tel:

Fax:

Email:

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

INVESTOR:

RTW Venture Fund Limited

By: /s/ Roderick Wong

Name: Roderick Wong

Title: Managing Member of the General Partner of the Investment Manager

ADDRESS FOR NOTICE

c/o:

Street: \_\_\_\_\_

City/State/Zip: \_

Attention:

Tel:

Fax:

Email:

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

INVESTOR:

RTW Innovation Master Fund, Ltd.

By: /s/ Roderick Wong  
Name: Roderick Wong  
Title: Director

ADDRESS FOR NOTICE

c/o:

Street: \_\_\_\_\_

City/State/Zip: \_

Attention:

Tel:

Fax:

Email:

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

INVESTOR:

Acuta Capital Fund, LP

By: /s/ Manfred Yu  
Name: Manfred Yu  
Title: Chief Operating Officer of the General Partner

ADDRESS FOR NOTICE

c/o:

Street: \_\_\_\_\_

City/State/Zip: \_

Attention:

Tel:

Fax:

Email:

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

INVESTOR:

Acuta Opportunity Fund, LP

By: /s/ Manfred Yu

Name: Manfred Yu

Title: Chief Operating Officer of the General Partner

ADDRESS FOR NOTICE

c/o:

Street: \_\_\_\_\_

City/State/Zip: \_

Attention:

Tel:

Fax:

Email:

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

INVESTOR:

Avoro Life Sciences Fund LLC

By: /s/ Behzad Aghazadeh

Name: Behzad Aghazadeh

Title: Managing Partner

ADDRESS FOR NOTICE

c/o:

Street: \_\_\_\_\_

City/State/Zip: \_

Attention:

Tel:

Fax:

Email:

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

INVESTOR:

Venrock healthcare capital partners iii, l.p.

By: VHCP Management III, LLC

Its: General Partner

Vhcp co-investment holdings iii, llc

By: VHCP Management III, LLC

Its: Manager

By: /s/ David L Stepp

Name: David L. Stepp

Title: Authorized Signatory

ADDRESS FOR NOTICE

Street: \_\_\_\_\_

City/State/Zip: \_

Attention:

Tel:

Fax:

Email:

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

INVESTOR:

Vivo Opportunity Fund, L.P.

By: /s/ Vivo Opportunity, LLC, General Partner

By: Albert Cha

Name: Albert Cha

Title: Managing Partner

ADDRESS FOR NOTICE

c/o:

Street: \_\_\_\_\_

City/State/Zip: \_

Attention:

Tel:

Fax:

Email:

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

INVESTOR:

Vivo Capital Fund IX, L.P.

By: /s/ Vivo Capital IX, LLC, General Partner

By: Albert Cha

Name: Albert Cha

Title: Managing Partner

ADDRESS FOR NOTICE

c/o:

Street: \_\_\_\_\_

City/State/Zip: \_

Attention:

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Annex A

PLAN OF DISTRIBUTION

We are registering the American Depositary Shares, or ADSs, which we refer to herein as Shares, issued to the selling stockholders to permit the resale of these Shares by the holders of the Shares from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the Shares. We will, or will procure to, bear all fees and expenses incident to our obligation to register the Shares.

The selling stockholders may sell all or a portion of the Shares beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the Shares are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The Shares may be sold on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market or in transactions otherwise than on these exchanges or systems or in the over-the-counter market and in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;



- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as amended, or the Securities Act, as permitted by that rule, or Section 4(a)(1) under the Securities Act, if available, rather than under this prospectus, provided that they meet the criteria and conform to the requirements of those provisions.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. If the selling stockholders effect such transactions by selling Shares to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the Shares for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2121.01.

