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, 2018

Commission file number: 000-28508

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland	**98-1341933**
State or other jurisdiction of incorporation or organization	**(I.R.S. Employer Identification No.)**
Block 10-1, Blanchardstown Corporate Park Ballycoolin Dublin 15, Ireland	**Not Applicable**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: +011-1-485-1200

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

American Depositary Shares* Ordinary Shares**	**NASDAQ Stock Market LLC (NASDAQ Global Market)**
Title of each class	**Name of exchange on which registered**

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

** Nominal value $0.01 per share. Not for trading, but only in connection with the listing of American Depositary Shares.

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 and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 $221,263,931 based on the closing sale price of the registrant's American Depositary Shares as reported by the Nasdaq Global Market on June 29, 2018. Such market value excludes 650,118 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 13, 2019 was 37,355,511.

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, 2018, 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 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements relate to our future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects, or other events. In some cases, forward-looking statements can be identified by the use of words such as "will," "may," "believe," "expect," "anticipate," "estimate," "project" and similar expressions, and the negatives thereof.

Our forward-looking statements are based on estimates and assumptions that are made within the bounds of our knowledge of our business and operations and that we consider reasonable. However, our business and operations are subject to significant risks and as a result there can be no assurance that actual results of our research, development and commercialization activities and the results of our business and operations will not differ materially from the results contemplated in such forward-looking statements. Factors that could cause actual results to differ from expectations in our forward-looking statements include, among others, those specified in "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, including:

(a) risks relating to our 2018 net loss and recent restructuring plan, including risks relating to the following:

- our ability to fully pursue our business strategy is limited due to a decrease in our available liquid assets;
- our recent restructuring plan may not be as effective as we anticipated and may have unintended negative impacts;
- further restructuring actions, if needed, may require third-party consents that may not be granted;
- the Chapter 11 bankruptcy filing by our subsidiary Avadel Specialty Pharmaceuticals LLC ("Specialty Pharma") may have unexpected adverse results; and
- a management-directed audit of the development program for our FT218 sodium oxybate product could result in changes that increase the cost of the program and further delay its completion; and

(b) risks relating to the following:

- our three products Bloxiverz®,Vazculep® and Akovaz®, which are not patent protected, and have a small number of customers for such products, produce a majority of our revenues, and such products could face further competition resulting in a loss of market share and/or forcing us to further reduce our prices for those products;
- we could fail to develop our current "unapproved marketed drug" (UMD) product candidate or future potential UMD product candidates, or competitors could develop such products and apply for FDA approval of such products before us;
- we could experience failure or delay in completing the Phase 3 clinical trial for our FT218 product, and if the FDA ultimately approves such product, the approval may not include any period of market exclusivity;
- Servicing our $143.75 million Exchangeable Senior Notes due 2023 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" event described in the indenture governing the 2023 Notes;
- our products may not reach the commercial market or gain market acceptance;
- we must invest substantial sums in research and development in order to remain competitive;
- we depend on one or a limited number of providers to develop certain of our products and drug delivery technologies, to manufacture certain of our products and to provide certain raw materials used in our products;
- our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do;
- we face challenges in protecting intellectual property underlying our products and drug delivery technologies; and
- we depend on key personnel to execute our business plan.

Forward-looking statements speak only as of the date they are made and are not guarantees of future performance. Accordingly, you should not place undue reliance on forward-looking statements. We do not undertake any obligation to publicly update or revise the forward-looking statements contained in this Annual Report.

PART I

Item 1. Business.

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

General Overview

Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel," the "Company," "we," "our," or "us") is a branded specialty pharmaceutical company. Our primarily focus is 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 excessive daytime sleepiness (EDS) and cataplexy. In addition, we market three sterile injectable drugs used in the hospital setting which were developed under our "unapproved marketed drug" (UMD) program. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit www.avadel.com..

Avadel is developing FT218, an investigational once-nightly formulation of sodium oxybate based on its propriety Micropump® drug delivery technology, for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. FT218 is currently being evaluated in a Phase 3 clinical trial called REST-ON. In addition, Avadel is developing a fourth UMD product, an as-yet undisclosed sterile injectable product intended for the hospital market.

Our current marketed products consist of:

- *Akovaz*® (ephedrine sulfate injection, USP), 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.

- *Bloxiverz*® (neostigmine methylsulfate injection), a cholinesterase inhibitor, is indicated for the reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery.

- *Vazculep*® (phenylephrine hydrochloride injection), an alpha-1 adrenergic receptor agonist indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

  Each of our *Akovaz*, *Bloxiverz* and *Vazculep* products is used primarily in the hospital setting and was developed under our UMD program.

- *Noctiva*™, a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. Due to disappointing results after a substantial investment of resources after *Noctiva's* commercial launch in March 2018, Specialty Pharma, the Avadel subsidiary responsible for the marketing and sale of *Noctiva*, made a voluntary filing for Chapter 11 bankruptcy protection on February 6, 2019. Although Specialty Pharma currently continues its marketing and sales efforts for this product, Avadel anticipates that Specialty Pharma will discontinue all activities with respect to *Noctiva* during 2019 as a result of the bankruptcy.

Corporate Information

The Company was incorporated on December 1, 2015 as an Irish private limited company, and re-registered as an Irish public limited company, or plc, on November 21, 2016. Our principal place of business is located at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15, Ireland. Avadel's phone number is 011-353-1-485-1200. Our website is www.avadel.com, where we make available free of charge our reports (and any amendments thereto) on Forms 10-K, 10-Q and 8-K as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission ("SEC"). These filings are also available to the public at www.sec.gov.

The Company is the successor to Flamel Technologies S.A., a French *société anonyme* ("Flamel"), as the result of the France-to-Ireland redomestication merger of Flamel with and into the Company completed on December 31, 2016 (the "Merger"). In the Merger, we changed our company name to Avadel Pharmaceuticals plc and our jurisdiction of organization to Ireland; we assumed all the assets and liabilities of Flamel; and we issued one Avadel ordinary share (either directly or in the form of an American Depositary Share (ADS)) in exchange for each formerly outstanding share of Flamel, all of which were canceled. Thus, an Avadel ordinary share held (either directly or represented by an ADS) immediately after the Merger continued to represent the same proportional interest in our equity owned by the holder of a share of Flamel immediately prior to the Merger. References in this Annual Report on Form 10-K 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. Additional details about the Merger are set forth below in this Item 1 under the caption " - The Reincorporation Merger."

The Company currently has 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 as noted above), (ii) Avadel Legacy Pharmaceuticals, LLC, (iii) Avadel Management Corporation, (iv) FSC Holding Company and (v) Avadel Operations Company, Inc. 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 which, Since December 16, 2014, has been the owner of substantially all of Avadel's intellectual property. 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 the Company's subsidiaries can be found in Exhibit 21.1 to this Annual Report on Form 10-K.

Recent Developments

Management Changes. In December 2018 and in January 2019, Avadel announced changes to its Board of Directors ("Board") and Management team. In December 2018, (a) Avadel appointed Kevin Kotler, founder and portfolio manager of Broadfin Capital, LLC, and Eric Ende, President of Ende BioMedical Consulting Group to the Company's Board, (b) Michael S. Anderson resigned as chief executive officer and member of the Board of Avadel, (c) the Board named Gregory J. Divis, formerly the Company's chief operating officer, as interim chief executive officer, (d) the Honorable Craig Stapleton stepped down as chairman of the Board but continues as a member of the Board, and (e) Geoffrey M. Glass, President of Clear Sciences, LLC, a current member of the Avadel Board, was named chairman of the Board.

Corporate Restructuring. In February 2019, Avadel announced a corporate restructuring in order to focus efforts and resources on the clinical development of FT218. In conjunction with the restructuring, Avadel will reduce its workforce by more than 50%, and Specialty Pharma made a voluntary filing for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code on February 6, 2019. As noted above, Specialty Pharma is a special-purpose entity and wholly-owned subsidiary responsible solely for the sales, marketing and distribution of *Noctiva*. These restructuring actions were taken to exit *Noctiva*™ quickly and efficiently, and are not expected to materially impact any other aspect of the Company's business, including the ability to operate its sterile injectables hospital business, complete the FT218 Phase 3 clinical trial, and complete development of the Company's fourth UMD product. The Company estimates that it will incur approximately $10 to $15 million of one-time pre-tax charges for severance and other costs related to the restructuring. See *Note 23: Subsequent Events* in the accompanying notes to the consolidated financial statements for additional information.

Business Strategies

Our primary business strategy is to 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 excessive daytime sleepiness (EDS) and cataplexy. In addition, we will continue to maximize our current approved hospital products portfolio, including obtaining FDA approval for and the commercialization of our fourth UMD product. Additionally, we will continue to evaluate opportunities to expand our product portfolio. These strategies are described below in greater detail.

FT218 (Micropump® sodium oxybate): FT218 (Micropump® sodium oxybate): Avadel is developing a product that uses our Micropump® drug-delivery technology for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. Avadel currently refers to this product as FT218. FT218 is a Micropump®-based formulation of sodium oxybate. Sodium oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid. Sodium oxybate has been described as a therapeutic agent with high medical value. Sodium oxybate is approved in Europe and the United States as a twice nightly formulation indicated for the treatment of EDS and cataplexy in patients with narcolepsy.

In preparation for a clinical trial of FT218, Avadel reached an agreement with the FDA for the design and planned analysis of our pivotal Phase 3 study, Rest-On through a Special Protocol Assessment ("SPA"). A SPA is an acknowledgment by the FDA that the design and planned analysis of a pivotal clinical trial adequately addresses the objectives necessary to support a regulatory submission. Pursuant to the SPA, in December 2016, Avadel initiated patient enrollment and dosing for the Rest-On clinical trial 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 study is a randomized, double-blind, placebo-controlled study of 264 patients being conducted in 45 to 55 clinical sites in the U.S., Canada, Western Europe and Australia. Avadel believes that, if successful, this study could demonstrate improved efficacy, safety and patient satisfaction over the current primary product serving this market, which is a twice nightly sodium oxybate formulation, which the marketer estimates will generate revenues of approximately $1.4 billion in 2018.

To date, due in part to narcolepsy being a rare disease with a small patient population with no significant geographic concentration, we have not completed patient enrollment for the FT218 clinical trial, nor have we announced a projected completion date for this clinical trial. Recently, we have engaged a third-party pharmaceutical consulting firm to assist us in evaluating our clinical development program for FT218 with the goal of ensuring a approvable and commercially viable FDA submission. This evaluation is currently under way, and while the results are not known at this time, they could cause us to modify our development plan with respect to FT218 in ways that materially increase the ultimate cost of development, further delay its completion or identify presently unknown risks with the product.

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 as the only once-nightly formulation. However, 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.

Development of Micropump®-Based Products

Avadel's versatile Micropump® drug delivery technology presents product development opportunities, 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 ("NCEs"). FT218 is formulated using this technology. If approved by the FDA, this product will be commercialized either by Avadel and/or by partners via licensing/distribution agreements.

Unapproved Marketed Drug ("UMD") Products

In 2006, the U.S. Food and Drug Administration (FDA) issued its Marketed Unapproved Drugs - Compliance Policy Guide with the intention to incentivize pharmaceutical companies to pursue approvals for pharmaceutical products, many of which pre-date the establishment of the FDA. Although these products are not protected by patents or similar intellectual property, the FDA's Compliance Policy Guide dictates that should FDA approve a new drug application (NDA) for any such products via a 505(b)(2) process, the FDA will remove competing unapproved manufacturers until a generic application is approved. Avadel believes that over a thousand unapproved drugs are marketed in the United States today and, while many of these products are outdated therapies, we strategically evaluate those UMD products that are more commonly used as candidates for possible future FDA approval and marketing under our UMD program.

To date, Avadel has received FDA approvals for three UMD products which we currently market under the brand names *Bloxiverz*® (neostigmine methylsulfate injection), *Vazculep*® (phenylephrine hydrochloride injection) and *Akovaz*® (ephedrine sulfate injection), each as more particularly described below.

- ***Bloxiverz*® (neostigmine methylsulfate injection),** Bloxiverz's NDA was filed on July 31, 2012. Bloxiverz was approved by the FDA on May 31, 2013 and was launched in July 2013. Bloxiverz is a drug used intravenously in the operating room for the reversal of 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 the most frequently used products for the reversal of the effects of other agents used for neuromuscular blocks. There are approximately 2.5 million vials sold annually in the U.S. In the future, sales of Bloxiverz are dependent upon the competitive market dynamics between Avadel and four other competitors in addition to any additional competitors who may obtain FDA approval of an abbreviated new drug application (ANDA) for a generic form of *Bloxiverz*.

- ***Vazculep*® (phenylephrine hydrochloride injection)** On June 28, 2013, Avadel filed an NDA for Vazculep (phenylephrine hydrochloride injection). The product was approved by the FDA on June 27, 2014 and is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. Avadel started shipping Vazculep (in 1mL single use vials, and 5mL and 10mL pharmacy bulk package vials) to wholesalers in October 2014. There are approximately 7 million vials sold annually in the U.S. Vazculep is the only FDA-approved version of phenylephrine hydrochloride to be available in all three vial sizes. Avadel competes against one other manufacturer who commercializes the 1mL single-dose vial. The volume of sales of Vazculep is dependent upon the competitive landscape in the marketplace, and potential for new competitors that may receive generic approvals in the future.

- **Akovaz® (ephedrine sulfate injection)**. On June 30, 2015, Avadel announced that our third NDA was accepted by the FDA; the FDA subsequently approved *Akovaz* on April 29, 2016. On August 12, 2016, Avadel launched Akovaz, into a market of approximately 7.5 million vials annually in the U.S. Avadel was the first 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. Avadel began shipping the product to wholesalers in August 2016 in cartons of twenty-five 50 mg/mL 1mL single use vials. During 2016 Akovaz was the only FDA approved version of ephedrine sulfate being commercially sold in the U.S. To date, there are three other approved manufacturers of ephedrine sulfate with whom Avadel competes. The volume of sales of Akovaz is dependent upon the competitive landscape in the marketplace, and potential for new competitors that may receive generic approvals in the future.

Additional UMD Products. Avadel is developing and intends to seek FDA approval of a NDA for UMD #4, a sterile injectable product used in the hospital setting. The Company anticipates submitting an NDA during the first quarter of 2019 on UMD #4, which, if approved, could contribute revenues to Avadel starting in 2020. In addition, Avadel continues to monitor and evaluate other UMDs with large existing markets and limited competition for feasibility of possible future NDAs. Avadel believes its strategy to create opportunities to commercialize UMD products in markets with a limited number of competitors may have a limited number of opportunities given the lack of patent protection from competition. Avadel believes this shorter-term strategy may provide us with near term revenue growth and provide cash flows that can be used to fund R&D and inorganic initiatives for other products.

Proprietary Product Pipeline

The status of Avadel's proprietary product pipelines is detailed in the followings table:

Proprietary Product Pipeline

Platform / Strategy	Drug/Product	Indication	Stage
Micropump®	Sodium oxybate	EDS / Cataplexy	Phase 3 trial ongoing
UMD #4	Sterile Injectable - Drug Undisclosed	Undisclosed	Development ongoing

Competition and Market Opportunities

Competition

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. Avadel competes 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 Avadel's business partners. There can be no assurance that Avadel's 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 Avadel's 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, as consolidation has reduced Avadel's pool of potential partners and acquisition opportunities within the specialty pharmaceutical space.

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

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, 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, Avadel anticipates 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.

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 Specialty Pharma 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. Specialty pharmaceutical 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 specialty pharmaceutical 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.

FT218

Narcolepsy is an orphan disease affecting approximately 200,000 people in the U.S. With low prevalence and an even lower diagnosis rate, an estimated 50,000 patients diagnosed and on treatment, many patients' needs are not being met and there are limited proven treatment options, particularly for those suffering from cataplexy. Currently, the only approved treatment option to treat both EDS and cataplexy is a liquid formulation of sodium oxybate dosed twice per night. This treatment requires patients to wake up in the middle of the night to take a second dose of medication, interrupting sleep and potentially causing a number of other issues related to their quality of life.

Avadel believes that our once nightly formulation of sodium oxybate in FT218 may have the potential to provide an uninterrupted night's sleep to patients, may have an improved safety profile, fewer potential side effects due to a lower Cmax (*i.e.*, the maximum concentration a drug achieves in the body) compared to the current approved product, and may provide other additional benefits related to quality of life. The marketer of the twice-nightly sodium oxybate product reported revenue of $1.4 billion in calendar year 2018 for the product; the number of patients reported as actively on treatment was approximately 14,000. Following the completion of Avadel's REST-ON clinical trial, if FT218 is able to adequately demonstrate an improved safety profile over the current approved product, the potential to receive Orphan Drug Designation may provide development and commercial incentives for FT218, including eligibility for a seven-year period of market exclusivity in the U.S. as the only once-nightly formulation.

Avadel's Drug Delivery Technologies

Avadel owns 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).

Avadel believes that its Micropump® technology permits the development of differentiated product profiles (modified/controlled release formulations) under various dosage forms including capsules, tablets, sachets and liquid suspensions (LiquiTime®) for oral use. In addition, with Trigger Lock™ potentially addressing the issue of narcotic/opioid analgesics abuse. A brief discussion of each of Avadel's drug delivery technologies is set forth below.

Micropump® Technology. *Micropump*® is a microparticulate system that allows the development and marketing 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. Avadel's Micropump® technology permits either extended or delayed delivery of small molecule drugs via the oral route. Micropump® consists of a multiple-particulate system containing 5,000 to 10,000 microparticles/nanoparticles per capsule or tablet. The 200-500 microns diameter-sized microparticles are released in the stomach and pass into the small intestine, where each microparticle, operating as a miniature delivery system, releases the drug at an adjustable rate and over an extended period of time. The design of the Micropump® microparticles allows an extended release in the Gastro-Intestinal ("GI") tract allowing mean plasma residence times to be extended for up to 24 hours. The microparticles' design can be adapted to each drug's specific characteristics by modifying the coating composition and thickness as well as the composition of the

excipients encapsulated with the drug. The resultant formulations can potentially offer improved efficacy (by extending therapeutic coverage), reduced toxicity and/or side effects (by reducing Cmax or peak drug concentration in the plasma, or by reducing intra- and inter-patient variability), and improved patient compliance (by reducing frequency of administration). The platform is applicable to poorly soluble (< 0.01mg/L) as well as highly soluble (> 500g/L) and to low dose (*e.g.*, 4 mg) or high dose (*e.g.*, 1,000 mg) drugs, while providing excellent mouth feel and taste masking properties. Micropump® allows the achievement of extremely precise pharmacokinetic profiles extended (and/or delayed) release of single or combination of drugs, in a variety of formats (such as tablets, capsules, sachet, or liquids (LiquiTime®), while preserving the targeted release rate over the shelf-life of the product.

LiquiTime®. *LiquiTime*® allows development of modified/controlled release oral products in a liquid suspension formulation particularly suited to children or for patients having issues swallowing tablets or capsules. Avadel's LiquiTime® technology uses Micropump's competitive advantages to allow the development of products with modified/controlled release (*e.g.*, zero-order kinetics) in liquid suspension formulations. The LiquiTime® products are particularly suitable for dosing to children and for use by patients having issues swallowing tablets or capsules. LiquiTime® does not have the limitation of having to work solely with ionic drugs and therefore has applicability to a much broader range of drug molecules. As with Micropump®, LiquiTime® can be applied to the development of combination products. Avadel believes that LiquiTime®, designed to provide a controlled, extended release of oral liquids principally for pediatric and geriatric patients, will enable Avadel to develop improved, patent protected prescription products to serve an unmet medical need in these patient populations. Avadel believes that the increasing number of geriatric patients and the demand for convenient drug delivery options for children offer opportunities for the development of LiquiTime®-based formulations. Although Avadel owns this technology, the Company is currently not pursuing any commercial pharmaceutical drug development opportunities using this technology

Trigger Lock™. *Trigger Lock*™ allows development of abuse-resistant modified/controlled release formulations of narcotic/opioid analgesics and other drugs susceptible to abuse. Although Avadel owns this technology, the Company is currently not pursuing any commercial pharmaceutical drug development opportunities using this technology

Medusa™. *Medusa*™ allows the development of extended/modified release of injectable dosage formulations of drugs (*e.g.*, peptides, polypeptides, proteins, and small molecules). Although Avadel owns this technology, the Company is currently not pursuing any commercial pharmaceutical drug development opportunities using this technology

Proprietary Intellectual Property

Parts of Avadel's 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, Avadel seeks patent protection of our inventions and also relies upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and develop competitive positions.

Drug Delivery Technology Patents. Avadel's drug delivery technologies are the subject of certain patents, including: (i) for Micropump®, patents relating to an efficacious coating formulation for providing delayed and sustained release of an active ingredient with absorption limited to the upper part of intestinal tract (expiring in 2025 in the U.S. and 2022 in foreign jurisdictions); (ii) for LiquiTime®, patents relating to film-coated microcapsules and a method comprising orally administering such microcapsules to a patient (expiring in 2023); (iii) for Trigger Lock™, patents relating to a solid oral drug form with at least part of the active ingredient contained in microparticles with anticrushing characteristics to prevent misuse (expiring in 2027); and (iv) 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 Avadel 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. Avadel 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 Avadel's licensed or owned patents will provide sufficient protection from competitors. Any of Avadel's 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 Avadel's Business and Industry – If Avadel cannot adequately protect our intellectual property and proprietary information, Avadel 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

Avadel attempts to maintain multiple suppliers in order to mitigate the risk of shortfall and inability to supply market demand. Nevertheless, for most of our products Avadel relies 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 cGMP-compliant and FDA-audited contract manufacturing organization ("CMOs") pursuant to supply agreements. Avadel will continue to outsource to third-party CMOs, and has no present plans to acquire manufacturing facilities. Avadel believes this outsourcing policy is beneficial to us for products to be marketed in the United States.

In 2014, Avadel sold a manufacturing facility located in Pessac, France (near Bordeaux). Under the contract of sale, Avadel continues to use this facility to manufacture clinical supplies of FT218. To date, this facility has not been used to manufacture products commercialized directly by Avadel.

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 United States, 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 United States 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 all of Avadel's pharmaceutical partners as well as its own products will 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 current good manufacturing practices ("cGMP") which are promulgated by the FDA in the United States 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 United States 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 will 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 ("IMPD") which likewise must contain pharmaceutical, pre-clinical and, if existing, previous clinical information on the drug substance and product. An overall risk-benefit assessment critically analyzing the non-clinical and clinical data in relation to the potential risks and benefits of the proposed trial must also be included. The intended clinical trial must be submitted for authorization by the regulatory authority(ies) of each EU Member States in which the trial is intended to be conducted prior to its commencement. The trial must be conducted on the basis of the protocol as approved by an Ethics Committee(s) in each EU Member State (EU equivalent to IRBs) before the trial commences. Before submitting an application to the competent authority, the sponsor must register the trial in the EudraCT database where 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 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 that there is substantial evidence that the drug candidate is effective and that the drug is safe for its intended use, an 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). It 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. (Although PDUFA also provides for a six-month "priority review" process, Avadel does not anticipate it applying to any of its products or its partners' products.) There can be no assurance that 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 that 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. 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, or ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the "Reference Listed Drug," or "RLD". Generally, an ANDA must contain data and information showing that 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 fact that the product is 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. With regard to certain UMD products, Avadel intends to submit 505(b)(2) NDAs, relying solely on published scientific literature. Avadel does not plan to conduct additional preclinical studies or clinical trials for these 505(b)(2) NDAs; and, if it were required to do so, would review the continued value of the product.

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, either because the patent is invalid or unenforceable or because the patent, even if valid, is 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 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, 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 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 if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

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.

A product that is not an NCE may qualify for a three-year period of exclusivity, if the NDA contains clinical data that were 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 a product 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 product for that use, the FDA could not approve an ANDA or 505(b)(2) application for another product with that active moiety for that use. For example, Coreg CR received three-year exclusivity for the clinical trials that demonstrated the safety and efficacy of the new, controlled-release dosage form; that exclusivity, which has expired, blocked other controlled-release products.

For a brief discussion of potential marketing exclusivity that could be available under certain conditions with respect to Avadel's 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 United States Patent and Trademark Office, or PTO, 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 United States. 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 United States and abroad in order to assure compliance with the applicable cGMP regulations and other requirements. Facilities also are subject to inspections by other 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 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 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. 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 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 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 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 federal and state "sunshine" laws that require pharmaceutical manufacturers to make reports to states on pricing and marketing information. Several 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 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 United States 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 state and federal authorities.

Government Price Reporting. For those marketed medicines which are covered in the United States 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 foreign 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.

The Reincorporation Merger

The Company is the successor to Flamel Technologies S.A., a French *société anonyme* ("Flamel"), as the result of the Merger described above, in which Flamel merged with and into the Company at 11:59:59 p.m., Central Europe Time, on December 31, 2016 (the "Merger") pursuant to the agreement between Flamel and Avadel entitled Common Draft Terms of Cross-Border Merger dated as of June 29, 2016 (the "Merger Agreement"). Immediately prior to the Merger, the Company was a wholly owned subsidiary of Flamel. In accordance with the Merger Agreement, as a result of the Merger:

- Flamel ceased to exist as a separate entity and the Company continued as the surviving entity and assumed all of the assets and liabilities of Flamel.
- our authorized share capital is $5,500 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
    - all outstanding ordinary shares of Flamel, €0.122 nominal value per share, were canceled and exchanged on a one-for-one basis for newly issued ordinary shares of the Company, $0.01 nominal value per share. This change in nominal value of our outstanding shares resulted in our reclassifying $5,937 on our balance sheet from ordinary shares to additional paid-in capital
    - our Board of Directors is authorized to issue preferred shares on a non-pre-emptive basis, for a maximum period of five years, at which point such an authorization may be renewed by shareholders. The Board of Directors has discretion to dictate terms attached to the preferred shares, including voting, dividend, conversion rights, and priority relative to other classes of shares with respect to dividends and upon a liquidation.
- all outstanding American Depositary Shares (ADSs) representing ordinary shares of Flamel were canceled and exchanged on a one-for-one basis for ADSs representing ordinary shares of the Company.

Thus, the Merger changed the jurisdiction of our incorporation from France to Ireland, and an ordinary share of the Company held (either directly or represented by an ADS) immediately after the Merger continued to represent the same proportional interest in our equity owned by the holder of a share of Flamel immediately prior to the Merger.

References in this Annual Report on Form 10-K 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.

Prior to completion of the Merger, the Flamel ADSs were listed on the Nasdaq Global Market ("Nasdaq") under the trading symbol "FLML"; and immediately after the Merger the Company's ADSs were listed for and began trading on Nasdaq on January 3, 2017 under the trading symbol "AVDL."

Further details about the reincorporation, the Merger and the Merger Agreement are contained in our definitive proxy statement filed with the SEC on July 5, 2016.

Employees

As of December 31, 2018, we had approximately 144 employees, all of which were full-time. Following implementation of our restructuring plan which we announced on February 7, 2019, we expect the number of our employees will be reduced to approximately 50. Except for employees at our French subsidiaries, none of the Company's other employees is subject to a union or other collective bargaining agreement. Additionally, employees at our French subsidiaries (approximately 50 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. The Company believes 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 2018 Net Loss and Recent Restructuring Plan

Our net loss and use of cash from operating activities in 2018 may limit our ability to fully pursue our business strategy.

We reported a net loss of $95.3 million in 2018 and a net use of cash from operating activities of $82.7 million. As a result, our cash and marketable securities as of December 31, 2018 totaled $99.9 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 obtaining FDA approval for and the commercialization of our fourth UMD product. Additionally, we will continue to evaluate opportunities to expand our product portfolio. 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. See also the discussions elsewhere in these Risk Factors under the captions *"We may fail to effectively execute our business strategy" and "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 our American Depositary Shares (ADSs)."*

Our recent restructuring plan may not be as effective as we 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%. In conjunction with the restructuring plan, we also announced the voluntary Chapter 11 bankruptcy filing by our subsidiary, Specialty Pharma, which is responsible solely for the sales, marketing and distribution of the Company's Noctiva™ product for the treatment of nocturia (i.e., waking up two or more times during the night to urinate due to a condition called nocturnal polyuria). We implemented the restructuring plan in light of disappointing results from the commercial launch of Noctiva, and in order to focus the Company's resources on other product development activities, in particular the ongoing Phase 3 clinical trial of its FT218 product for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from Narcolepsy. The restructuring plan requires the devotion of management attention as well as significant Company resources, including one-time pre-tax cash charges which we estimated at $10.0 million to $15.0 million, and may pose significant risks. The restructuring plan 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 in the February 2019 restructuring, it may be difficult in the near future to retain certain remaining employees who are critical to our ability to successfully pursue our business plan. See also the discussion elsewhere in these Risk Factors under the caption *"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."*

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

Our management may determine that 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 possible future restructuring actions, including sales of assets, that management may consider in this regard could require consents of third parties, such as (but not necessarily limited to) holders of our Exchangeable Senior Notes (the "2023 Notes"). For example, the voluntary Chapter 11 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 that we will be successful in obtaining additional consents in the future from such holders or from other third parties whose consents may be necessary for further restructuring actions. Failure to obtain these third-party consents would prevent us

from taking the 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.

Our subsidiary Specialty Pharma filed for Chapter 11 bankruptcy protection in February 2019. Avadel US Holdings Inc., which is Specialty Pharma's immediate parent and is our wholly owned subsidiary, agreed to provide debtor-in-possession financing to Specialty Pharma of up to $2.7 million. In its bankruptcy proceeding, Specialty Pharma may pursue a possible sale of its Noctiva business to an unrelated third-party purchaser, although there is currently no term sheet or definitive contract signed with any prospective purchaser for such a sale. Any such sale may involve the transfer of certain of Specialty Pharma's rights related to the exclusive license agreement with Serenity Pharmaceuticals. Other parties interested in the bankruptcy case, including Serenity Pharmaceuticals, could dispute Specialty Pharma's right to make such a sale and there can be no assurance that the bankruptcy court would order any such sale to be completed. In addition, there could be other unexpected results from the bankruptcy proceeding, including but not limited to greater than expected costs in the case that may exceed the amount of financing that Avadel US Holdings Inc. has committed to provide. Adverse or unexpected results from the bankruptcy proceeding could impair our success in achieving the goals of the restructuring plan we announced in February 2019.

The clinical trial for our FT218 product has no estimated completion date and 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.

At present, we have not completed patient enrollment in the clinical trial for our FT218 product and we have not announced an estimated completion date for the clinical trial. Moreover, the FT218 product development program has become substantially more important to our success in the aftermath of the disappointing sales results for Noctiva and the Specialty Pharma bankruptcy filing. Accordingly, management has determined to re-focus on all aspects of the FT218 program with an evaluation assisted by pharmaceutical industry consulting firms. While the final results of this evaluation are not known, such results could cause us to modify our development plan with respect to FT218 in ways that 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 2018, we derived $97.5 million, or 96.2%, of our $101.4 million in revenues from sales of our three hospital products, Bloxiverz®, Vazculep® and Akovaz®. Sales of these three products declined in the aggregate from 2017 to 2018 by $66.9 million, or 40.7%, from $164.4 million to $97.5 million, although Vazculep® sales increased by $4.7 million, or 12.4%, in 2018 compared to the prior year. 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. Four customers accounted for approximately 86.8% of total revenues from sales of these products in 2018. These four customers comprise a significant portion of the distribution network for pharmaceutical products in the U.S.

Competition for our hospital products in 2018 caused significant downward pricing pressure and, with the exception of Vazculep, loss of market share by the Company resulting in lower aggregate revenues for these products; and 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 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 these 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.

We must invest substantial sums in 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 2018, we spent $39.3 million on R&D, including expenditures related to our FT218 and UMD#4 product candidates. Our ongoing investments in R&D for these two products 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. For example, we currently have not completed patient enrollment for the clinical trial of FT218, nor have we announced a projected completion date for this clinical trial. 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 Drug ("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; 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, in particular products using our drug delivery technologies, and such strategy involves risks that could impair our prospects for realizing profits from such products.

The Company expects 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;
- in the case of any new "unapproved-marketed-drug" product we may successfully pursue, whether and the extent to which the FDA removes competing products from the market;
- 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 depend 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, Avadel uses 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. For details see the discussion in the "Business - Information on the Company" in this Part I, Item 1 of this Annual Report on Form 10-K. 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 deliver sufficient quantities of supplies of product or these raw materials could have a material adverse effect on our business.

Currently, we depend on a limited number of CMOs for three products, Bloxiverz®, Vazculep® and Akovaz®, from which we derive a majority of our revenues and a single contract manufacturer for Noctiva™. 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, 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 Good Manufacturing Practices ("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 (for details, see the discussion in the "Business of Avadel" under "Competition and Market Opportunities - Competition and Market Opportunities" in Part I, Item 1 of this Annual Report on Form 10-K). In particular, New Biological Entities ("NBEs") 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 drug 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 new administration has made public and social media statements causing uncertainty as to future federal U.S. government

policies regulating drug prices. And the trend toward increased availability of generic products has contributed to overall pricing pressures in the pharmaceutical industry. 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 obtaining FDA approval for and commercializing our fourth UMD product candidate as well as potentially additional future UMD product candidates, continue to seek FDA approval for FT218 which is in Phase 3 clinical trial. 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. See also the discussions elsewhere in these Risk Factors under the caption "*Our net loss in 2018 and the resulting decrease in our available liquid assets may limit our ability to fully pursue our business strategy."*

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 Avadel's products may benefit from protections afforded by patents, Avadel faces 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 that we have made or may make relating to our potential products or technologies may not result in patents being issued. 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 period of effective patent protection for a marketed product is frequently substantially shorter than the duration of the patent.

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. 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 that we will have adequate remedies. Further, we cannot guaranty 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 guaranty that 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.

The implementation of the Leahy-Smith America Invents Act of 2011 may adversely affect our business.

The Leahy-Smith America Invents Act of 2011 ("AIA") changes the current U.S. "first-to-invent" system to a 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 eliminates the ability to rely on prior research to lay claim to patent rights. Disputes will be resolved through new derivation proceedings and the AIA creates mechanisms to allow challenges to issued patents in reexamination, inter partes review and post grant proceedings. New bases and procedures 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.

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, in connection with us seeking regulatory approval for FT218, companies that produce any branded pharmaceutical versions of such products may allege that FT218 infringes their patents or other intellectual property rights and file suit to prevent us from commercializing FT218. In response to any claim of infringement, we may have to seek licenses, defend infringement actions or challenge the validity or enforceability of those patent rights in court. If we cannot obtain required licenses, are found liable for infringement or are not able to have such patent rights declared invalid or unenforceable. We may be liable for significant monetary damages, 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. 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.

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 must be paid for such licenses, which could reduce the net revenues and royalties we may 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 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.

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. Additionally, we will be required to comply with the General Data Protection Regulation ("GDPR") (Regulation EU 2016/679) by May 25, 2018. 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 states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. GDPR will require Avadel to ensure that personal data Avadel collects is gathered legally and under strict conditions and 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;
- 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;
- changes in domestic or international tax laws or the interpretation of such tax laws;
- adjustments to estimated taxes upon finalization of various tax returns;
- changes in available tax credits;
- changes in share-based compensation expense;
- changes in the valuation of our deferred tax assets and liabilities;
- the resolution of issues arising from tax audits with various tax authorities; and
- 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.

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 interim 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 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 fourth UMD product and our FT218 product, as well as products that 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 data, 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 Food and Drug Administration Amendments Act of 2007 ("FDAAA"), we or our partners may be required to develop Risk Evaluations and Mitigation Strategies ("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 clearances and 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, or to generate data in clinical trials to support expansion of the therapeutic uses for our existing products, 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. 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 or delay in completing our REST-ON Phase 3 clinical trial would prevent or delay the commercialization of our sodium oxybate product, which could 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:

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

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the medicine candidate being studied in relation to other available therapies, including any new drugs or biologics that may be approved for the indications we are investigating. Furthermore, 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 United States or, if they affect more than 200,000 individuals in the United States, there is no reasonable expectation of recovering the cost of developing and making the product available in the United States for the applicable disease or condition.

Our proposed product FT218 obtained orphan drug designation from the FDA in January 2018. 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 product with such FDA approval. However, in limited circumstances, including if the FDA concludes that FT218 is safer, more effective or makes a major contribution to patient care, the FDA could award FT218 with such marketing exclusivity. The orphan drug designation for FT218 does not guaranty that the FDA would ultimately award this product with orphan drug status for purposes of marketing 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 product. Thus, there can be no assurance that the FDA will ultimately grant orphan drug status, or marketing exclusivity, for FT218. In addition, even if such orphan drug marketing exclusivity rights were granted by the FDA, such 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.

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 our American Depositary Shares (ADSs) has been volatile and may continue to be volatile.

The trading price of our American Depositary Shares (ADSs) has been, and is likely to continue to be, highly volatile. The market value of an investment in our ADSs may fall sharply at any time due to this volatility. During the year ended December 31, 2018, the closing sale price of our ADSs as reported on the Nasdaq Global ranged from $1.74 to $11.70. During the year ended December 31, 2017, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $8.03 to $11.57. 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 2018 and we will likely incur a net loss in 2019, 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 $95.3 million for the year ended December 31, 2018 and net income of $68.3 million for the year ended December 31, 2017. In addition, in part because we expect sales of our hospital products to suffer further substantial declines during 2019 and we will incur substantial expenses to develop our products, we will likely incur a net loss in 2019 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 our American Depositary Shares (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 our ADSs. See also the discussion elsewhere in these Risk Factors under the caption "*Our net loss in 2018 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 our 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 our ADSs, or could otherwise adversely affect the price of our 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 the shares of our share capital entitled to vote generally at a meeting of shareholders to amend or repeal certain provisions of our articles of association.

We believe these provisions may provide some protection to holders of our ADSs from coercive or otherwise unfair takeover tactics. These provisions are not intended to make us immune from takeovers. However, these provisions will apply even if some holders of our 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 our ADSs. These provisions may also prevent or discourage attempts to remove and replace incumbent directors.

In addition, several mandatory provisions of Irish law could prevent or delay our acquisition 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 our ADSs in certain circumstances.

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

Irish law differs from the laws in effect in the United States and might afford less protection to the holders of our ADSs.

Holders of our 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 the Irish Companies Act 2014, 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 United States courts, including those predicated on the civil liability provisions of the federal securities laws of the United States, 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 United States court judgments based upon the civil liability provisions of the United States 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 United States 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 United States predicated upon the civil liability provisions of the securities laws of the United States 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 United States 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 United States, 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 January 25, 2019, Brandes Investment Partners L.P. owned approximately 19.1% of Avadel’s outstanding shares (in the form of ADRs), Broadfin Capital and certain of its affiliates beneficially owned approximately 8.3% of our outstanding shares (in the form of ADRs) and Deerfield Capital and certain of its affiliates beneficially owned approximately 7.3% of Avadel’s outstanding shares (in the form of ADRs). 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.

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 2018 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 ADS), 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 Avadel's 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 stockholders' 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. Neither we nor Avadel can 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 ADS.

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.

Risks Related to Recent Tax Legislation

The effect of comprehensive U.S. tax reform legislation on us, whether adverse or favorable, is uncertain.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act (H.R. 1) (the "Tax Act"). Among a number of significant changes to the U.S. federal income tax rules, the Tax Act reduces the marginal U.S. corporate income tax rate from 35% to 21%, limits the deduction for net interest expense, shifts the United States toward a more territorial tax system, and imposes new rules to combat erosion of the U.S. federal income tax base. The Internal Revenue Service ("IRS") has issued limited regulations and guidance under the Tax Act, and is expected to issue additional guidance the impact of which is uncertain but could differ from the interpretations and assumptions that we have made, which could have a material adverse effect on our cash tax liabilities, results of operations and financial condition. Investors should consult their own tax advisers regarding the impact of the Tax Act on their investments in Avadel securities.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

(Amounts in thousands, except square foot amounts)

Avadel Research SAS, our research center, is located in Venissieux, France (a suburb of Lyon) in three adjacent leased facilities totaling approximately 51,600 square feet. One building of approximately 12,800 square feet houses administrative offices and analytical research laboratories. The lease on this facility expires in March 2022. A second facility comprising approximately 12,800 square feet houses equipment dedicated to our Micropump, LiquiTime and Trigger Lock platforms has a lease which expires in March 2022. The lease for the third facility of approximately 26,000 square feet houses research and biochemistry (Medusa) laboratories and quality/regulatory affairs was terminated on December 31, 2018.