In connection with sales of the Shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the Shares in the course of hedging in positions they assume. The selling stockholders may also sell Shares short and if such short sale shall take place after the date that this Registration Statement is declared effective by the Commission, the selling stockholders may deliver Shares covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge Shares to broker-dealers that in turn may sell such shares, to the extent permitted by applicable law. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). Notwithstanding the foregoing, the selling stockholders have been advised that they may not use shares registered on this registration statement to cover short sales of our ADSs made prior to the date the registration statement, of which this prospectus forms a part, has been declared effective by the SEC.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the Shares owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the Shares from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the Shares in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer or agents participating in the distribution of the Shares may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Selling Stockholders who are "underwriters" within the meaning of Section 2(11) of the Securities Act will be subject to the applicable prospectus delivery requirements of the Securities Act including Rule 172 thereunder and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Each selling stockholder has informed the Company that it is not a registered broker-dealer and does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the Shares. Upon the Company being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of ADSs through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such the Shares were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In no event shall any broker-dealer receive fees, commissions and markups, which, in the aggregate, would exceed eight percent (8.0%).

Under the securities laws of some U.S. states, the Shares may be sold in such states only through registered or licensed brokers or dealers. In addition, in some U.S. states the Shares may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the Shares registered pursuant to the shelf registration statement, of which this prospectus forms a part.

Each selling stockholder and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the Shares by the selling stockholder and any other participating person. To the extent applicable, Regulation M may also restrict the ability of any person engaged in the distribution of the Shares to engage in market-making activities with respect to the Shares. All of the foregoing may affect the marketability of the Shares and the ability of any person or entity to engage in market-making activities with respect to the Shares.

We will pay all expenses of the registration of the Shares pursuant to the registration rights agreement, including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with state securities or “blue sky” laws; *provided, however*, that each selling stockholder will pay all underwriting discounts and selling commissions, if any and any related legal expenses incurred by it. We will indemnify the selling stockholders against certain liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreement, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholders specifically for use in this prospectus, in accordance with the related registration rights agreements, or we may be entitled to contribution.

Annex B

#### SELLING STOCKHOLDER NOTICE AND QUESTIONNAIRE

The undersigned holder of shares of the (i) Ordinary Shares, nominal value \$0.01, of Avadel Pharmaceuticals plc (the “Company”) and/or (ii) Series A Non-Voting Convertible Preferred Shares, nominal value \$0.01, of the Company issued pursuant to a certain Securities Purchase Agreement by and among the Company and the Purchasers named therein, dated as of \_\_\_\_\_, 2020 (the “Agreement”), understands that the Company intends to file with the Securities and Exchange Commission a registration statement on Form S-3 (the “Resale Registration Statement”) for the registration and the resale under Rule 415 of the Securities Act of 1933, as amended (the “Securities

Act”), of the Registrable Securities in accordance with the terms of the Agreement. All capitalized terms not otherwise defined herein shall have the meanings ascribed thereto in the Agreement.

In order to sell or otherwise dispose of any Registrable Securities pursuant to the Resale Registration Statement, a holder of Registrable Securities generally will be required to be named as a selling stockholder in the related prospectus or a supplement thereto (as so supplemented, the “*Prospectus*”), deliver the Prospectus to purchasers of Registrable Securities (including pursuant to Rule 172 under the Securities Act) and be bound by the provisions of the Agreement (including certain indemnification provisions, as described below). Holders must complete and deliver this Notice and Questionnaire in order to be named as selling stockholders in the Prospectus. **Holders of Registrable Securities who do not complete, execute and return this Notice and Questionnaire within three (3) Trading Days following the date of the Agreement (1) will not be named as selling stockholders in the Resale Registration Statement or the Prospectus and (2) may not use the Prospectus for resales of Registrable Securities.**

Certain legal consequences arise from being named as a selling stockholder in the Resale Registration Statement and the Prospectus. Holders of Registrable Securities are advised to consult their own securities law counsel regarding the consequences of being named or not named as a selling stockholder in the Resale Registration Statement and the Prospectus.

#### NOTICE

The undersigned holder (the “*Selling Stockholder*”) of Registrable Securities hereby gives notice to the Company of its intention to sell or otherwise dispose of Registrable Securities owned by it and listed below in Item (3), unless otherwise specified in Item (3), pursuant to the Resale Registration Statement. The undersigned, by signing and returning this Notice and Questionnaire, understands and agrees that it will be bound by the terms and conditions of this Notice and Questionnaire and the Agreement.