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.

We have intellectual property, clinical, quality, regulatory, and supply chain activities located in Dublin, Ireland. The office space consists of 5,059 square feet and the lease expires in 2025.

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

Item 3. Legal Proceedings.

Voluntary Chapter 11 Bankruptcy Filing by Avadel Specialty Pharmaceuticals, LLC

On February 6, 2019, our indirect wholly owned subsidiary Avadel Specialty Pharmaceuticals, LLC ("Specialty Pharma") filed a voluntary petition for reorganization under Chapter 11 of the U.S. Bankruptcy Code in the United States District Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"), Case No. 19-10248 (CSS). The case has been assigned to Judge Christopher

Sontchi. Specialty Pharma is responsible solely for the sales, marketing and distribution of the Company's Noctiva™ product for the treatment of nocturia. Specialty Pharma is the licensee under a license agreement with Serenity Pharmaceuticals LLC ("Serenity") for the patents and other intellectual property relating to Noctiva™. Our direct wholly owned subsidiary Avadel US Holdings, Inc. ("US Holdings") is the parent of Specialty Pharma. On February 8, 2019, the Bankruptcy Court approved, on an interim basis, a binding term sheet (the "Binding Term Sheet") between US Holdings and Specialty Pharma pursuant to which US Holdings will provide debtor-in-possession financing to Specialty Pharma of up to a maximum amount of $2.7 million. The Binding Term Sheet received final approval by the Bankruptcy Court on March 11, 2019. The financing under the Binding Term Sheet is a non-amortizing revolving credit facility bearing interest at a rate of 5.0% per annum; advances will be used for purposes consistent with the budget approved by the Bankruptcy Court; the amounts loaned under the facility have the status of pre-petition unsecured claims and a ranking parri passu with other pre-petition unsecured claims that may be allowed by the Bankruptcy Court; and all such advances will be due on February 6, 2020 or earlier upon certain events specified in the Binding Term Sheet.

Specialty Pharma has also filed motions with the Bankruptcy Court for approval to sell its assets with bids due by April 1, 2019 and, if qualified bids are received, an auction on April 3, 2019. If a bid is accepted at the auction, there will be a hearing in the Bankruptcy Court on April 10, 2019 to consider approval of the proposed sale. Specialty Pharma also moved to reject its supply contract with Renaissance Lakewood, LLC relating to the manufacture of certain specified quantities of Noctiva™. The rejection of the agreement with Renaissance was approved by the Bankruptcy Court over Serenity's objection at a hearing on March 13, 2019. In addition, Ferring International Center S.A. has moved for relief from the automatic stay in bankruptcy so that it may proceed in its litigation against Specialty Pharma which is described below under the caption "Noctiva Patent Litigation."

Noctiva Patent Litigation

Specialty Pharma is a party to Case No. 17-cv-9922 in the United States District Court for the Southern District of New York brought in April 2017 by Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc. (collectively referred to hereafter as "Ferring") against Serenity and Reprise Biopharmaceutics, LLC ("Reprise"). In this proceeding, Ferring is seeking a court judgment to declare as invalid and unenforceable three patents relating to Noctiva, which have been licensed to Specialty Pharma by Serenity, and a further court judgment that Ferring's Nocdurna product does not infringe those patents. In June 2018, Serenity and Reprise filed an answer, which Specialty Pharma joined as a party defendant, asserting defenses and counterclaims for, among other things, infringement by Nocdurna of certain of Serenity's patents and seeking a declaratory judgment that the name "Noctiva" does not infringe any Ferring trademark for "Nocdurna"; subsequently, Ferring asserted a claim for alleged trademark infringement by Noctiva™ with respect Nocdurna. No date is set for a hearing or trial on the various pending motions or on the underlying claims. As noted above, Specialty Pharma is the debtor in a voluntary Chapter 11 bankruptcy case. If Ferring is successful on any of the claims it is asserting in its case in the U.S. District Court, the amount that Specialty Pharma may obtain for a sale of its assets would be limited.

By way of background, Noctiva™ is our brand name for the drug desmopressin acetate which is FDA-approved for treatment of nocturia due to nocturnal polyuria (overproduction of urine during the night) in adults. Noctiva™ is an emulsified low-dose vasopressin analog administered through a preservative-free nasal spray 30 minutes before bedtime. Ferring's product Nocdurna is desmopressin acetate in the form of a sublingual tablet (i.e., to be dissolved under the tongue) which on June 21, 2018 received FDA approval for marketing in the U.S. for the treatment of nocturia.

A separate litigation (Case No. C.A. No. 12-cv 2650 in the United States District Court for the Southern District of New York) is pending between Ferring, on the one hand, and Serenity, Reprise and certain related parties, on the other hand. In this case, Ferring has alleged that certain Ferring employees should be the sole named inventors of the three patents relating to Noctiva, and has also alleged related claims that the defendants breached certain contractual and common law duties. The court in this case has dismissed Ferring's claims, but Ferring may appeal the dismissals. Neither Specialty Pharma nor any other Avadel company is a party to this litigation. However, if the defendants are ultimately unsuccessful in defending Ferring's allegations in this case, Specialty Pharma (or any person who might purchase its assets) would be required to seek a license for the patents from Ferring in order to continue to market Noctiva™, and we would not have the right to enforce any of the patents against competitors or other third parties.

Some of the patents covering our 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 (the "Ferring Litigation"), 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. Avadel's indirectly wholly owned subsidiary, Specialty Pharma and certain other parties including Serenity Pharmaceuticals, LLC ("Serentiy") (the licensor of the Noctiva Patents) have been actively defending this litigation, and have made certain 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 has 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. Adverse outcomes from this litigation could have material adverse effects on the value of the Specialty Pharma's license to Noctiva™.

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 the Company's securities in ADSs is the NASDAQ Global Market. There is no foreign trading market for the Company's ordinary shares, ADSs or any other equity security issued by the Company. 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 13, 2019, there were 37,355,511 ordinary shares outstanding, and the closing stock price of the Company was $1.98 per share.

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

	2018 Price Range		2017 Price Range	
	High	Low	High	Low
First quarter	$ 11.70	$ 6.76	$ 12.30	$ 8.87
Second quarter	7.78	5.89	11.72	8.75
Third quarter	7.14	4.08	11.18	8.14
Fourth quarter	4.66	1.74	11.53	7.52

Holders

As of March 13, 2019, there were 75 holders of record of our ordinary shares and 32 accounts registered with The Bank of New York Mellon, the depositary of our ADS program, as holders of ADSs, one of which ADS accounts is registered to the Depositary Trust Corporation (DTC). Because our ADSs are generally held of record by brokers, nominees and other institutions as participants in DTC on behalf of the beneficial owners of such ADSs, we are unable to estimate the total number of beneficial owners of the ADSs held by these record holders.

Dividends

The Company has never declared or paid a cash dividend on any of our capital stock and does not anticipate declaring cash dividends in the foreseeable future.

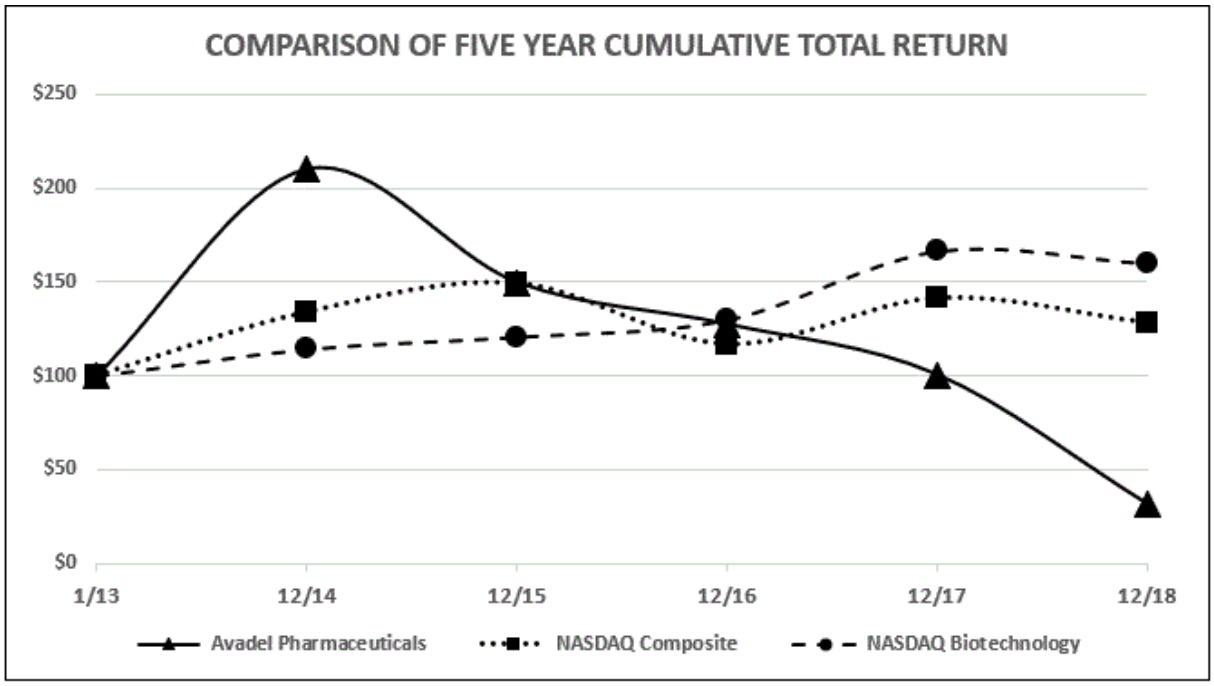
Issuer Purchases of Equity Securities

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 10: 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.

The Company fully completed its authorized share buyback program. There were no shares repurchased during the three months ended December 31, 2018.

Stock 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, 2018. 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 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. The Company's historical results are not necessarily indicative of the results to be expected in any future period.

Statement of (Loss) Income Data:	**2018**	**2017**	**2016**	**2015**	**2014**
Total revenues	$ 103,269	$ 173,245	$ 150,246	$ 173,009	$ 14,975
Gross profit [(a)]	85,753	156,944	136,998	161,599	11,592
Operating (loss) income	(104,926)	89,505	(4,965)	70,758	(93,657)
Net (loss) income from continuing operations	(95,304)	68,271	(41,276)	41,798	(89,487)
Net income from discontinued operations	—	—	—	—	4,018
Net (loss) income	(95,304)	68,271	(41,276)	41,798	(85,469)
Net (loss) income per share - basic:					
Continuing operations	(2.55)	1.69	(1.00)	1.03	(2.47)
Discontinued operations	—	—	—	—	0.11
Net (loss) income per share - basic	(2.55)	1.69	(1.00)	1.03	(2.36)
Net (loss) income per share - diluted:					
Continuing operations	(2.55)	1.63	(1.00)	0.96	(2.47)
Discontinued operations	—	—	—	—	0.11
Net (loss) income per share - diluted	(2.55)	1.63	(1.00)	0.96	(2.36)

Balance Sheet Data:	**2018**	**2017**	**2016**	**2015**	**2014**
Cash and cash equivalents	$ 9,325	$ 16,564	$ 39,215	$ 65,064	$ 39,760
Marketable securities	90,590	77,511	114,980	79,738	53,074
Goodwill	18,491	18,491	18,491	18,491	18,491
Intangible assets, net	1,629	92,289	22,837	15,825	28,389
Total assets	190,300	253,277	245,482	215,081	174,382
Long-term debt (incl. current portion)	115,840	267	815	1,118	3,717
Long-term related party payable (incl. current portion)	28,840	98,925	169,347	122,693	114,750

[(a)] Gross profit is computed by subtracting cost of products from total revenues.

Quarterly Financial Data (Unaudited):

The following tables present certain unaudited consolidated quarterly financial information for each quarter of 2018 and 2017. 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.

2018:	**March 31**	**June 30**	**September 30**	**December 31**
Revenues	$ 33,293	$ 29,230	$ 19,826	$ 20,920
Gross profit [(a)]	26,701	25,718	16,706	16,628
Operating loss [(b)]	(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)

2017:	**March 31**	**June 30**	**September 30**	**December 31**
Revenues	$ 52,507	$ 46,311	$ 39,675	$ 34,752
Gross profit [(a)]	48,605	41,750	35,885	30,704
Operating income (loss)	33,341	34,126	26,118	(4,080)
Net income (loss)	25,910	28,927	21,679	(8,245)
Net income (loss) per share - basic	0.63	0.70	0.54	(0.21)
Net income (loss) per share - diluted	0.61	0.68	0.52	(0.21)

[(a)] Gross profit is computed by subtracting cost of products from total revenues.
[(b)] The Company 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.

Overview

Nature of Operations

Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel," the "Company," "we," "our," or "us") is a branded specialty pharmaceutical company. Our primarily focus is 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 excessive daytime sleepiness (EDS) and cataplexy. In addition, we market three sterile injectable drugs used in the hospital setting which were developed under our "unapproved marketed drug" (UMD) program. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit www.avadel.com..

Avadel is developing FT218, an investigational once-nightly formulation of sodium oxybate based on its propriety Micropump® drug delivery technology, for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. FT218 is currently being evaluated in a Phase 3 clinical trial called REST-ON. In addition, Avadel is developing a fourth UMD product, an as-yet undisclosed sterile injectable product intended for the hospital market.

Our current marketed products include:

- *Akovaz*® (ephedrine sulfate injection, USP), 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.

- *Bloxiverz*® (neostigmine methylsulfate injection), a cholinesterase inhibitor, is indicated for the reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery.

- *Vazculep*® (phenylephrine hydrochloride injection), an alpha-1 adrenergic receptor agonist indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

  Each of our *Akovaz*, *Bloxiverz* and *Vazculep* products is used primarily in the hospital setting and was developed under our UMD program.

- *Noctiva*™, a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. Due to disappointing results after a substantial investment of resources after *Noctiva's* commercial launch in March 2018, Specialty Pharma, the Avadel subsidiary responsible for the marketing and sale of *Noctiva*, made a voluntary filing for Chapter 11 bankruptcy protection on February 6, 2019. Although Specialty Pharma currently continues its marketing and sales efforts for this product, Avadel anticipates that Specialty Pharma will discontinue all activities with respect to *Noctiva* during 2019 as a result of the bankruptcy.

Corporate Information

The Company was incorporated on December 1, 2015 as an Irish private limited company, and re-registered as an Irish public limited company, or plc, on November 21, 2016. Our principal place of business is located at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15, Ireland. Avadel's phone number is 011-353-1-485-1200. Our website is www.avadel.com, where

we make available free of charge our reports (and any amendments thereto) on Forms 10-K, 10-Q and 8-K as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission ("SEC"). These filings are also available to the public at www.sec.gov.

The Company is the successor to Flamel Technologies S.A., a French *société anonyme* ("Flamel"), as the result of the France-to-Ireland redomestication merger of Flamel with and into the Company completed on December 31, 2016 (the "Merger"). In the Merger, we changed our company name to Avadel Pharmaceuticals plc and our jurisdiction of organization to Ireland; we assumed all the assets and liabilities of Flamel; and we issued one Avadel ordinary share (either directly or in the form of an American Depositary Share (ADS)) in exchange for each formerly outstanding share of Flamel, all of which were canceled. Thus, an Avadel ordinary share held (either directly or represented by an ADS) immediately after the Merger continued to represent the same proportional interest in our equity owned by the holder of a share of Flamel immediately prior to the Merger. References in this Annual Report on Form 10-K 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. Additional details about the Merger are set forth in Item 1 under the caption " - The Reincorporation Merger."

The Company currently has 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 as noted above), (ii) Avadel Legacy Pharmaceuticals, LLC, (iii) Avadel Management Corporation, (iv) FSC Holding Company and (v) Avadel Operations Company, Inc. 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 which, Since December 16, 2014, has been the owner of substantially all of Avadel's intellectual property. 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 the Company's 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.

Business Strategies

Our primary business strategy is to 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 excessive daytime sleepiness (EDS) and cataplexy. In addition, we will continue to maximize our current approved hospital products portfolio, including obtaining FDA approval for and the commercialization of our fourth UMD product. Additionally, we will continue to evaluate opportunities to expand our product portfolio. These strategies are described below in greater detail.

FT218 (Micropump® sodium oxybate): FT218 (Micropump® sodium oxybate): Avadel is developing a product that uses our Micropump® drug-delivery technology for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. Avadel currently refers to this product as FT218. FT218 is a Micropump®-based formulation of sodium oxybate. Sodium oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid. Sodium oxybate has been described as a therapeutic agent with high medical value. Sodium oxybate is approved in Europe and the United States as a twice nightly formulation indicated for the treatment of EDS and cataplexy in patients with narcolepsy.

In preparation for a clinical trial of FT218, Avadel reached an agreement with the FDA for the design and planned analysis of our pivotal Phase 3 study, Rest-On through a Special Protocol Assessment ("SPA"). A SPA is an acknowledgment by the FDA that the design and planned analysis of a pivotal clinical trial adequately addresses the objectives necessary to support a regulatory submission. Pursuant to the SPA, in December 2016, Avadel initiated patient enrollment and dosing for the Rest-On clinical trial 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 study is a randomized, double-blind, placebo-controlled study of 264 patients being conducted in 45 to 55 clinical sites in the U.S., Canada, Western Europe and Australia. Avadel believes that, if successful, this study could demonstrate improved efficacy, safety and patient satisfaction over the current primary product serving this market, which is a twice nightly sodium oxybate formulation, which the marketer estimates will generate revenues of approximately $1.4 billion in 2018.

To date, due in part to narcolepsy being a rare disease with a small patient population with no significant geographic concentration, we have not completed patient enrollment for the FT218 clinical trial, nor have we announced a projected completion date for this clinical trial. Recently, we have engaged a third-party pharmaceutical consulting firm to assist us in evaluating our clinical

development program for FT218 with the goal of ensuring a approvable and commercially viable FDA submission. This evaluation is currently under way, and while the results are not known at this time, they could cause us to modify our development plan with respect to FT218 in ways that materially increase the ultimate cost of development, further delay its completion or identify presently unknown risks with the product.

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 as the only once-nightly formulation. However, 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.

Development of Micropump®-Based Products

Avadel's versatile Micropump® drug delivery technology presents product development opportunities, 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 ("NCEs"). FT218 is formulated using this technology. If approved by the FDA, this product will be commercialized either by Avadel and/or by partners via licensing/distribution agreements.

Unapproved Marketed Drug ("UMD") Products

In 2006, the U.S. Food and Drug Administration (FDA) issued its Marketed Unapproved Drugs - Compliance Policy Guide with the intention to incentivize pharmaceutical companies to pursue approvals for pharmaceutical products, many of which pre-date the establishment of the FDA. Although these products are not protected by patents or similar intellectual property, the FDA's Compliance Policy Guide dictates that should FDA approve a new drug application (NDA) for any such products via a 505(b)(2) process, the FDA will remove competing unapproved manufacturers until a generic application is approved. Avadel believes that over a thousand unapproved drugs are marketed in the United States today and, while many of these products are outdated therapies, we strategically evaluate those UMD products that are more commonly used as candidates for possible future FDA approval and marketing under our UMD program.

To date, Avadel has received FDA approvals for three UMD products which we currently market under the brand names *Bloxiverz*® (neostigmine methylsulfate injection), *Vazculep*® (phenylephrine hydrochloride injection) and *Akovaz*® (ephedrine sulfate injection).

Additional UMD Products. Avadel is developing and intends to seek FDA approval of a NDA for UMD #4, a sterile injectable product used in the hospital setting. The Company anticipates submitting an NDA during the first quarter of 2019 on UMD #4, which, if approved, could contribute revenues to Avadel starting in 2020. In addition, Avadel continues to monitor and evaluate other UMDs with large existing markets and limited competition for feasibility of possible future NDAs. Avadel believes its strategy to create opportunities to commercialize UMD products in markets with a limited number of competitors may have a limited number of opportunities given the lack of patent protection from competition. Avadel believes this shorter-term strategy may provide us with near term revenue growth and provide cash flows that can be used to fund R&D and inorganic initiatives for other products.