The undersigned hereby provides the following information to the Company and represents and warrants that such information is accurate and complete:

#### QUESTIONNAIRE

**1. Name.**

(a) Full Legal Name of Selling Stockholder:

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(b) Full Legal Name of Registered Holder (if not the same as (a) above) through which Registrable Securities Listed in Item 3 below are held:

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(c) Full Legal Name of Natural Control Person (which means a natural person who directly or indirectly alone or with others has power to vote or dispose of the securities covered by the questionnaire):

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**2. Address for Notices to Selling Stockholder:**

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Telephone:

Fax:

Contact Person:

E-mail address of Contact Person: \_\_\_\_\_

**3. Beneficial Ownership of Registrable Securities Issuable Pursuant to the Purchase Agreement:**

(a) Type and Number of Registrable Securities beneficially owned and issued pursuant to the Agreement:

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(b) Number of American Depositary Shares to be registered pursuant to this Notice for resale:

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**4. Broker-Dealer Status:**

(a) Are you a broker-dealer?

Yes No

(b) If “yes” to Section 4(a), did you receive your Registrable Securities as compensation for investment banking services to the Company?

Yes No

Note: If no, the Commission’s staff has indicated that you should be identified as an underwriter in the Registration Statement.

(c) Are you an affiliate of a broker-dealer?

Yes No

Note: If yes, provide a narrative explanation below:

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(c) If you are an affiliate of a broker-dealer, do you certify that you bought the Registrable Securities in the ordinary course of business, and at the time of the purchase of the Registrable Securities to be resold, you had no agreements or understandings, directly or indirectly, with any person to distribute the Registrable Securities?

Yes No

Note: If no, the Commission's staff has indicated that you should be identified as an underwriter in the Registration Statement.

**5. Beneficial Ownership of Other Securities of the Company Owned by the Selling Stockholder.**

*Except as set forth below in this Item 5, the undersigned is not the beneficial or registered owner of any securities of the Company other than the Registrable Securities listed above in Item 3.*

Type and amount of other securities beneficially owned:

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**6. Relationships with the Company:**

*Except as set forth below, neither the undersigned nor any of its affiliates, officers, directors or principal equity holders (owners of 5% or more of the equity securities of the undersigned) has held any position or office or has had any other material relationship with the Company (or its predecessors or affiliates) during the past three years.*

State any exceptions here:

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**7. Plan of Distribution:**

*The undersigned has reviewed the form of Plan of Distribution attached as Annex A to the Registration Rights Agreement, and hereby confirms that, except as set forth below, the information contained therein regarding the undersigned and its plan of distribution is correct and complete.*

State any exceptions here:

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The undersigned agrees to promptly notify the Company of any inaccuracies or changes in the information provided herein that may occur subsequent to the date hereof and prior to the effective date of any applicable Resale Registration Statement. All notices hereunder and pursuant to the Agreement shall be made in writing, by hand delivery, confirmed or facsimile transmission, first-class mail or air courier guaranteeing overnight delivery at the address set forth below. In the absence of any such notification, the Company shall be entitled to continue to rely on the accuracy of the information in this Notice and Questionnaire.

By signing below, the undersigned consents to the disclosure of the information contained herein in its answers to Items (1) through (7) above and the inclusion of such information in the Resale Registration Statement and the Prospectus. The undersigned understands that such information will be relied upon by the Company in connection with the preparation or amendment of any such Registration Statement and the Prospectus.

By signing below, the undersigned acknowledges that it understands its obligation to comply, and agrees that it will comply, with the provisions of the Exchange Act and the rules and regulations thereunder, particularly Regulation M in connection with any offering of Registrable Securities pursuant to the Resale Registration Statement. The undersigned also acknowledges that it understands that the answers to this Questionnaire are furnished for use in connection with Registration Statements filed pursuant to the Registration Rights Agreement and any amendments or supplements thereto filed with the Commission pursuant to the Securities Act.