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 the Company.

- **Possible Net Loss from Operations in 2019:** In part because we expect sales of our hospital products to significantly decline from 2018's levels and we will incur substantial expenses to further the clinical development of FT218, we likely will incur a net loss in 2019, the amount of which is not known to us at this time.

Recent Developments

Management Changes. In December 2018 and in January 2019, Avadel announced changes to its Board of Directors ("Board") and Management team. In December 2018, (a) Avadel appointed Kevin Kotler, founder and portfolio manager of Broadfin Capital, LLC, and Eric Ende, President of Ende BioMedical Consulting Group to the Company's Board, (b) Michael S. Anderson resigned as chief executive officer and member of the Board of Avadel, (c) the Board named Gregory J. Divis, formerly the Company's chief operating officer, as interim chief executive officer, (d) the Honorable Craig Stapleton stepped down as chairman of the Board but continues as a member of the Board, and (e) Geoffrey M. Glass, President of Clear Sciences, LLC, a current member of the Avadel Board, was named chairman of the Board.

Corporate Restructuring. In February 2019, Avadel announced a corporate restructuring in order to focus efforts and resources on the clinical development of FT218. In conjunction with the restructuring, Avadel will reduce its workforce by more than 50%, and Specialty Pharma made a voluntary filing for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code on February 6, 2019. As noted above, Specialty Pharma is a special-purpose entity and wholly-owned subsidiary responsible solely for the sales, marketing and distribution of *Noctiva*. These restructuring actions were taken to exit *Noctiva*™ quickly and efficiently, and are not expected to materially impact any other aspect of the Company's business, including the ability to operate its sterile injectables hospital business, complete the FT218 Phase 3 clinical trial, and complete development of the Company's fourth UMD product. The Company estimates that it will incur approximately $10 to $15 million of one-time pre-tax charges for severance and other costs related to the restructuring. See *Note 23: Subsequent Events* in the accompanying notes to the consolidated financial statements for additional information.

Financial Highlights

Highlights of our consolidated results for the year ended December 31, 2018 are as follows:

- Revenue was $103,269 for the year ended December 31, 2018 compared to $173,245 in the same period last year. This decrease was primarily the result of increased competition driving lower prices in our hospital injectables products as noted above in our discussion of *Key Business Trends and Highlights*. We experienced price declines across all of our hospital products and a unit volume decline with our Akovaz product due to additional competition.

- Operating loss was $104,926 for the year ended December 31, 2018 compared to operating income of $89,505 for the year ended December 31, 2017. The primary reasons for the decrease in operating income was due to a decrease in gross margin of $71,191 driven by lower revenue as described above, impairment of the Noctiva intangible asset of $66,087 and higher SG&A of $41,499 primarily driven by sales and marketing costs related to Noctiva.

- Net loss was $95,304 for the year ended December 31, 2018 compared to net income of $68,271 in the same period last year.

- Diluted net loss per share was $2.55 for the year ended December 31, 2018 compared to diluted net income per share of $1.63 in the same period last year.

- Cash and marketable securities increased $5,840 to $99,915 at December 31, 2018 from $94,075 at December 31, 2017. The increase primarily results from net proceeds from our February 2018 debt issuance of $137,560, partially offset by our use of cash in operating activities of $82,716, a milestone payment of $20,000 for Noctiva and $27,637 in cash used as a return to shareholders through our share buyback program.

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

The Company sells products primarily through wholesalers and considers these wholesalers to be its customers. Revenue from product sales is recognized when the customer obtains control of the Company's product, which occurs typically upon receipt by the customer. As is customary in the pharmaceutical industry, the Company's 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.

For generic products and branded products where the ultimate net selling price to customer is estimable, the Company recognizes revenues upon delivery to the wholesaler. For new product launches the Company recognizes revenue if sufficient data is available to determine product acceptance in the marketplace such that product returns may be estimated based on historical or analog product data and there is probable evidence of reorders and consideration is made of wholesaler inventory levels. As part of the third quarter 2016 launch of Akovaz, the Company determined that sufficient data was available to determine the ultimate net selling price to the customer and therefore recognized revenue upon delivery to our wholesaler customers.

Prior to the second quarter 2016, the Company did not have sufficient historical or analog product data to estimate certain revenue deductions. As such, we could not accurately estimate the ultimate net selling price of our hospital portfolio of products and as a result delayed revenue recognition until the wholesaler sold the product through to end customers.

During the second quarter of 2016, it was determined that we now had sufficient evidence, history, data and internal controls to estimate the ultimate selling price of our products upon shipment from our warehouse to our customers, the wholesalers. Accordingly, we discontinued the sell-through revenue approach and now recognize revenue once the product is delivered to the wholesaler. As a result of this change in accounting estimate, we recognized $5,981 in additional revenue, or $0.05 per diluted share, for the twelve months ended December 31, 2016 that previously would have been deferred until sold by the wholesalers to the hospitals.

License Revenue

The Company from time to time may enter into out-licensing agreements under which it licenses to third parties certain rights to its products or intellectual property. The terms of these arrangements typically include payment to the Company 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 year ended December 31, 2018, the Company recognized $1,846 of revenue from license agreements.

Research and Development ("R&D"). R&D expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, and other R&D expenses. Clinical studies and outside services costs relate primarily to services performed

by clinical research organizations and related clinical or development manufacturing costs, materials and supplies, filing fees, regulatory support, and other third-party fees. Personnel expenses relate primarily to salaries, benefits and stock-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.

The Company recognizes R&D tax credits received from the French government for spending on innovative R&D as an offset of R&D expenses.

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

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

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

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in a multitude of jurisdictions across our global operations. A tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

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

We have not recorded a deferred tax liability for any income or withholding taxes that may arise as the result of the distribution of unremitted earnings within our Company. At December 31, 2018, the Company has unremitted earnings of $2,798 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. The Company has determined that we operate in a single segment and has a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is 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. The Company tests goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. During the fourth quarter of 2018, we performed our required annual impairment test of goodwill and have determined that no impairment of goodwill existed at December 31, 2018 or 2017.

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 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*). The Company had determined that no impairment existed at December 31, 2017.

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 11: Long-Term Related Party Payable* and *Note 16: 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 11: 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 11: 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 income (expense) - 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):

				Increase / (Decrease)			
	Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
Comparative Statements of (Loss) Income:	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Product sales	$ 101,423	$ 172,841	$ 147,222	$ (71,418)	(41.3)%	$ 25,619	17.4 %
License revenue	1,846	404	3,024	1,442	356.9 %	(2,620)	(86.6)%
Total revenues	103,269	173,245	150,246	(69,976)	(40.4)%	22,999	15.3 %
Operating expenses:							
Cost of products	17,516	16,301	13,248	1,215	7.5 %	3,053	23.0 %
Research and development expenses	39,329	33,418	34,611	5,911	17.7 %	(1,193)	(3.4)%
Selling, general and administrative expenses	100,359	58,860	44,179	41,499	70.5 %	14,681	33.2 %
Intangible asset amortization	6,619	3,659	13,888	2,960	80.9 %	(10,229)	(73.7)%
(Gain) loss - changes in fair value of related party contingent consideration	(22,731)	(31,040)	49,285	8,309	26.8 %	(80,325)	(163.0)%
Impairment of intangible asset	66,087	—	—	66,087	100.0 %	—	— %
Restructuring costs	1,016	2,542	—	(1,526)	(60.0)%	2,542	100.0 %
Total operating expenses	208,195	83,740	155,211	124,455	148.6 %	(71,471)	(46.0)%
Operating (loss) income	(104,926)	89,505	(4,965)	(194,431)	(217.2)%	94,470	1,902.7 %
Investment and other income, net	452	2,136	2,758	(1,684)	(78.8)%	(622)	(22.6)%
Interest expense	(10,622)	(1,052)	(963)	9,570	909.7 %	89	*9.2 %*
Other income (expense) - changes in fair value of related party payable	1,899	2,071	(6,548)	172	8.3 %	(8,619)	(131.6)%
(Loss) income before income taxes	(113,197)	92,660	(9,718)	(205,857)	(222.2)%	102,378	1,053.5 %
Income tax (benefit) provision	(17,893)	24,389	31,558	(42,282)	(173.4)%	(7,169)	(22.7)%
Net (loss) income	$ (95,304)	$ 68,271	$ (41,276)	$ (163,575)	(239.6)%	$ 109,547	265.4 %
Net (loss) income per share - diluted	$ (2.55)	$ 1.63	$ (1.00)	$ (4.18)	(256.4)%	$ 2.63	263.0 %

The revenues for each of the Company's significant products were as follows:

				Increase / (Decrease)			
	Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
Revenues	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Bloxiverz	$ 20,850	$ 45,596	$ 82,896	$ (24,746)	(54.3)%	$ (37,300)	(45.0)%
Vazculep	42,916	38,187	39,796	4,729	12.4 %	(1,609)	(4.0)%
Akovaz	33,759	80,617	16,831	(46,858)	(58.1)%	63,786	379.0 %
Noctiva	1,204	—	—	1,204	100.0 %	—	*n/a*
Other	2,694	8,441	7,699	(5,747)	(68.1)%	742	9.6 %
Total product sales	101,423	172,841	147,222	(71,418)	(41.3)%	25,619	17.4 %
License revenue	1,846	404	3,024	1,442	356.9 %	(2,620)	(86.6)%
Total revenues	$ 103,269	$ 173,245	$ 150,246	$ (69,976)	(40.4)%	$ 22,999	15.3 %

2018 Compared to 2017

Total product sales were $101,423 for the year ended December 31, 2018, compared to $172,841 for the same prior year period. Bloxiverz's revenue declined $24,746 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 2017 and 2018 and continued market penetration from an alternative molecule to neostigmine. Vazculep's revenue increased by $4,729 due primarily an increase in unit volumes partially offset by lower net realized net selling prices when compared to the prior year. Akovaz's revenue decreased $46,858 driven by lower unit volumes and net selling prices due largely to new competitors that entered the market in 2017. Total product sales during the year ended

December 31, 2018 also include $1,204 of revenues attributable to Noctiva, which launched in March 2018. Other revenues, which includes the pediatric products which were divested in February 2018, declined when compared to the prior year due to the divestiture of those products.

License and research revenue was $1,846 for the year ended December 31, 2018 compared to $404 in the same period last year. In December 2018, the Company 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.

2017 Compared to 2016

Product sales were $172,841 for the year ended December 31, 2017, compared to $147,222 for the year ended December 31, 2016. Revenues for the year ended December 31, 2016 include $5,981 in additional revenue as a result of our change in accounting estimate previously described in our Form 10-K for the year ended December 31, 2016. Bloxiverz's revenue declined $37,300 when compared to the same period last year, primarily due to a loss of market share and decrease in net selling price driven largely by two factors: a) lost business as a result of three new competitors in the neostigmine market who entered the market in the first quarter of 2016, the second and fourth quarters of 2017 and b) a new molecule approved by the FDA in late 2015 and launched in 2016 with a similar indicated use as Bloxiverz. Additionally, the decline in Bloxiverz's revenue was partially offset by an increase of $4,597 related to the change in the revenue estimate noted above. Vazculep's revenue declined slightly by $1,609 driven by the effect of the non-recurring revenue estimate change of $1,384 which did not repeat in 2017. Revenue from Akovaz, which was launched in August 2016, contributed $80,617 to product sales for the year ended December 31, 2017. Other revenues, which includes our pediatric products, were up $742 in the year ended December 31, 2017 compared to the same prior year period. Revenues from our pediatric products, which were acquired in February 2016 and disposed of in February 2018, were $8,044 for the year ended December 31, 2017, compared to $5,985 in the same prior year period.

License revenue was $404 for the year ended December 31, 2017 compared to $3,024 in the same period in the prior year. During 2017, the Company made a determination that the performance period associated with a specific license will be longer than previously estimated and, accordingly, reduced license revenue by approximately $2,155 to reflect the Company's current expected performance period. The longer than expected performance period is the result of a reassessment of the time it will take for the Company to complete certain contractual requirements mandated by the license.

				Increase / (Decrease)			
	Years Ended December 31,			**2018 vs. 2017**		**2017 vs. 2016**	
Cost of Products	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Cost of products	$ 17,516	$ 16,301	$ 13,248	$ 1,215	7.5%	$ 3,053	23.0%
Percentage of sales	17.0%	9.4%	8.8%				

Cost of products increased $1,215, or 7.5% during the year ended December 31, 2018 compared to the prior year. As a percentage of sales, cost of products sold was higher than the prior year driven by an increase of $3,718 primarily in inventory obsolescence reserves, of which $2,583 relates to the Noctiva product and lower product revenues due to lower net selling prices.

Cost of products increased $3,053, or 23.0% during the year ended December 31, 2017 as compared to the same period in 2016. As a percentage of sales, cost of products sold was up slightly to 9.4% compared to 8.8% as a result of product mix changes and lower selling prices.

				Increase / (Decrease)			
	Years Ended December 31,			**2018 vs. 2017**		**2017 vs. 2016**	
Research and Development Expenses	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Research and development expenses	$ 39,329	$ 33,418	$ 34,611	$ 5,911	17.7%	$ (1,193)	(3.4)%
Percentage of sales	38.1%	19.3%	23.0%				

R&D expenses increased $5,911 or 17.7% during the year ended December 31, 2018 as compared to the same period in 2017. This increase is largely due to higher spending on the Company's FT218 Phase 3 sodium oxybate clinical study. The Company continues to spend a substantial portion of its R&D spending on this study. Additionally, a portion of this increase was due to increased R&D costs of approximately $1,100 associated with Noctiva.

R&D expenses were slightly lower in 2017 than in 2016. During 2017, the Company continued to spend a substantial portion of its R&D spending on the FT218 Phase 3 sodium oxybate clinical study.

				Increase / (Decrease)			
	Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
Selling, General and Administrative Expenses	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Selling, general and administrative expenses	$ 100,359	$ 58,860	$ 44,179	$ 41,499	70.5%	$ 14,681	33.2%
Percentage of sales	97.2%	34.0%	29.4%				

Selling, general and administrative (SG&A) expenses increased $41,499 or 70.5% during the year ended December 31, 2018 as compared to the prior year. This increase was primarily due to approximately $48,500 of sales and marketing costs associated with the March 2018 launch of Noctiva, partially offset by approximately $8,700 of lower SG&A spend related to the February 2018 divestiture of the Company's pediatric assets.

SG&A expenses increased $14,681 or 33.2% and increased as a percentage to sales to 34.0% during the year ended December 31, 2017 as compared to the prior year. This increase was primarily due to approximately $14,000 of costs associated with the anticipated 2018 launch of Noctiva.

				Increase / (Decrease)			
	Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
Intangibles Asset Amortization	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Intangible asset amortization	$ 6,619	$ 3,659	$ 13,888	$ 2,960	80.9%	$ (10,229)	(73.7)%
Percentage of sales	6.4%	2.1%	9.2%				

Intangible asset amortization expense increased $2,960 or 80.9% during the year ended December 31, 2018 as compared to the prior year driven by the amortization of the intangible asset related to Noctiva, which began in September 2017, partially offset by lower amortization of the pediatrics products' intangible assets due to the February 2018 disposition of these products.

Intangible asset amortization expense decreased $10,229 or 73.7% during the year ended December 31, 2017 as compared to the same prior year period primarily driven by the Bloxiverz in process R&D asset being fully amortized as of December 31, 2016.

				Increase / (Decrease)			
	Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
Changes in Fair Value of Related Party Contingent Consideration	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
(Gain) loss - changes in fair value of related party contingent consideration	$ (22,731)	$ (31,040)	$ 49,285	$ 8,309	26.8%	$ (80,325)	(163.0)%
Percentage of sales	(22.0)%	(17.9)%	32.8%				

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 sheet.

As a result of changes in the underlying assumptions used to determine the estimated fair values of a) our acquisition-related contingent consideration earn-out payments - Éclat, b) acquisition-related warrants, of which 2,200 warrants were exercised and 1,100 warrants expired worthless during the three months ended March 31, 2018 and c) acquisition-related FSC royalty liabilities which were disposed of during the sale of our pediatric products in February 2018, we recorded gains of $22,731 and $31,040 and lowered the fair value of the acquisition-related contingent consideration earn-out payments - Éclat for the years ended December 31, 2018 and 2017, respectively.

For the year ended December 31, 2018, as a result of changes to these estimates when compared to the same estimates at December 31, 2017, we recorded a decrease in the fair value of our contingent consideration liabilities, primarily as a result of a

weaker long-term sales and gross profit outlook for Bloxiverz, Vazculep and Akovaz due to more competition and other changes in certain underlying market conditions of the acquisition-related contingent consideration earn-out payments - Éclat.

For the year ended December 31, 2017, as a result of changes to these estimates when compared to the same estimates at December 31, 2016, we recognized a gain of $21,997 to lower the fair value of acquisition related liabilities for the Éclat products primarily as a result of a weaker long-term sales and gross profit outlook for Bloxiverz and Akovaz due to more competition. Additionally, we decreased the fair value of the acquisition related warrants which resulted in a gain of $8,738, primarily due to changes in the AVDL stock price at December 31, 2017 compared to December 31, 2016, changes in the volatility of AVDL stock and a shorter remaining term of the warrants.

				Increase / (Decrease)			
	Years Ended December 31,			**2018 vs. 2017**		**2017 vs. 2016**	
Impairment of Intangible Asset	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Impairment of intangible asset	$ 66,087	$ —	$ —	$ 66,087	100.0%	$ —	*n/a*
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, the Company 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 the Company recorded a full impairment charge. The February 6, 2019 Chapter 11 bankruptcy filing of Specialty Pharma, the subsidiary which markets, sells and distributes Noctiva, confirmed management's conclusion on the impairment. There were no such impairment costs during the years ended December 31, 2017 and 2016.

				Increase / (Decrease)			
	Years Ended December 31,			**2018 vs. 2017**		**2017 vs. 2016**	
Restructuring Costs	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Restructuring costs	$ 1,016	$ 2,542	$ —	$ (1,526)	(60.0)%	$ 2,542	100.0%
Percentage of sales	1.0%	1.5%	—%				

Restructuring costs of $1,016, which were primarily comprised of a provision related to a dispute with certain severed employees associated with our Lyon, France site of $776, were recognized during the year ended December 31, 2018. During the first quarter of 2017, we announced a plan to reduce our workforce at our Lyon, France site by approximately 50%. This reduction is an effort to align the Company's cost structure with our ongoing and future planned projects. The reduction was substantially complete at December 31, 2018. See *Note 17: Restructuring Costs - France*.

				Increase / (Decrease)			
	Years Ended December 31,			**2018 vs. 2017**		**2017 vs. 2016**	
Investment and Other Income, net	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Investment and other income, net	$ 452	$ 2,136	$ 2,758	$ (1,684)	(78.8)%	$ (622)	(22.6)%
Percentage of sales	0.4%	1.2%	1.8%				

Investment and other income, net decreased $1,684 during the year ended December 31, 2018 as compared to the same prior year period driven by lower realized and unrealized gains on our marketable securities during the current period when compared to the prior year period. Investment and other income, net for the year ended December 31, 2018 included $956 of net unrealized losses related to available-for-sale equity investments. See *Note 5*: *Marketable Securities* for discussion of the Company's adoption of ASU 2016-01 on January 1, 2018. The decrease in investment income was partially offset by a decrease in foreign exchange loss.

				Increase / (Decrease)			
	Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
Interest Expense	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Interest expense	$ 10,622	$ 1,052	$ 963	$ 9,570	909.7%	$ 89	9.2%
Percentage of sales	(10.3)%	(0.6)%	(0.6)%				

Interest expense increased $9,570 for the year ended December 31, 2018 when compared to the year ended December 31, 2017 as a result of as a result of imputed interest recorded on the 2023 Notes issued in February 2018.

				Increase / (Decrease)			
	Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
Other Income (Expense) - Changes in Fair Value of Related Party Payable:	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Other income (expense) - changes in fair value of related party payable	$ 1,899	$ 2,071	$ (6,548)	$ 172	8.3%	$ (8,619)	(131.6)%
Percentage of sales	1.8%	1.2%	(4.4)%				

We recorded income of $1,899 and $2,071 to reduce the fair value of these liabilities during the years ended December 31, 2018 and 2017, respectively, 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 our critical accounting estimates section, 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 present valuing the related cash flows. These estimates often do change based on changes in current market conditions, competition and other factors.

				Increase / (Decrease)			
	Years Ended December 31,			2018 vs. 2017		2017 vs. 2016	
Income Taxes:	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Income tax (benefit) provision	$ (17,893)	$ 24,389	$ 31,558	$ (42,282)	(173.4)%	$ (7,169)	(22.7)%
Percentage of income (loss) before income taxes	15.8%	26.3%	(324.7)%				

The items accounting for the difference between the income tax (benefit) provision computed at statutory tax rates and the Company's effective tax rate are as follows for the years ended December 31:

Reconciliation to Effective Income Tax Rate:	**2018**	**2017**	**2016**
Statutory tax rate	12.5 %	12.5 %	12.5 %
Differences in international tax rates	8.0 %	22.2 %	(31.9)%
Nondeductible changes in fair value of contingent consideration	4.0 %	(11.6)%	(165.0)%
Income tax deferred charge	— %	— %	(9.7)%
Change in valuation allowances	(5.3)%	(0.7)%	11.8 %
Nondeductible stock-based compensation	(1.3)%	(0.4)%	(14.8)%
Cross border merger	— %	0.3 %	(100.6)%
Unrealized tax benefits	(1.3)%	1.4 %	(15.2)%
State and local taxes (net of federal)	(0.3)%	0.3 %	(9.6)%
Change in U.S. tax law	(0.2)%	3.8 %	— %
Nondeductible interest expense	(1.1)%	— %	— %
Other	0.7 %	(1.5)%	(2.3)%
Effective income tax rate	15.7 %	26.3 %	(324.8)%

Income tax (benefit) provision - at statutory tax rate	$ (14,149)	$ 11,582	$ (1,215)
Differences in international tax rates	(9,039)	20,557	3,097
Nondeductible changes in fair value of contingent consideration	(4,559)	(10,779)	16,036
Income tax deferred charge	—	—	938
Change in valuation allowances	5,998	(610)	(1,143)
Nondeductible stock-based compensation	1,499	(375)	1,436
Cross-border merger	—	265	9,773
Unrecognized tax benefits	1,440	1,296	1,475
State and local taxes (net of federal)	299	252	934
Change in U.S. tax law	274	3,513	—
Nondeductible interest expense	1,269	—	—
Other	(925)	(1,312)	227
Income tax (benefit) provision - at effective income tax rate	$ (17,893)	$ 24,389	$ 31,558

In 2018, the income tax provision decreased by $42,282 when compared to the same period in 2017. 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 the decrease in taxable income in Ireland. 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.

In 2017, the income tax provision decreased by $7,169 when compared to the same period in 2016. 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. in 2017, when compared to 2016. In 2017, the Company did not incur any significant additional income tax provision associated with the Cross-Border Merger as a majority of the transaction was completed in 2016. In 2017, the Company recorded $3,513 of tax provision associated with the U.S. Tax Cuts and Jobs Act signed into law in the U.S. in December of 2017.

Liquidity and Capital Resources

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

				Increase / (Decrease)			
	Years Ended December 31,			**2018 vs. 2017**		**2017 vs. 2016**	
Net Cash Provided By (Used In):	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Operating activities	$ (82,716)	$ 16,662	$ 18,901	$ (99,378)	(596.4)%	$ (2,239)	(11.8)%
Investing activities	(36,981)	(15,698)	(36,630)	(21,283)	(135.6)%	20,932	57.1 %
Financing activities	112,659	(23,318)	(7,954)	135,977	583.1 %	(15,364)	(193.2)%

Operating Activities

Net cash used in operating activities was $82,716 for the year ended December 31, 2018 compared to net cash provided by operating activities of $16,662 in the prior year. This decrease in operating cash flow is primarily due to lower cash earnings (net income or loss adjusted for non-cash credits and charges) of $100,134 when compared to the same period last year. This decrease is principally due to lower gross margins, higher SG&A expenses driven from the launch of Noctiva and higher R&D due to increased spending on the Company's FT218 Phase 3 sodium oxybate clinical study. The decrease in operating cash flow was also due to the decrease in accounts payable and accrued expenses of $26,454, partially offset by lower earn-out and royalty payments for related party contingent payable of $13,759 during the year ended December 31, 2018 compared to the prior year.

Net cash provided by operating activities of $16,662 for the year ended December 31, 2017 decreased $2,239 compared to the same prior year period. This slight decline in operating cash flow is due to higher earn-out payments for related party contingent consideration in excess of acquisition-date fair value and an increase in prepaid expenses and other current assets due to a cash deposit that was prepaid related to the Noctiva launch, partially offset by higher cash earnings (net income adjusted for non-cash credits and charges) when compared to the same period last year, largely driven by higher revenues, partially offset by higher selling, general and administrative expenses.

Investing Activities

Cash used in investing activities of $36,981 for the year ended December 31, 2018 decreased $21,283 compared to the same prior year period. In 2018, the Company used cash of $16,803 for the purchase of marketable securities compared to generating cash of $38,004 from the sale of marketable securities during the year ended December 31, 2017. Additionally, the Company also had a $20,000 Noctiva related milestone payment as part of the Exclusive License and Assignment Agreement (ELAA) with Serenity Pharmaceuticals, LLC during the year ended December 31, 2018.

Cash used in investing activities of $15,698 for the year ended December 31, 2017 increased $20,932 compared to the same prior year period. In 2017 the Company generated cash of $38,004 from the sale of marketable securities compared to cash used for the purchase of marketable securities in 2016 of $36,057. Additionally, the Company used $53,111 of cash in 2017 to license Noctiva.

Financing Activities

Cash provided by financing activities of $112,659 for the year ended December 31, 2018 increased $135,977 compared to cash used in financing activities of $23,318 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.

Cash used in financing activities of $23,318 for the year ended December 31, 2017 decreased $15,364 compared to the same prior year period. The increase was primarily attributable to our use of $22,361 in cash for share repurchases during 2017, that did not occur in 2016.

Share Repurchase Program

In March 2017, the Board of Directors approved an authorization to repurchase up to $25,000 of Avadel ordinary shares represented by ADSs in the open market with an indefinite duration. 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 2023 Notes offering completed on February 16, 2018. On March 27, 2018, the Board of Directors authorized a share

repurchase program of up to $7,000 of Avadel ordinary shares represented by ADSs. Each of these programs has been completed through the date of this report.

Liquidity and Risk Management

The adequacy of our cash resources depends on the outcome of certain business conditions including the funding required and timing to complete our FT218 development program, the ultimate resolution associated with the exit of Noctiva and other factors set forth in "Risk Factors". The FT218 development program will require us to commit substantial resources. Our cash and marketable securities is anticipated to be sufficient to fund operations into 2021. This is based on the current level of cash and marketable securities, the full year run rate of anticipated cost reductions resulting from our recent restructuring actions of $80 to $90 million and long-range revenue projections for our sterile hospital injectable products. Our assumptions concerning our long range revenue forecast, the ultimate success of our restructuring actions, the timing, outcome and ultimate cost to complete the FT218 development program may prove to be wrong or other factors may adversely affect our business. The outcome of these and other other business conditions, could exhaust or significantly decrease our available cash and marketable securities which could, among other things, force us to raise additional funds and/or force us to further reduce our cost structure, 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.

Other Matters

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, 2018 and December 31, 2017, 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.

Some of the patents covering our 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 (the "Ferring Litigation"), 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. Avadel's indirectly wholly owned subsidiary, Specialty Pharma and certain other parties including Serenity Pharmaceuticals, LLC ("Serentiy") (the licensor of the Noctiva Patents) have been actively defending this litigation, and have made certain 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 has 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. Adverse outcomes from this litigation could have material adverse effects on the value of the Specialty Pharma's license to Noctiva™.

On January 21, 2019, Serenity provided notice to Specialty Pharma of an alleged breach of the parties' Noctiva license agreement. Serenity alleges principally 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. Adverse outcomes from this potential litigation could have material adverse effects on the financial position of Specialty Pharma.

On February 6, 2019, Specialty Pharma commenced a Chapter 11 bankruptcy case under the U.S. Bankruptcy Code to fulfill its strategic objective of divesting from the business of marketing and distributing Noctiva™. As a result of the commencement of the bankruptcy case, all pending litigation against Specialty Pharma is automatically stayed and will remain stayed during the pendency of the Chapter 11 case unless and until the bankruptcy court enters an order modifying or lifting the stay. The automatic stay of the bankruptcy code also precludes the commencement of any new litigation against Specialty Pharma unless the bankruptcy court orders otherwise. See Part I, Item 3 of this Annual Report on Form 10-K for more discussion.

Material Commitments

At December 31, 2018, the Company has 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:

Purchase Commitments:	**Balance**
2019	$ 10,754
2020	5,948
2021	4,880
2022	4,880
2023	220
Thereafter	—
Total	$ 26,682

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, 2018. Subsequent to the initial build and preparation of the production suite, this commitment also includes annual production suite fees of approximately $3,000 to $4,000 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.

Included in the purchase commitments above, is approximately $15,308 of an obligation of Specialty Pharma, which on February 6, 2019, filed for Chapter 11 bankruptcy protection.

The Company and our subsidiaries lease office facilities under noncancelable operating leases expiring at various dates. Rent expense, net of rental income, was $1,213, $1,146 and $970 in 2018, 2017, and 2016, respectively. Minimum rental commitments for non-cancelable leases in effect at December 31, 2018 are as follows:

Lease Commitment:	**Balance**
2019	$ 1,191
2020	1,208
2021	1,008
2022	767
2023	695
Thereafter	967
Total	$ 5,836

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, long-term related party payable, and post-retirement benefit plan obligations which are disclosed in *Item 8. Financial Statements and Supplementary Data*, *Note 10: Long-Term Debt*, *Note 11: Long-Term Related Party Payable*, and *Note 13: Post-Retirement Benefit Plans*, respectively.

Aggregate Contractual Obligations

The following table presents contractual obligations of the Company at December 31, 2018:

	Payments Due by Period				
Contractual Obligations:	**Total**	**Less than 1 Year**	**1 to 3 Years**	**3 to 5 Years**	**More than 5 Years**
Long-term debt and interest	$ 173,009	$ 6,575	$ 12,981	$ 153,453	$ —
Long-term related party payable (undiscounted)	51,284	9,439	8,713	7,250	25,882
Purchase commitments	26,682	10,754	10,828	5,100	—
Operating leases	5,836	1,191	2,217	1,461	967
Total contractual cash obligations	$ 256,811	$ 27,959	$ 34,739	$ 167,264	$ 26,849

Included in the purchase commitments total above, is approximately $15,308 of an obligation of Specialty Pharma, which on February 6, 2019, filed for Chapter 11 bankruptcy protection.

See *Note 10: Long-Term Debt* and *Note 11: Long-Term Related Party Payable* to the Company's consolidated financial statements contained in Item 8 – Financial Statements for obligations with respect to the respective items within the above table.

See *Note 13: Post-Retirement Benefit Plans* to the Company's consolidated financial statements contained in Item 8 – Financial Statements for obligations with respect to the Company's post-retirement benefit plans. Obligations of $1,024 related to the post-retirement benefit plans are not included within the above table.

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

Interest Rate Risk

The Company is subject to interest rate risk as a result of our portfolio of marketable securities. The primary objectives of our investment policy are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and competitive yield. Although our investments are subject to market risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or certain types of investment. Our investment policy allows us to maintain a portfolio of cash equivalents and marketable securities in a variety of instruments, including U.S. federal government and federal agency securities, European Government bonds, corporate bonds or commercial paper issued by U.S. or European corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, tax-exempt obligations of states, agencies, and municipalities in the U.S and Europe, and equities.

Foreign Exchange Risk

We are exposed to foreign currency exchange risk as the functional currency financial statements of a foreign subsidiary is translated to U.S. dollars. The assets and liabilities of this foreign 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 foreign 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 foreign subsidiaries that have functional currencies denominated in the euro as of December 31, 2018 would have had an immaterial impact on net loss for the year ended December 31, 2018.

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, 2018, 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, 2018.

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,		
	2018	**2017**	**2016**
Revenues:			
Product sales	$ 101,423	$ 172,841	$ 147,222
License revenue	1,846	404	3,024
Total revenues	103,269	173,245	150,246
Operating expenses:			
Cost of products	17,516	16,301	13,248
Research and development expenses	39,329	33,418	34,611
Selling, general and administrative expenses	100,359	58,860	44,179
Intangible asset amortization	6,619	3,659	13,888
(Gain) loss - changes in fair value of related party contingent consideration	(22,731)	(31,040)	49,285
Impairment of intangible asset	66,087	—	—
Restructuring costs	1,016	2,542	—
Total operating expenses	208,195	83,740	155,211
Operating (loss) income	(104,926)	89,505	(4,965)
Investment and other income, net	452	2,136	2,758
Interest expense	(10,622)	(1,052)	(963)
Other income (expense) - changes in fair value of related party payable	1,899	2,071	(6,548)
(Loss) income before income taxes	(113,197)	92,660	(9,718)
Income tax (benefit) provision	(17,893)	24,389	31,558
Net (loss) income	$ (95,304)	$ 68,271	$ (41,276)
Net (loss) income per share - basic	$ (2.55)	$ 1.69	$ (1.00)
Net (loss) income per share - diluted	$ (2.55)	$ 1.63	$ (1.00)
Weighted average number of shares outstanding - basic	37,325	40,465	41,248
Weighted average number of shares outstanding - diluted	37,325	41,765	41,248

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2018	**2017**	**2016**
Net (loss) income	$ (95,304)	$ 68,271	$ (41,276)
Other comprehensive income (loss), net of tax:			
Foreign currency translation (loss) gain	(419)	134	(1,024)
Net other comprehensive income, net of ($18), $28, $16 tax, respectively	269	165	116
Total other comprehensive (loss) income, net of tax	(150)	299	(908)
Total comprehensive (loss) income	$ (95,454)	$ 68,570	$ (42,184)

See accompanying notes to consolidated financial statements.

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

	December 31,	
	2018	**2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,325	$ 16,564
Marketable securities	90,590	77,511
Accounts receivable	11,330	14,785
Inventories, net	4,770	6,157
Prepaid expenses and other current assets	8,836	8,958
Total current assets	124,851	123,975
Property and equipment, net	1,911	3,001
Goodwill	18,491	18,491
Intangible assets, net	1,629	92,289
Research and development tax credit receivable	7,272	5,272
Other non-current assets	36,146	10,249
Total assets	$ 190,300	$ 253,277
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 106	$ 111
Current portion of long-term related party payable	9,439	25,007
Accounts payable	3,503	7,477
Deferred revenue	114	2,007
Accrued expenses	21,695	50,926
Income taxes	73	414
Other current liabilities	3,453	597
Total current liabilities	38,383	86,539
Long-term debt, less current portion	115,734	156
Long-term related party payable, less current portion	19,401	73,918
Other non-current liabilities	14,002	7,084
Total liabilities	187,520	167,697
Shareholders' equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; none issued or outstanding at December 31, 2018 and December 31, 2017, respectively	—	—
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 42,720 issued and 37,313 outstanding at December 31, 2018, and 41,463 issued and 39,346 outstanding at December 31, 2017	427	414
Treasury shares, at cost, 5,407 and 2,117 shares held at December 31, 2018 and December 31, 2017, respectively	(49,998)	(22,361)
Additional paid-in capital	433,756	393,478
Accumulated deficit	(357,989)	(262,685)
Accumulated other comprehensive loss	(23,416)	(23,266)
Total shareholders' equity	2,780	85,580
Total liabilities and shareholders' equity	$ 190,300	$ 253,277

See accompanying notes to consolidated financial statements.

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

	Ordinary shares		Additional	Accumulated	Accumulated other comprehensive	Treasury Shares		Total shareholders'
	Shares	Amount	paid-in capital	deficit	(loss) income	Shares	Amount	equity
Balance, December 31, 2015	41,241	$ 6,331	$ 363,984	$ (278,524)	$ (22,657)	—	$ —	$ 69,134
Net loss	—	—	—	(41,276)	—	—	—	(41,276)
Other comprehensive loss	—	—	—	—	(908)	—	—	(908)
Subscription of warrants	—	—	326	—	—	—	—	326
Exercise of stock options or warrants	15	2	112	—	—	—	—	114
Vesting of restricted shares	115	18	(18)	—	—	—	—	—
Stock-based compensation expense	—	—	14,679	—	—	—	—	14,679
Cross-border merger nominal value adjustment	—	(5,937)	5,937	—	—	—	—	—
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	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	8,062	—	—	—	—	8,062
Share repurchases	—	—	—	—	—	2,117	(22,361)	(22,361)
Adjustment to accumulated deficit (see *Note 12: Income Taxes)*	—	—	—	(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
Stock-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

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities:			
Net (loss) income	$ (95,304)	$ 68,271	$ (41,276)
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization	7,430	4,883	14,489
Impairment of intangible asset	66,087	—	—
Amortization of premiums on marketable securities	2,823	732	918
Remeasurement of related party acquisition-related contingent consideration	(22,731)	(31,040)	49,285
Remeasurement of related party financing-related contingent consideration	(1,899)	(2,071)	6,548
Amortization of debt discount and debt issuance costs	4,830	—	—
Change in deferred tax and income tax deferred charge	(19,152)	3,556	(4,000)
Stock-based compensation expense	7,852	8,072	14,679
Other adjustments	1,365	(968)	(331)
Net changes in assets and liabilities			
Accounts receivable	3,452	3,054	(10,050)
Inventories, net	711	(2,899)	1,831
Prepaid expenses and other current assets	3,577	(3,741)	3,412
Research and development tax credit receivable	(2,545)	(3,141)	397
Accounts payable & other current liabilities	(2,032)	595	(434)
Deferred revenue	(1,892)	(216)	(2,923)
Accrued expenses	(10,640)	13,187	6,764
Accrued income taxes	(341)	(786)	1,778
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(19,468)	(31,636)	(20,252)
Royalty payments for related party payable in excess of original fair value	(2,838)	(4,429)	(2,469)
Other assets and liabilities	(2,001)	(4,761)	535
Net cash (used in) provided by operating activities	(82,716)	16,662	18,901
Cash flows from investing activities:			
Purchases of property and equipment	(178)	(591)	(1,201)
Acquisitions of businesses, including cash acquired and other adjustments	—	—	628
Purchase of intangible assets	(20,000)	(53,111)	—
Proceeds from sales of marketable securities	359,507	189,009	71,546
Purchases of marketable securities	(376,310)	(151,005)	(107,603)
Net cash used in investing activities	(36,981)	(15,698)	(36,630)
Cash flows from financing activities:			
Proceeds from debt issuance	143,750	—	—
Payments for debt issuance costs	(6,190)	—	—
Earn-out payments for related party contingent consideration	(645)	(1,246)	(6,892)
Royalty payments for related party payable	—	—	(1,225)
Exercise of warrants	2,911	—	—
Proceeds from issuance of ordinary shares and warrants	577	404	440
Share repurchases	(27,637)	(22,361)	—
Other financing activities, net	(107)	(115)	(277)
Net cash provided by (used in) financing activities	112,659	(23,318)	(7,954)
Effect of foreign currency exchange rate changes on cash and cash equivalents	(201)	(297)	(166)
Net change in cash and cash equivalents	(7,239)	(22,651)	(25,849)
Cash and cash equivalents at January 1	16,564	39,215	65,064
Cash and cash equivalents at December 31	$ 9,325	$ 16,564	$ 39,215
Supplemental disclosures of cash flow information:			
Income tax paid	$ 776	$ 19,143	$ 27,180
Interest paid	3,359	1,050	788

See accompanying notes to consolidated financial statements.

NOTE 1: Summary of Significant Accounting Policies

Nature of Operations. Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel," the "Company," "we," "our," or "us") is a branded specialty pharmaceutical company. Our primarily focus is 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 excessive daytime sleepiness (EDS) and cataplexy. In addition, we market three sterile injectable drugs used in the hospital setting which were developed under our "unapproved marketed drug" (UMD) program. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit www.avadel.com..

Our current marketed products include:

- *Akovaz*® (ephedrine sulfate injection, USP), 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

- *Bloxiverz*® (neostigmine methylsulfate injection), a cholinesterase inhibitor, is indicated for the reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery.