The undersigned hereby acknowledges and is advised of the following Question 239.10 of the Securities Act Rules Compliance and Disclosure Interpretations regarding short selling:

*“An Issuer filed a Form S-3 registration statement for a secondary offering of common stock which is not yet effective. One of the selling stockholders wanted to do a short sale of common stock “against the box” and cover the short sale with registered shares after the effective date. The issuer was advised that the short sale could not be made before the registration statement become effective, because the shares underlying the short sale are deemed to be sold at the time such sale is made. There would, therefore, be a violation of Section 5 if the shares were effectively sold prior to the effective date.”*

By returning this Questionnaire, the undersigned will be deemed to be aware of the foregoing interpretation.

I confirm that, to the best of my knowledge and belief, the foregoing statements (including without limitation the answers to this Questionnaire) are correct.

IN WITNESS WHEREOF the undersigned, by authority duly given, has caused this Questionnaire to be executed and delivered either in person or by its duly authorized agent.

Dated:      Beneficial Owner:

By:

Name:

Title:



## List of Subsidiaries

Name	Jurisdiction
Avadel Pharmaceuticals plc (the Registrant):	Ireland
1) Avadel US Holdings, Inc. ( <i>f/k/a Flamel US Holdings, Inc.</i> )	United States (Delaware)
A. FSC Holding Company, LLC	United States (Delaware)
i. Avadel Pharmaceuticals (USA), Inc. ( <i>f/k/a FSC Laboratories, Inc.</i> )	United States (Delaware)
1. Avadel Pediatrics, Inc. ( <i>f/k/a FSC Pediatrics, Inc.</i> )	United States (Delaware)
ii. FSC Therapeutics, LLC	United States (Delaware)
B. Avadel Legacy Pharmaceuticals, LLC ( <i>f/k/a Éclat Pharmaceuticals LLC</i> )	United States (Delaware)
i. Avadel Generics, LLC ( <i>f/k/a Talec Pharma, Inc.</i> )	United States (Delaware)
C. Avadel Management Corporation	United States (Delaware)
D. Avadel Operations Company, Inc.	United States (Delaware)
E. Avadel Specialty Pharmaceuticals	United States (Delaware)
F. Avadel CNS Pharmaceuticals, LLC	United States (Delaware)
2) Avadel Ireland Ltd. ( <i>f/k/a Flamel Ireland Ltd.</i> )	Ireland
3) Avadel Investment Company, Ltd.	Cayman Islands
4) Avadel France Holding SAS	France
A. Avadel Research SAS	France
5) Avadel Finance Ireland Designated Activity Company	Ireland
A. Avadel Finance Cayman Ltd.	Cayman Islands

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No.'s 333-213154, 333-212585, 333-177591 and 333-219016 on Form S-8 and 333-183961 and 333-236258 on Form S-3 of our reports dated March 16, 2020, relating to the consolidated financial statements of Avadel Pharmaceuticals plc (the "Company") and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K of Avadel Pharmaceuticals plc for the year ended December 31, 2019.

/s/ Deloitte and Touche LLP  
St. Louis, Missouri  
March 16, 2020

**CERTIFICATION**

**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Gregory J. Divis, certify that:

1. I have reviewed this Annual Report on Form 10-K of Avadel Pharmaceuticals plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2020

/s/ Gregory J. Divis

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Gregory J. Divis

Chief Executive Officer

**CERTIFICATION**

**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Thomas S. McHugh, certify that:

1. I have reviewed this Annual Report on Form 10-K of Avadel Pharmaceuticals plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2020

/s/ Thomas S. McHugh

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Thomas S. McHugh

Senior Vice President and Chief Financial Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of Avadel Pharmaceuticals plc (the “Company”) on Form 10-K for the period ending December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Gregory J. Divis, Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. §1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Gregory J. Divis

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Gregory J. Divis

Chief Executive Officer

Avadel Pharmaceuticals plc

March 16, 2020

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of Avadel Pharmaceuticals plc (the “Company”) on Form 10-K for the period ending December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Thomas S. McHugh, Senior Vice President and Chief Financial Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Thomas S. McHugh

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Thomas S. McHugh

Senior Vice President and Chief Financial Officer

Avadel Pharmaceuticals plc

March 16, 2020