- *Vazculep*® (phenylephrine hydrochloride injection), an alpha-1 adrenergic receptor agonist indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

  Each of our *Akovaz*, *Bloxiverz* and *Vazculep* products is used primarily in the hospital setting and was developed under our UMD program.

- *Noctiva*™, a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. Due to disappointing results after a substantial investment of resources after *Noctiva's* commercial launch in March 2018, Avadel Specialty Pharmaceuticals LLC, ("Specialty Pharma"), the Avadel subsidiary responsible for the marketing and sale of *Noctiva*, made a voluntary filing for Chapter 11 bankruptcy protection on February 6, 2019. Although Specialty Pharma currently continues its marketing and sales efforts for this product, Avadel anticipates that Specialty Pharma will discontinue all activities with respect to *Noctiva* during 2019 as a result of the bankruptcy.

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, United States, and Lyon, France.

The Company is the successor to Flamel Technologies S.A., a French *société anonyme* ("Flamel"), as the result of the Merger described above, in which Flamel merged with and into the Company at 11:59:59 p.m., Central Europe Time, on December 31, 2016 (the "Merger") pursuant to the agreement between Flamel and Avadel entitled Common Draft Terms of Cross-Border Merger dated as of June 29, 2016 (the "Merger Agreement"). Immediately prior to the Merger, the Company was a wholly owned subsidiary of Flamel. In accordance with the Merger Agreement, as a result of the Merger:

- Flamel ceased to exist as a separate entity and the Company continued as the surviving entity and assumed all of the assets and liabilities of Flamel.

- our authorized share capital is $5,500 divided into 500,000 ordinary shares with a nominal value of $0.01 each and 50,000 preferred shares with a nominal value of $0.01 each

    - all outstanding ordinary shares of Flamel, €0.122 nominal value per share, were canceled and exchanged on a one-for-one basis for newly issued ordinary shares of the Company, $0.01 nominal value per share. This change in nominal value of our outstanding shares resulted in our reclassifying $5,937 on our balance sheet from ordinary shares to additional paid-in capital

    - our Board of Directors is authorized to issue preferred shares on a non-pre-emptive basis, for a maximum period of five years, at which point such an authorization may be renewed by shareholders. The Board of Directors has discretion to dictate terms attached to the preferred shares, including voting, dividend, conversion rights, and priority relative to other classes of shares with respect to dividends and upon a liquidation.

- all outstanding American Depositary Shares (ADSs) representing ordinary shares of Flamel were canceled and exchanged on a one-for-one basis for ADSs representing ordinary shares of the Company.

Thus, the Merger changed the jurisdiction of our incorporation from France to Ireland, and an ordinary share of the Company held (either directly or represented by an ADS) immediately after the Merger continued to represent the same proportional interest in our equity owned by the holder of a share of Flamel immediately prior to the Merger.

Prior to completion of the Merger, the Flamel ADSs were listed on the Nasdaq Global Market ("Nasdaq") under the trading symbol "FLML"; and immediately after the Merger the Company's ADSs were listed for and began trading on Nasdaq on January 3, 2017 under the trading symbol "AVDL."

Further details about the reincorporation, the Merger and the Merger Agreement are contained in our definitive proxy statement filed with the SEC on July 5, 2016.

Under Irish law, the Company can only pay dividends and repurchase shares out of distributable reserves, as discussed further in the Company's proxy statement filed with the SEC as of July 5, 2016. Upon completion of the Merger, the Company did not have any distributable reserves. On February 15, 2017, the Company filed a petition with the High Court of Ireland seeking the court's confirmation of a reduction of the Company's share premium so that it can be treated as distributable reserves for the purposes of Irish law. On March 6, 2017, the High Court issued its order approving the reduction of the Company's share premium by $317,254 which can be treated as distributable reserves.

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

Our results of operations for the period January 1, 2018 through February 16, 2018 and for the years ended December 31, 2017 and 2016 include the results of FSC Therapeutics and FSC Laboratories, Inc., (collectively "FSC"), prior to its February 16, 2018 disposition date. See *Note 16: Divestiture of the Pediatric Assets*, for additional information. All intercompany accounts and transactions have been eliminated.

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" 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 3: Revenue Recognition* for expanded disclosures related to this new pronouncement.

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

Product Sales

The Company sells products primarily through wholesalers and considers these wholesalers to be its customers. Revenue from product sales is recognized when the customer obtains control of the Company's product, which occurs typically upon receipt by the customer. As is customary in the pharmaceutical industry, the Company's 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.

For generic products and branded products where the ultimate net selling price to customer is estimable, the Company recognizes revenues upon delivery to the wholesaler. For new product launches the Company recognizes revenue if sufficient data is available to determine product acceptance in the marketplace such that product returns may be estimated based on historical or analog product data and there is probable evidence of reorders and consideration is made of wholesaler inventory levels. As part of the third quarter 2016 launch of Akovaz, the Company determined that sufficient data was available to determine the ultimate net selling price to the customer and therefore recognized revenue upon delivery to our wholesaler customers.

Prior to the second quarter 2016, the Company did not have sufficient historical or analog product data to estimate certain revenue deductions. As such, we could not accurately estimate the ultimate net selling price of our hospital portfolio of products and as a result delayed revenue recognition until the wholesaler sold the product through to end customers.

During the second quarter of 2016, it was determined that we now had sufficient evidence, history, data and internal controls to estimate the ultimate selling price of our products upon shipment from our warehouse to our customers, the wholesalers. Accordingly, we discontinued the sell-through revenue approach and now recognize revenue once the product is delivered to the wholesaler. As a result of this change in accounting estimate, we recognized $5,981 in additional revenue, or $0.05 per diluted share, for the twelve months ended December 31, 2016 that previously would have been deferred until sold by the wholesalers to the hospitals.

License Revenue

The Company from time to time may enter into out-licensing agreements under which it licenses to third parties certain rights to its products or intellectual property. The terms of these arrangements typically include payment to the Company 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 3: Revenue Recognition*.

Government Grants. The Company receives financial support for various research or investment projects from governmental agencies.

From time to time we receive funds, primarily from the French government, to finance certain R&D projects. These funds are repayable on commercial success of the project. In the absence of commercial success, the Company is released of our obligation to repay the funds and as such the funds are recognized in the consolidated statements of (loss) income as an offset to R&D expense. The absence of commercial success must be formally confirmed by the granting authority. Should the Company wish to discontinue the R&D to which the funding is associated, the granting authority must be informed and a determination made as to how much, if any, of the grant must be repaid.

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 stock-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.

The Company recognizes R&D tax credits received from the French 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 $17,562, $2,214 and $1,294 for the years ended December 31, 2018, 2017 and 2016, respectively.

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

Income Taxes. 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 income ("AOCI") in shareholders' equity, with the exception of 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. The Company has determined that we operate in a single segment and has a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is 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. The Company tests goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. During the fourth quarter of 2018, we performed our required annual impairment test of goodwill and have determined that no impairment of goodwill existed at December 31, 2018 or 2017.

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 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*). The Company had determined that no impairment existed at December 31, 2017.

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 11: Long-Term Related Party Payable* and *Note 16: 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 11: 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 11: 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 income (expense) - changes in fair value of related party payable.

Foreign Currency Translation. At December 31, 2018, the reporting currency of the Company and our wholly-owned subsidiaries is the U.S. dollar. Prior to December 31, 2016, each of the Company's non-U.S. subsidiaries and the parent entity, Flamel, used the Euro as their functional currency. At December 31, 2016, in conjunction with the Merger described above, Avadel determined the U.S. dollar is our functional currency. Subsidiaries and entities that do not use the U.S. dollar as their functional currency translate 1) profit and loss accounts at the average exchange rates during the reporting period, 2) assets and liabilities at period end exchange rates and 3) shareholders' equity accounts at historical rates. Resulting translation gains and losses are included as a separate component of shareholders' equity in accumulated other comprehensive loss. Assets and liabilities, excluding available-for-sale marketable securities, denominated in a currency other than the subsidiary's functional currency are translated to the subsidiary's functional currency at period end exchange rates with resulting gains and losses recognized in the consolidated statements of (loss) income.

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

NOTE 2: Effect of New Accounting Standards

Recently Adopted Accounting Guidance

In March 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2017-07, "Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Costs." The standard requires the service component of pension and other postretirement benefit expense to be presented in the same statement

of income lines as other employee compensation costs, however, the other components will be presented outside of operating income. In addition, only the service cost component will be eligible for capitalization in assets. The Company adopted this standard in the first quarter of 2018 and it had an immaterial impact on our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, "*Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*." ASU 2016-15 identifies how certain cash receipts and cash payments are presented and classified in the Statement of Cash Flows under Topic 230. ASU 2016-15 is effective for the Company for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. ASU 2016-15 should be applied retrospectively and early adoption is permitted, including adoption in an interim period. The Company adopted this standard in the first quarter of 2018 and it had an immaterial impact on our consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09 "*Revenue from Contracts with Customers*" which supersedes the most current revenue recognition requirements. This ASU requires entities to recognize revenue in a way that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services. Through May 2016, the FASB issued ASU 2016-08 "Principal versus Agent Considerations (Reporting Revenue Gross versus Net)," ASU 2016-10 "Identifying Performance Obligations and Licensing," and ASU 2016-12, "Narrow-Scope Improvements and Practical Expedients," which provide supplemental adoption guidance and clarification to ASU 2014-09, respectively. The Company adopted this pronouncement under the modified retrospective method of transition in the first quarter of 2018. The adoption of the new standard did not have a material effect on the overall timing or amount of revenue recognized when compared to current accounting standards. The impact to the Company of adopting the new revenue standard primarily relates to additional and expanded disclosures. See *Note 3: Revenue Recognition*.

In January 2016, the FASB issued ASU 2016-01, "*Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*." The amendments in this update address certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The new guidance required the change in fair value of equity investments with readily determinable fair values to be recognized through the statement of income. Upon adoption, the change in the fair value of our available-for-sale equity investments is recognized in our consolidated statement of income (loss) rather than as a component of our consolidated statement of comprehensive income (loss). The Company adopted this standard in the first quarter of 2018 and it had an immaterial impact on our consolidated financial statements.

Recent Accounting Guidance Not Yet Adopted

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.

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. The Company will assess the timing of adoption and impact of this guidance to future impairment considerations.

In February 2016, the 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.

On adoption, the Company currently expects to recognize additional operating liabilities of approximately $5,100, with corresponding Right of Use (ROU) assets of approximately the same amount based on the present value of the remaining minimum rental payments. The new standard also provides practical expedients for a company's ongoing accounting. We currently expect to elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term

leases of those assets in transition. We also currently expect to elect the practical expedient to not separate lease and non-lease components for all of our leases.

NOTE 3: 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 is generally realized or realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the seller's price to the buyer is fixed or determinable, and collectability is 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 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.

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 results in license revenues.

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, the Company recognizes 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 21: Company Operations by Product, Customer and Geography.*

Contract Balances

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

A receivable is recognized in the period the Company sells its products and when the Company's right to consideration is unconditional. See the consolidated balance sheets for the balance of accounts receivable at December 31, 2018.

See below for contract liability discussion and balance related to a license agreement.

There were no material deferred contract costs at December 31, 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 2018 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, the Company 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, 2018, the deferred revenue balance related to this obligation is $0.

The Company has elected certain of the practical expedients from the disclosure requirement for remaining performance obligations for specific situations in which an entity need not estimate variable consideration to recognize revenue. Accordingly, the Company

applies the practical expedient in ASC 606 to its stand-alone contracts and does not disclose information about variable consideration from remaining performance obligations for which the Company recognizes revenue.

NOTE 4: Fair Value Measurements

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

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

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

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

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

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

	As of December 31, 2018			As of December 31, 2017		
Fair Value Measurements:	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Marketable securities (see *Note 5)*						
Equity securities	$ 9,145	$ —	$ —	$ 468	$ —	$ —
Money market funds	52,996	—	—	44,481	—	—
Corporate bonds	—	6,339	—	—	9,262	—
Government securities - U.S.	—	12,701	—	—	19,050	—
Other fixed-income securities	—	9,409	—	—	4,250	—
Total assets	$ 62,141	$ 28,449	$ —	$ 44,949	$ 32,562	$ —
Related party payable (see *Note 11)*	—	—	28,840	—	—	98,925
Total liabilities	$ —	$ —	$ 28,840	$ —	$ —	$ 98,925

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, 2018, there were no transfers in and out of Level 1, 2, or 3. During the twelve months ended December 31, 2018, 2017 and 2016, 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, 2018 based on recent trading activity was $81,490 compared to a book value of $115,691.

Additionally, the Company's other debt is reflected in the balance sheet at carrying value, which approximates fair value, as these represent non-interest bearing grants from the French government and are repayable only if the research project is technically or commercially successful.

See *Note 10: Long-Term Debt* for additional information regarding our debt obligations.

NOTE 5: Marketable Securities

The Company has 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 income (loss). For the year ended December 31, 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 $956. The net unrealized gain on our available-for-sale equity investments was immaterial for the year ended December 31, 2017 and $344 for the year ended December 31, 2016. These amounts were recorded as other comprehensive income in shareholders' equity, net of income tax effects for the year ended December 31, 2017.

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, 2018 and 2017, respectively:

	2018			
Marketable Securities:	**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

	2017			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Equity securities	$ 443	$ 31	$ (6)	$ 468
Money market funds	44,525	—	(44)	44,481
Corporate bonds	9,285	1	(24)	9,262
Government securities - U.S.	19,080	—	(30)	19,050
Other fixed-income securities	4,259	—	(9)	4,250
Total	$ 77,592	$ 32	$ (113)	$ 77,511

We determine realized gains or losses on the sale of marketable securities on a specific identification method. We recognized gross realized gains of $317, $1,677, and $1,265 for the twelve months ended December 31, 2018, 2017, and 2016, respectively. These realized gains were offset by realized losses of $565, $1,390, and $586 for the twelve-months ended December 31, 2018, 2017, and 2016, 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, 2018:

	Maturities				
Marketable Debt Securities:	**Less than 1 Year**	**1-5 Years**	**5-10 Years**	**Greater than 10 Years**	**Total**
Corporate bonds	$ 1,511	$ 4,828	$ —	$ —	$ 6,339
Government securities - U.S.	771	11,145	281	504	12,701
Other fixed-income securities	—	9,409	—	—	9,409
Total	$ 2,282	$ 25,382	$ 281	$ 504	$ 28,449

The Company has 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 6: Inventories

The principal categories of inventories, net reserves of $4,757 and $1,039 at December 31, 2018 and 2017, respectively, are comprised of the following:

Inventory:	**2018**	**2017**
Finished goods	$ 4,270	$ 4,774
Raw materials	500	1,383
Total	$ 4,770	$ 6,157

Total net reserves increased by $3,718 during the year ended December 31, 2018 driven largely by approximately $2,583 of reserves related to Noctiva inventory.

NOTE 7: Property and Equipment, net

The principal categories of property and equipment, net at December 31, 2018 and 2017, respectively, are as follows:

Property and Equipment, net:	**2018**	**2017**
Laboratory equipment	$ 8,864	$ 10,135
Software, office and computer equipment	2,487	3,115
Furniture, fixtures and fittings	3,715	4,779
Less - accumulated depreciation	(13,155)	(15,028)
Total	$ 1,911	$ 3,001

Depreciation expense for the years ended December 31, 2018, 2017 and 2016 was $811, $1,224 and $601, respectively.

NOTE 8: Acquisitions

On February 5, 2016, the Company acquired 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 CSF”), a related party. The Company disposed of these pediatric assets on February 16, 2018. See *Note 16: Divestiture of the Pediatric Assets*.

This acquisition was accounted for using the acquisition method of accounting and, accordingly, its results were included in the Company’s consolidated financial statements from the date of acquisition until the date of divestiture. Total consideration to acquire FSC was $21,659, and was funded with a combination of the following, partially offset by $467 as a result of a net working capital settlement from the seller:

- $15,000 long-term liability to Deerfield CSF. Under the terms of the acquisition agreement, the Company will pay $1,050 annually for five years with a final payment in January 2021 of $15,000.
- an estimate of $6,659 in contingent consideration to Deerfield CSF. Under the terms of the acquisition agreement, the Company shall pay quarterly a 15% royalty on the net sales of certain FSC products, up to $12,500 for a period not exceeding ten years.

These items were reported in related party payable within the Company's consolidated balance sheet at December 31, 2017, and is further disclosed in *Note 11: Long-Term Related Party Payable*. These related party payables were disposed of as a part of the February 2018 sale. *See Note 16: Divestiture of the Pediatric Assets*.

The fair values assigned to the acquired assets and liabilities were recognized as follows:

Assigned Fair Value:	**Amount**
Accounts receivable	$ 142
Inventories	1,135
Prepaid expenses and other current assets	1,712
Intangible assets:	
Acquired product marketing rights	16,600
Acquired developed technology	4,300
Deferred tax assets	853
Other assets	277
Accounts payable and other liabilities	(3,827)
Total	$ 21,192

A portion of the transaction attributable to certain intangible assets was taxable for income tax purposes which resulted in recording some of the assets at fair value for both book and tax purposes. Transaction expenses were not material. The useful lives on FSC acquired intangible assets ranged from nine to fifteen years.

After its acquisition on February 5, 2016, FSC contributed $5,985 to the Company's net sales for the twelve-month period ended December 31, 2016. FSC incurred a loss of $5,839 for the twelve-month period ended December 31, 2016.

Had the FSC acquisition been completed as of the beginning of 2016, the Company's unaudited pro forma net revenue and net loss for the twelve months ended December 31, 2016 would have been as follows:

Pro Forma Net Revenue and Income (Loss):	**2016**
Net revenue	$ 150,721
Net loss	(42,290)

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. See *Note 16: Divestiture of the Pediatric Assets*.

NOTE 9: Goodwill and Intangible Assets

The Company's amortizable and unamortizable intangible assets at December 31, 2018 and 2017, respectively, are as follows:

	2018				2017		
Goodwill and Intangible Assets:	**Gross Value**	**Accumulated Amortization**	**Impairment**	**Net Carrying Amount**	**Gross Value**	**Accumulated Amortization**	**Net Carrying Amount**
Amortizable intangible assets:							
Acquired developed technology - Noctiva	$ 73,111	$ (7,024)	$ (66,087)	$ —	$ 73,111	$ (1,401)	$ 71,710
Acquired developed technology - Vazculep	12,061	(10,432)	—	1,629	12,061	(9,616)	2,445
Acquired product marketing rights [1]	—	—	—	—	16,600	(2,132)	14,468
Acquired developed technology [1]	—	—	—	—	4,300	(634)	3,666
Total amortizable intangible assets	$ 85,172	$ (17,456)	$ (66,087)	$ 1,629	$ 106,072	$ (13,783)	$ 92,289
Unamortizable intangible assets:							
Goodwill	$ 18,491	$ —	$ —	$ 18,491	$ 18,491	$ —	$ 18,491
Total unamortizable intangible assets	$ 18,491	$ —	$ —	$ 18,491	$ 18,491	$ —	$ 18,491

[1] These intangible assets were purchased by the buyer as part of the disposition of the pediatrics products on February 16, 2018. See *Note 16: Divestiture of the Pediatric Assets*.

The Company recorded amortization expense related to amortizable intangible assets of $6,619, $3,659 and $13,888 for the years ended December 31, 2018, 2017 and 2016, respectively.

During the year ended December 31, 2017, the Company acquired $73,111 in developed technology as part of the Exclusive License and Assignment Agreement (ELAA) with Serenity Pharmaceuticals, LLC. The aggregate cost was composed of an upfront payment of $50,000, an accrued payment of $20,000 which was paid for Noctiva during the year ended December 31, 2018, and $3,111 of transaction costs. The Company amortizes the developed technology over a 13 year period, which began October 1, 2017. 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, the Company 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 the Company recorded a full impairment charge of $66,087 at December 31, 2018 related to the acquired developed technology associated with Noctiva. The February 6, 2019 Chapter 11 bankruptcy filing of Specialty Pharma, the subsidiary which markets, sells and distributes 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, 2018, total future amortization of intangible assets for the next five years is as follows:

Estimated Amortization Expense:	**Amount**
2019	$ 815
2020	814
2021	—
2022	—
2023	—

NOTE 10: Long-Term Debt

Long-Term debt is summarized as follows:

	December 31, 2018	December 31, 2017
Principal amount of 4.50% exchangeable senior notes due 2023	$ 143,750	$ —
Less: unamortized debt discount and issuance costs, net	(28,059)	—
Net carrying amount of liability component	115,691	—
Other debt	149	267
Subtotal	115,840	267
Less: current maturities	(106)	(111)
Long-term debt	$ 115,734	$ 156

Equity component:		
Equity component of exchangeable notes, net of issuance costs	$ (26,699)	$ —

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.

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

Other Debt

French government agencies provide financing to French companies for R&D. At December 31, 2018 and 2017, the Company had outstanding loans of $149 and $267, respectively for various programs. These loans do not bear interest and are repayable only in the event the research project is technically or commercially successful. Potential repayment is scheduled to occur through 2019.

During the years ended December 31, 2018, 2017 and 2016, the Company repaid $193, $115 and $277, of loans associated with specific research projects, respectively. In addition, during 2017, the Company received a waiver of repayment for the remaining portion of certain loans of $539, on the basis of limited commercial and technical success. Amounts waived are reported as reductions to R&D expenses in the Company's consolidated statements of (loss) income. No such waivers were received during 2018 or 2016.

NOTE 11: 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, 2018 and 2017, respectively:

		Activity during the Twelve Months Ended December 31, 2018					
			Changes in Fair Value of Related Party Payable				
	Balance, December 31, 2017	Payments to Related Parties	Operating (Gain) Expense	Other Income	Expiration of Warrants	Disposal	Balance, December 31, 2018
Acquisition-related contingent consideration:							
Warrants - Éclat Pharmaceuticals [a]	$ 2,479	$ —	$ (312)	$ —	$ (2,167)	$ —	$ —
Earn-out payments - Éclat Pharmaceuticals [b]	67,744	(19,468)	(22,661)	—	—	—	25,615
Royalty agreement - FSC [c]	5,740	(645)	242	—	—	(5,337)	—
Financing-related:							
Royalty agreement - Deerfield [d]	5,392	(1,922)	—	(1,286)	—	—	2,184
Royalty agreement - Broadfin [e]	2,570	(916)	—	(613)	—	—	1,041
Long-term liability - FSC [f]	15,000	—	—	—	—	(15,000)	—
Total related party payable	98,925	$ (22,951)	$ (22,731)	$ (1,899)	$ (2,167)	$ (20,337)	28,840
Less: Current portion	(25,007)						(9,439)
Total long-term related party payable	$ 73,918						$ 19,401

Each of the above items is associated with related parties as further described in *Note 22: Related Party Transactions.*

(a) As part of the consideration for the Company's acquisition of Éclat Pharmaceuticals, LLC on March 13, 2012, the Company issued two warrants to a related party with a six-year term which allow for the purchase of a combined total of 3,300 ordinary shares of Avadel. One warrant was exercisable for 2,200 ordinary shares at an exercise price of $7.44 per share, and the other warrant was exercisable for 1,100 ordinary shares at an exercise price of $11.00 per share. On February 23, 2018, the related party exercised in full the warrant for 2,200 ordinary shares. On March 12, 2018, the remaining warrant for 1,100 ordinary shares expired worthless.

The fair value of the warrants was estimated on a quarterly basis using a Black-Scholes option pricing model with the following assumptions as of December 31:

Assumptions for the Warrant Valuation:	2017
Stock price	$ 8.20
Weighted average exercise price per share	8.63
Expected term (years)	0.25
Expected volatility	37.90%
Risk-free interest rate	1.39%
Expected dividend yield	—

These Black-Scholes 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. The fair value of the warrant consideration is most sensitive to movement in the Company's share price and expected volatility at the balance sheet date.

Expected term: The expected term of the options or warrants represents the period of time between the grant date and the time the options or warrants are either exercised or forfeited, including an estimate of future forfeitures for outstanding options or warrants. Given the limited historical data and the grant of stock options and warrants 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.

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

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

At the closing date of the 2012 Éclat acquisition and at December 31, 2017, it was uncertain whether the Company would ultimately fulfill its obligation under these warrants using ordinary shares or cash. Accordingly, pursuant to the guidance of ASC 480, the Company determined that these warrants should be classified as a liability. This classification as a liability was further supported by the Company's determination, pursuant to the guidance of ASC 815-40-15-7(i), that these warrants could also not be considered as being indexed to the Company's own ordinary shares, on the basis that the exercise price for the warrants is determined in U.S. dollars, although the functional currency of the Company at the closing date of the Éclat acquisition was the Euro.

(b) 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.

(c) In February 2016, the Company acquired all of the membership interests of FSC from Deerfield. The consideration for this transaction in part included a commitment to pay quarterly a 15% royalty on the net sales of certain FSC products, up to $12,500 for a period not exceeding ten years. This obligation was assumed by the buyer as part of the disposition of the pediatrics products on February 16, 2018. *See Note 16: Divestiture of the Pediatric Assets.*

(d) 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 Eclat products.

(e) 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.

(f) In February 2016, the Company acquired all of the membership interests of FSC from Deerfield. The consideration for this transaction in part consisted of payments totaling $1,050 annually for five years with a final payment in January 2021 of $15,000. Substantially all of FSC's, and its subsidiaries, assets were pledged as collateral under this agreement. This obligation was assumed by the buyer as part of the disposition of the pediatrics products on February 16, 2018. *See Note 16: Divestiture of the Pediatric Assets.*

At December 31, 2018, the fair value of each related party payable listed in (b), (d) and (e) 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 15%. 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 - changes in fair value of related party payable" for items (d) and (e) 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.

The Company has chosen to make a fair value election pursuant to ASC 825, "Financial Instruments" for its royalty agreements detailed in items (d) and (e) 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 – 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, 2018, 2017 and 2016:

Related Party Payable:	Balance
Balance at December 31, 2015	$ 122,693
Additions [2]	21,659
Payments of related party payable	(30,838)
Fair value adjustments [1]	55,833
Balance at December 31, 2016	169,347
Payments of related party payable	(37,311)
Fair value adjustments [1]	(33,111)
Balance at December 31, 2017	98,925
Payments of related party payable	(22,951)
Fair value adjustments [1]	(24,630)
Expiration of warrants	(2,167)
Disposition of the pediatrics assets	(20,337)
Balance at December 31, 2018	$ 28,840

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

[2] Relates to the acquisition of FSC. See items (c) and (f) above.

NOTE 12: Income Taxes

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

(Loss) Income Before Income Taxes:	2018	2017	2016
Ireland	$ (42,604)	$ (3,123)	$ (22,866)
United States	(70,340)	92,754	32,786
France	(253)	3,029	(19,638)
Total (loss) income before income taxes	$ (113,197)	$ 92,660	$ (9,718)

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

Income Tax (Benefit) Provision:	2018	2017	2016
Current:			
United States - Federal	$ —	$ 18,064	$ 30,738
United States - State	330	331	1,081
France	—	265	5,267
Total current	330	18,660	37,086
Deferred:			
United States - Federal	(19,503)	4,686	(6,443)
United States - State	1,280	1,043	(23)
France	—	—	938
Total deferred	(18,223)	5,729	(5,528)
Income tax (benefit) provision	$ (17,893)	$ 24,389	$ 31,558

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

Reconciliation to Effective Income Tax Rate:	**2018**	**2017**	**2016**
Statutory tax rate	12.5 %	12.5 %	12.5 %
Differences in international tax rates	8.0 %	22.2 %	(31.9)%
Nondeductible changes in fair value of contingent consideration	4.0 %	(11.6)%	(165.0)%
Income tax deferred charge	— %	— %	(9.7)%
Change in valuation allowances	(5.3)%	(0.7)%	11.8 %
Nondeductible stock-based compensation	(1.3)%	(0.4)%	(14.8)%
Cross border merger	— %	0.3 %	(100.6)%
Unrealized tax benefits	(1.3)%	1.4 %	(15.2)%
State and local taxes (net of federal)	(0.3)%	0.3 %	(9.6)%
Change in U.S. tax law	(0.2)%	3.8 %	— %
Nondeductible interest expense	(1.1)%	— %	— %
Other	0.7 %	(1.5)%	(2.3)%
Effective income tax rate	15.7 %	26.3 %	(324.8)%

Income tax (benefit) provision - at statutory tax rate	$ (14,149)	$ 11,582	$ (1,215)
Differences in international tax rates	(9,039)	20,557	3,097
Nondeductible changes in fair value of contingent consideration	(4,559)	(10,779)	16,036
Income tax deferred charge	—	—	938
Change in valuation allowances	5,998	(610)	(1,143)
Nondeductible stock-based compensation	1,499	(375)	1,436
Cross-border merger	—	265	9,773
Unrecognized tax benefits	1,440	1,296	1,475
State and local taxes (net of federal)	299	252	934
Change in U.S. tax law	274	3,513	—
Nondeductible interest expense	1,269	—	—
Other	(925)	(1,312)	227
Income tax (benefit) provision - at effective income tax rate	$ (17,893)	$ 24,389	$ 31,558

In 2018, the income tax provision decreased by $42,282 when compared to the same period in 2017. 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 the decrease in taxable income in Ireland. 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.

In 2017, the income tax provision decreased by $7,169 when compared to the same period in 2016. 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. in 2017, when compared to 2016. In 2017, the Company did not incur any significant additional income tax provision associated with the Cross-Border Merger as a majority of the transaction was completed in 2016. In 2017, the Company recorded $3,513 of tax provision associated with the U.S. Tax Cuts and Jobs Act signed into law in the U.S. in December of 2017.

Unrecognized Tax Benefits

The Company or one of its subsidiaries files income tax returns in Ireland, France, U.S. and various states. With few exceptions, the Company is no longer subject to Irish, French, U.S. Federal, and state and local examinations for years before 2014. 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. 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	2018	2017	2016
Balance at January 1:	$ 3,954	$ 1,686	$ 448
Additions based on tax positions related to the current year	1,087	2,268	1,578
Increases (decreases) for tax positions of prior years	274	—	(340)
Balance at December 31:	$ 5,315	$ 3,954	$ 1,686

The Company does not expect within the next twelve months, as a result of activities performed in various jurisdictions, that the unrecognized tax benefits will change. However, interest and penalties could change by up to $500.

At December 31, 2018, 2017, and 2016, there are $4,597, $3,349, and $1,565 of unrecognized tax benefits that if recognized would affect the annual effective tax rate.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2018, 2017, and 2016, the Company recognized approximately $725, $304, and $26 in interest and penalties. The Company had approximately $1,057, and $331 for the payment of interest and penalties accrued at December 31, 2018, and 2017, 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, 2018 and 2017 resulted from the following temporary differences:

Net Deferred Tax Assets and Liabilities:	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 19,510	$ 9,831
Amortization	20,642	7,563
Stock based compensation	4,587	4,375
Fair value royalty agreements	—	635
Fair value contingent consideration	384	870
Other	479	406
Gross deferred tax assets	45,602	23,680
Deferred tax liabilities:		
Amortization	(308)	(2,419)
Accounts receivable	(661)	(936)
Prepaid expenses	(405)	(1,094)
Gross deferred tax liabilities	(1,374)	(4,449)
Less: valuation allowances	(21,199)	(15,354)
Net deferred tax assets	$ 23,029	$ 3,877

At December 31, 2018, the Company had $72,453 of net operating losses in Ireland and $3,259 of net operating losses in France that do not have an expiration date and $25,840 of net operating losses and carryforwards in the U.S. Of the $25,840 of net operating losses and carryforwards in the U.S., $10,365 were acquired due to the acquisition of FSC in 2016 and $15,475 is due to the losses and carryforwards generated at U.S. Holdings in 2018. 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. While the Company believes it is more likely than not that it will be able to realize the deferred tax assets in the U.S., the Company continues to monitor 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. 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 may not be fully utilized before they expire.

We recorded a valuation allowance against all of our net operating losses in Ireland and France as of both December 31, 2018, and December 31, 2017. We intend to continue maintaining a full valuation allowance on the Irish and French net operating losses until there is sufficient evidence to support the reversal of all or some portion of these allowances.

At December 31, 2018, the Company has unremitted earnings of $2,798 outside of Ireland as measured on a U.S. GAAP basis. Whereas the measure of earnings for purposes of taxation of a distribution may be different for tax purposes, these earnings, which are considered to be invested indefinitely, would become subject to income tax if they were remitted as dividends or if the Company were to sell 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, 2018, the Company's research tax credit receivable, net amounts to $7,555 and represents a French gross research tax credit of $6,922 and an Irish gross research tax credit of $633. As of December 31, 2017, the Company's net research tax credit receivable amounted to $5,272 and represented a French gross research tax credit of $4,754 and an Irish gross research tax credit of $518.

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, the Company 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, the Company 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 the Company will be able to utilize these benefits.

Cross-Border Merger

In 2016, we changed our jurisdiction of incorporation from France to Ireland by merging with and into our wholly owned Irish subsidiary. Information about the reincorporation was included in the definitive proxy statement filed with the Securities and Exchange Commission on July 5, 2016. Prior to the merger, the Company submitted a request to the French tax authorities seeking to benefit from a special regime for mergers and demergers, conditional upon a formal consent of the French tax authority, which would allow for the deferral of a portion of the tax cost of the cross-border merger. In 2017, the Company received a letter from the French tax authorities indicating that our request to benefit from the special regime had been declined. Completion of the cross-border merger resulted in the recognition of a net income tax provision of $4,266, after considering tax benefits from the utilization of current and prior year French net operating losses. The Company was able to utilize $4,266 of French research and development tax credits to offset the remaining cost of the transaction. The Company also removed $111,495 of French net operating losses as the carryforward of these losses was contingent on receiving favorable consent from the French tax authority. The French net operating losses had a full valuation allowance, resulting in no impact to the income tax provision from their removal.

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, the Company recognized a 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 are effective January 1, 2018.

NOTE 13: 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 these plans. (Income) expenses recognized for these plans were $(69) in 2018, $123 in 2017, and $348 in 2016. The 2018 and 2017 pension expense does not include the retirement indemnity curtailment gains of $148 and $717, respectively, which was associated with the reduction of certain defined benefit retirement plan liabilities due to the reduction in force. See *Note 17: Restructuring Costs - France* for more discussion.

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.

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:

Retirement Benefit Obligation Assumptions:	**2018**	**2017**	**2016**
Compensation rate increase	2.75%	3.00%	3.00%
Discount rate	1.50%	1.25%	1.31%
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:

Retirement Benefit Obligation Activity:	**2018**	**2017**
Retirement indemnity benefit obligation, beginning of year	$ 1,303	$ 2,431
Service cost	93	132
Interest cost	17	21
Plan amendment	—	(829)
Benefits paid	(12)	—
Curtailment gain	(148)	(717)
Actuarial loss	(178)	(25)
Exchange rate changes	(51)	290
Retirement indemnity benefit obligation, end of year	$ 1,024	$ 1,303

The lump sum retirement indemnity is accrued 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.

The future expected benefits to be paid over the next five years and for the five years thereafter is as follows for the years ended December 31:

Future Retirement Indemnity Benefit Obligation:	Balance
2019	$ —
2020	—
2021	—
2022	17
2023	—
Next five years	158
Total	$ 175

NOTE 14: Other Assets and Liabilities

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

Prepaid Expenses and Other Current Assets:	2018	2017
Valued-added tax recoverable	$ 1,378	$ 1,206
Prepaid and other expenses	2,145	7,106
Guarantee from Armistice (see *Note 16*)	534	—
Income tax receivable	921	518
Research and development tax credit receivable	283	—
Short-term deposit	3,350	—
Other	225	128
Total	$ 8,836	$ 8,958

Other Non-Current Assets:	2018	2017
Deferred tax assets	$ 23,029	$ 3,877
Long-term deposits	1,477	3,350
Guarantee from Armistice (see *Note 16*)	5,697	—
Right of use assets at contract manufacturing organizations	5,894	2,909
Other	49	113
Total	$ 36,146	$ 10,249

Accrued Expenses:	2018	2017
Accrued compensation	$ 3,971	$ 3,157
Accrued social charges	1,009	1,204
Accrued restructuring (see *Note 17*)	879	1,000
Customer allowances	6,541	10,613
Accrued ELAA payment	—	20,000
Accrued contract research organization charges	1,000	156
Accrued contract manufacturing organization costs	2,028	2,327
Accrued contract sales organization and marketing costs	3,469	7,641
Other	2,798	4,828
Total	$ 21,695	$ 50,926

Other Non-Current Liabilities:	2018	2017
Provision for retirement indemnity	$ 1,024	$ 1,303
Customer allowances	1,352	1,636
Unrecognized tax benefits	5,315	3,954
Guarantee to Deerfield (see *Note 16*)	5,717	—
Other	594	191
Total	$ 14,002	$ 7,084

NOTE 15: 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, 2018 and December 31, 2017, 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.

Some of the patents covering our 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 (the "Ferring Litigation"), 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. Avadel's indirectly wholly owned subsidiary, Specialty Pharma and certain other parties including Serenity Pharmaceuticals, LLC ("Serentiy") (the licensor of the Noctiva Patents) have been actively defending this litigation, and have made certain 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 has 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. Adverse outcomes from this litigation could have material adverse effects on the value of the Specialty Pharma's license to Noctiva™.

On January 21, 2019, Serenity provided notice to Specialty Pharma of an alleged breach of the parties' Noctiva license agreement. Serenity alleges principally 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. Adverse outcomes from this potential litigation could have material adverse effects on the financial position of Specialty Pharma.

On February 6, 2019, Specialty Pharma commenced a Chapter 11 bankruptcy case under the U.S. Bankruptcy Code to fulfill its strategic objective of divesting from the business of marketing and distributing Noctiva™. As a result of the commencement of the bankruptcy case, all pending litigation against Specialty Pharma is automatically stayed and will remain stayed during the pendency of the Chapter 11 case unless and until the bankruptcy court enters an order modifying or lifting the stay. The automatic stay of the bankruptcy code also precludes the commencement of any new litigation against Specialty Pharma unless the bankruptcy court orders otherwise. See Part I, Item 3 of this Annual Report on Form 10-K for more discussion.

Material Commitments

At December 31, 2018, the Company has 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:

Purchase Commitments:	**Balance**
2019	$ 10,754
2020	5,948
2021	4,880
2022	4,880
2023	220
Thereafter	—
Total	$ 26,682

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, 2018. Subsequent to the initial build and preparation of the production suite, this commitment also includes annual production suite fees of approximately $3,000 to $4,000 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.

Included in the purchase commitments above, is approximately $15,308 of an obligation of Specialty Pharma, which on February 6, 2019, filed for Chapter 11 bankruptcy protection.

For the year ended December 31, 2018, the Company paid $9,965 related to the above purchase commitments.

The Company and our subsidiaries lease office facilities under noncancelable operating leases expiring at various dates. Rent expense, net of rental income, was $1,213, $1,146 and $970 in 2018, 2017, and 2016, respectively. Minimum rental commitments for non-cancelable leases in effect at December 31, 2018 are as follows:

Lease Commitment:	**Balance**
2019	$ 1,191
2020	1,208
2021	1,008
2022	767
2023	695
Thereafter	967
Total	$ 5,836

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, long-term related party payable, and post-retirement benefit plan obligations which are disclosed in *Note 10: Long-Term Debt*, *Note 11: Long-Term Related Party Payable*, and *Note 13: Post-Retirement Benefit Plans*, respectively.

Contractual Obligations

The following table presents contractual obligations of the Company at December 31, 2018:

	Payments Due by Period				
Contractual Obligations:	**Total**	**Less than 1 Year**	**1 to 3 Years**	**3 to 5 Years**	**More than 5 Years**
Long-term debt and interest	$ 173,009	$ 6,575	$ 12,981	$ 153,453	$ —
Long-term related party payable (undiscounted)	51,284	9,439	8,713	7,250	25,882
Purchase commitments	26,682	10,754	10,828	5,100	—
Operating leases	5,836	1,191	2,217	1,461	967
Total contractual cash obligations	$ 256,811	$ 27,959	$ 34,739	$ 167,264	$ 26,849

Included in the purchase commitments total above, is approximately $15,308 of an obligation of Specialty Pharma, which on February 6, 2019, filed for Chapter 11 bankruptcy protection.

NOTE 16: 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 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.

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. At December 31, 2018, the carrying value of this liability was $6,253.

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. At December 31, 2018, the carrying value of this asset was $6,231.

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, 2017 and 2016 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 17: Restructuring Costs - France

During the first quarter of 2017, the Company announced a plan to reduce our workforce at our Venniseux, France site by approximately 50%. This reduction is 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 is substantially complete at December 31, 2018. Restructuring charges for the year ended December 31, 2018 of $1,016, include a provision related to a dispute with severed employees of $776 related to severance benefits and is also net of the curtailment gain of $148. Restructuring charges of $2,542 for the year ended December 31, 2017, are net of the curtailment gain of $717. The following table sets forth activities for the Company's cost reduction plan obligations for the year ended December 31, 2018:

Restructuring Obligation:	**2018**	**2017**
Balance of restructuring accrual at January 1,	$ 1,000	$ —
Charges for employee severance, benefits and other	1,164	3,259
Payments	(1,261)	(2,600)
Foreign currency impact	(24)	341
Balance of restructuring accrual at December 31,	$ 879	$ 1,000

The restructuring accrual at December 31, 2018 is included the consolidated balance sheet in accrued expenses.

NOTE 18: Equity Instruments and Stock-Based Compensation

Capital Stock

We have 500,000 shares of authorized ordinary shares with a nominal value of $0.01 per common share. As of December 31, 2018, we had 42,720 and 37,313 shares of 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 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 10: 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. As of December 31, 2018, the Company had repurchased 5,407 ordinary shares for $49,998.

Stock-Based Compensation

Compensation expense included in the Company's consolidated statements of (loss) income for all stock-based compensation arrangements was as follows for the periods ended December 31:

Stock-based Compensation Expense:	**2018**	**2017**	**2016**
Research and development	$ 880	$ 672	$ 3,523
Selling, general and administrative	6,972	7,400	11,156
Total stock-based compensation expense	$ 7,852	$ 8,072	$ 14,679

As of December 31, 2018, the Company expects $6,726 of unrecognized expense related to granted, but non-vested stock-based compensation arrangements to be incurred in future periods. This expense is expected to be recognized over a weighted average period of 2.3 years.

The excess tax benefit related to stock-based compensation recorded by the Company was $0 for the year ended December 31, 2018 and not material for the years ended December 31, 2017 and 2016.

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

At December 31, 2018, there were 1,873,147 shares authorized for stock option grants, warrant grants and restricted share award grants in subsequent periods.

Determining the Fair Value of Stock Options and Warrants

The Company measures the total fair value of stock options and warrants 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 or warrant 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 and warrant grants as of December 31, 2018, 2017 and 2016, are as follows:

Stock Option and Warrant Assumptions:	**2018**	**2017**	**2016**
Stock option grants:			
Expected term (years)	6.25	6.25	6.25
Expected volatility	56.59%	58.82%	58.39%
Risk-free interest rate	2.68%	2.20%	2.04%
Expected dividend yield	—	—	—
Warrant grants:			
Expected term (years)	—	0	2.50
Expected volatility	—%	—%	60.57%
Risk-free interest rate	—%	—%	0.82%
Expected dividend yield	—	—	—

Expected term: The expected term of the options or warrants represents the period of time between the grant date and the time the options or warrants are either exercised or forfeited, including an estimate of future forfeitures for outstanding options or warrants. Given the limited historical data and the grant of stock options and warrants 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: The Company has not distributed any dividends since our inception, and has no plan to distribute dividends in the foreseeable future.

Stock Options

A summary of the combined stock option activity and other data for the Company's stock option plans for the year ended December 31, 2018 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, 2018	5,041	$ 11.34		
Granted	138	6.67		
Exercised	(82)	6.52		
Forfeited	(428)	10.04		
Expired	(68)	12.41		
Stock options outstanding, December 31, 2018	4,601	$ 11.39	7.25 years	$ —
Stock options exercisable, December 31, 2018	3,005	$ 11.99	6.66 years	$ —

The aggregate intrinsic value of options exercisable at December 31, 2018, 2017 and 2016 was $0, $1,161, and $58, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2018, 2017 and 2016 was $3.60, $5.20 and $6.14 per share, respectively.

Warrants

A summary of the combined warrant activity and other data for the year ended December 31, 2018 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, 2018	894	$ 16.77		
Granted	—	—		
Exercised	—	—		
Forfeited	—	—		
Expired	(298)	14.87		
Warrants outstanding, December 31, 2018	596	$ 17.72	1.03 years	$ —
Warrants exercisable, December 31, 2018	596	$ 17.72	1.03 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, 2018, 2017 and 2016.

The weighted average grant date fair value of warrants granted during the year ended December 31, 2016 was $2.99 per share. There were no warrants granted during the years ended December 31, 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, LLC on March 13, 2012. These warrants are not considered stock-based compensation and are therefore excluded from the above tables, and instead are addressed within *Note 11: 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 prior to 2016 generally cliff vest at the end of a four-year vesting period, and are expensed over a two or four-year service period. Restricted share awards granted during 2016 are fully expensed at the date of grant as they contain no service requirement. Employees, however, have a two-year acquisition period from grant date and are then free to trade these awards. 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, 2018, 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, 2018	819	$ 11.51
Granted	279	5.87
Vested	(548)	12.78
Forfeited	(59)	8.95
Non-vested restricted share awards outstanding, December 31, 2018	491	$ 7.20

The weighted average grant date fair value of restricted share awards granted during the years ended December 31, 2018, 2017 and 2016 was $5.87, $8.95 and $12.11, 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. As of December 31, 2018, the Company has issued 25 ordinary shares to employees.

NOTE 19: Net (Loss) Income Per Share

Basic net (loss) income per share is calculated by dividing net (loss) income by the weighted average number of shares outstanding during each period. Diluted net (loss) income per share is calculated by dividing net (loss) income 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 employee stock purchase plan ("ESPP") and the exercise of contingent consideration warrants, all 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 or 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, is as follows:

Net (Loss) Income Per Share:	**2018**	**2017**	**2016**
Net (loss) income	$ (95,304)	$ 68,271	$ (41,276)
Weighted average shares:			
Basic shares	37,325	40,465	41,248
Effect of dilutive securities—employee and director equity awards outstanding and 2023 Notes	—	1,300	—
Diluted shares	37,325	41,765	41,248
Net (loss) income per share - basic	$ (2.55)	$ 1.69	$ (1.00)
Net (loss) income per share - diluted	$ (2.55)	$ 1.63	$ (1.00)

Potential common shares of 17,529, 6,368, and 8,564 were excluded from the calculation of weighted average shares for the years ended December 31, 2018, 2017 and 2016, respectively, because their effect was considered to be anti-dilutive. For the years ended December 31, 2018 and 2016, the effects of dilutive securities were entirely excluded from the calculation of net (loss) income per share as a net loss was reported in these periods.

NOTE 20: Comprehensive (Loss) Income

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

Accumulated Other Comprehensive (Loss) Income:	2018	2017	2016
Foreign currency translation adjustment:			
Beginning balance	$ (23,202)	$ (23,336)	$ (22,312)
Net other comprehensive (loss) income	(419)	134	(1,024)
Balance at December 31,	(23,621)	(23,202)	(23,336)
Unrealized gain (loss) on marketable securities, net			
Beginning balance	(64)	(229)	(345)
Net other comprehensive income, net of ($18), $28, $16, tax, respectively	269	165	116
Balance at December 31,	205	(64)	(229)
Accumulated other comprehensive loss at December 31,	$ (23,416)	$ (23,266)	$ (23,565)

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

The Company has 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 interim CEO. The interim 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, 2018, 2017, and 2016:

Revenue by Product:	2018	2017	2016
Bloxiverz	$ 20,850	$ 45,596	$ 82,896
Vazculep	42,916	38,187	39,796
Akovaz	33,759	80,617	16,831
Noctiva	1,204	—	—
Other	2,694	8,441	7,699
Total product sales	101,423	172,841	147,222
License revenue	1,846	404	3,024
Total revenues	$ 103,269	$ 173,245	$ 150,246

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, 2018, 2017, and 2016:

Revenue by Significant Customer:	2018	2017	2016
Customer A	$ 26,794	$ 44,762	$ 51,648
Customer B	25,413	37,965	39,359
Customer C	18,620	25,691	30,916
Customer D	9,653	53,342	17,728
Others	20,943	11,081	7,571
Total product sales	101,423	172,841	147,222
License revenue	1,846	404	3,024
Total revenues	$ 103,269	$ 173,245	$ 150,246

As of December 31, 2018, the Company had four customers, each of which are substantial wholesale distributors, and accounted for 10% or more of the accounts receivable balance. One customer accounted for 32%, or $3,571, a second customer accounted for 24% or $2,755, a third customer accounted for 24% or $2,789, and a fourth customer accounted for 10% or $1,174. As of December 31, 2018, 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, 2018, 2017, and 2016:

Revenue by Geographic Region:	2018	2017	2016
United States	$ 101,423	$ 172,841	$ 147,283
Ireland	1,846	404	2,963
Total revenues	$ 103,269	$ 173,245	$ 150,246

Currently we depend on a single contract manufacturing organization for the manufacture of Bloxiverz, Vazculep and Noctiva 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, 2018, 2017, and 2016:

Long-lived Assets by Geographic Region:	2018	2017	2016
United States	$ 27,761	$ 116,536	$ 42,021
France	1,365	2,257	2,524
Ireland	6,028	1,360	202
Total	$ 35,154	$ 120,153	$ 44,747

NOTE 22: 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. At December 31, 2018, 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"). 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. The Company has 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 their 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 16: Divestiture of the Pediatric Assets.* See *Note 16* for further discussion around the divestiture.

NOTE 23: Subsequent Events

Corporate Restructuring. In February 2019, Avadel announced a corporate restructuring in order to focus efforts and resources on the clinical development of FT218. In conjunction with the restructuring, Avadel will reduce its workforce by more than 50%, and Specialty Pharma made a voluntary filing for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code on February 6, 2019. As noted above, Specialty Pharma is a special-purpose entity and wholly-owned subsidiary responsible solely for the sales, marketing and distribution of *Noctiva*. These restructuring actions were taken to exit *Noctiva*™ quickly and efficiently, and are not expected to materially impact any other aspect of the Company's business, including the ability to operate its sterile injectables hospital business, complete the FT218 Phase 3 clinical trial, and complete development of the Company's fourth UMD product. The Company estimates that it will incur approximately $10 to $15 million of one-time pre-tax charges for severance and other costs related to the restructuring.

For the years ended December 31, 2018 and 2017, the Company generated sales of $1,204 and $0, respectively, and incurred selling, general and administrative expenses of $62,268 and $13,536, respectively and research and development expenses of $2,782 and $1,688, respectively, related to the Noctiva product.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Avadel Pharmaceuticals plc
Dublin, Ireland

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Avadel Pharmaceuticals plc and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of (loss) income, comprehensive (loss) income, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and financial statement schedule listed in 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, 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 15, 2019 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 15, 2019

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Avadel Pharmaceuticals plc
Dublin, Ireland

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Avadel Pharmaceuticals plc and subsidiaries (the "Company") as of December 31, 2018, 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, 2018, 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, 2018, of the Company and our report dated March 15, 2019 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 15, 2019

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, 2018. 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, 2018, the Company's internal control over financial reporting is effective based on those criteria.

Changes in Internal Control Over Financial Reporting

There have been no other changes in the Company's internal control over financial reporting (as defined by Rule 13a-15(f)) that occurred during the year ended December 31, 2018 that have materially affected the Company's 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 2019 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2018.

Item 11. Executive Compensation.

Information regarding Executive Compensation is hereby incorporated by reference to our Definitive 2019 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2018.

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 2019 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2018.

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 2019 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2018.

Item 14. Principal Accountant Fees and Services.

Information regarding Principal Accountant Fees and Services is hereby incorporated by reference to our Definitive 2019 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2018.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report:

1. *Financial Statements*

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

2. *Financial Statement Schedules*

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

Schedule II

Valuation and Qualifying Accounts

(In thousands)

Deferred Tax Asset Valuation Allowance:	Balance, Beginning of Period	Additions (a)	Deductions (b)	Other Changes (c)	Balance, End of Period
2018	$ 15,354	$ 6,089	$ (75)	$ (169)	$ 21,199
2017	$ 7,599	$ 391	$ (664)	$ 8,028	$ 15,354
2016	$ 45,516	$ 6,873	$ (42,417)	$ (2,373)	$ 7,599

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 and removal 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 and account method changes.

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

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

Index to Exhibits

Exhibit Number	Exhibit Description
3.1	Constitution (containing the Memorandum and Articles of Association) of Avadel Pharmaceuticals plc (incorporated by reference to Appendix 15 of Exhibit 2.1 to the registrant's current report on Form 8-K, filed on July 1, 2016)
4.1	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)
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)
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*	Note Agreement among Flamel Technologies S.A., Flamel U.S. Holdings, Inc. and Éclat Holdings, LLC dated March 13, 2012 (incorporated by reference to Exhibit 4.1 to the registrant's current report on Form 6-K, filed on March 21, 2012)
10.3	Registration Rights Agreement between Flamel Technologies S.A. and Éclat Holdings, LLC dated March 13, 2012 (incorporated by reference to Exhibit 4.5 to the registrant's current report on Form 6-K, filed on March 21, 2012)
10.4	Facility Agreement among Flamel US Holdings, Inc., Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. dated December 31, 2012 (incorporated by reference to Exhibit 4.7 to the registrant's annual report on Form 20-F for the year ended December 31, 2012, filed on April 30, 2013)
10.5*	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)
10.6*	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)
10.7	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)
10.8*	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)
10.9	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)
10.10	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)

10.11	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)
10.12	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)
10.13*	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)
10.14*	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)
10.15	Lease Agreement by and between Nine East, LLC and Eclat Pharmaceuticals LLC dated July 23, 2013 (incorporated by reference to Exhibit 10.15 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.16	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)
10.17	Lease Agreement by and between Channor Limited, Blanchardstown Corporate Park Management Limited, Flamel Ireland Limited, and Flamel Technologies S.A. dated July 3, 2015 (incorporated by reference to Exhibit 10.17 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.18‡	Employment Agreement by and between Flamel Technologies S.A. and Sandra Hatten dated July 8, 2015 (incorporated by reference to Exhibit 10.18 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.19‡	Employment Agreement by and between Flamel Technologies S.A. and Phillandas T. Thompson dated July 7, 2015 (incorporated by reference to Exhibit 10.19 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.20	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)
10.21‡	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)
10.22‡	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)
10.23‡	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)
10.24‡	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)

10.25‡	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)
10.26‡	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)
10.27	Common Draft Terms of Cross-Border Merger dated as of June 29, 2016 between Flamel Technologies S.A. and Avadel Pharmaceuticals Limited (subsequently renamed Avadel Pharmaceuticals plc) (incorporated by reference to Exhibit 2.1 to the registrant's current report on Form 8-K, filed on July 1, 2016)
10.28‡	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)
10.29‡	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)
10.30‡	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)
10.31‡	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)
10.32‡	Employment Agreement by and between Avadel Pharmaceuticals plc and Gregory J. Divis, dated January 4, 2017 (incorporated by reference to Exhibit 10.32 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 28, 2017)
10.33‡	Employment Agreement by and between Avadel Management Corporation and Michael S. Anderson dated August 15, 2017 (incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 9, 2017)
10.34‡	Employment Agreement by and between Avadel Management Corporation and Gregory J. Divis dated September 5, 2017 (incorporated by reference to Exhibit 10.2 to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 9, 2017)
10.35‡	Employment Agreement by and between Avadel Management Corporation and Sandra Hatten dated August 15, 2017 (incorporated by reference to Exhibit 10.3 to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 9, 2017)
10.36‡	Employment Agreement by and between Avadel Management Corporation and Michael F. Kanan dated September 5, 2017 (incorporated by reference to Exhibit 10.4 to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 9, 2017)
10.37‡	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)
10.38*	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)

10.39*	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)
10.40*	Manufacturing Agreement by and between Renaissance Lakewood, LLC (formerly DPT Lakewood, LLC) and Serenity Pharmaceuticals, LLC dated as of July 14, 2014 (incorporated by reference to Exhibit 10.8A to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 9, 2017)
10.41	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)
10.42	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)
10.43*	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)
10.44*	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)
10.45*	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)
10.46*	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)
10.47	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)
10.48‡	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)
10.49	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)
14.1	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)
14.2	Financial Integrity Policy (incorporated by reference to Exhibit 14.2 to the registrant's current report on Form 8-K, filed on March 7, 2017)

21.1	List of Subsidiaries (filed herewith)
23.1	Consent of Deloitte & Touche, LLP (filed herewith)
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32.1	Certification of the Chief Executive Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith) (1)
32.2	Certification of the Principal Financial Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith) (1)
101.INS	XBRL Instant Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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

‡ 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 15, 2019

By: /s/ Gregory J. Divis

Name: Gregory J. Divis

Title: Interim 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, Kevin Kotler, Linda S. Palczuk, Craig R. Stapleton 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.

Signature	Title	Date
/s/ Gregory J. Divis Gregory J. Divis	Interim Chief Executive Office (Principal Executive Officer)	March 15, 2019
/s/ Michael F. Kanan Michael F. Kanan	Chief Financial Officer (Principal Financial Officer)	March 15, 2019
/s/ David P. Gusky David P. Gusky	Corporate Controller (Principal Accounting Officer)	March 15, 2019
/s/ Geoffrey M. Glass Geoffrey M. Glass	Non-Executive Chairman of the Board and Director	March 15, 2019
/s/ Dr. Eric J. Ende Dr. Eric J. Ende	Director	March 15, 2019
/s/ Kevin Kotler Kevin Kotler	Director	March 15, 2019
/s/ Linda S. Palczuk Linda S. Palczuk	Director	March 15, 2019
/s/ Craig R. Stapleton Craig R. Stapleton	Director	March 15, 2019
/s/ Peter Thornton Peter Thornton	Director	March 15, 2019

Exhibit 21.1

List of Subsidiaries

Name	Jurisdiction
Avadel Pharmaceuticals plc (the Registrant):	Ireland
1) Avadel US Holdings, Inc. *(f/k/a Flamel US Holdings, Inc.)*	United States (Delaware)
A. FSC Holdings, LLC	United States (Delaware)
i. Avadel Pharmaceuticals (USA), Inc. *(f/k/a FSC Laboratories, Inc.)*	United States (Delaware)
1. Avadel Pediatrics, Inc. *(f/k/a FSC Pediatrics, Inc.)*	United States (Delaware)
ii. FSC Therapeutics, LLC	United States (Delaware)
B. Avadel Legacy Pharmaceuticals, LLC *(f/k/a Éclat Pharmaceuticals LLC)*	United States (Delaware)
i. Avadel Generics, LLC *(f/k/a Talec Pharma, Inc.)*	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)
2) Avadel Ireland Ltd. *(f/k/a Flamel Ireland Ltd.)*	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 on Form S-3 of our reports dated March 15, 2019, relating to the consolidated financial statements and financial statement schedule of Avadel Pharmaceuticals plc and subsidiaries (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, 2018.

/s/ Deloitte and Touche LLP
St. Louis, Missouri
March 15, 2019

Exhibit 31.1
CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

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; and

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.

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 15, 2019

/s/ Gregory J. Divis

Gregory J. Divis

Interim Chief Executive Officer

Exhibit 31.2
CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Michael F. Kanan, 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; and

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.

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 15, 2019

/s/ Michael F. Kanan

Michael F. Kanan

Senior Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AND EXCHANGE ACT RULE 13a-14(b)

In connection with the annual report of Avadel Pharmaceuticals plc (the "Company") on Form 10-K for the period ending December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gregory J. Divis, Interim Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. §1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ Gregory J. Divis

Gregory J. Divis
Interim Chief Executive Officer
Avadel Pharmaceuticals plc
March 15, 2019

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AND EXCHANGE ACT RULE 13a-14(b)

In connection with the annual report of Avadel Pharmaceuticals plc (the "Company") on Form 10-K for the period ending December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael F. Kanan, 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/ Michael F. Kanan

Michael F. Kanan
Senior Vice President and Chief Financial Officer
Avadel Pharmaceuticals plc
March 15, 2019