

**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, 2017

Commission file number: 000-28508

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

**Ireland**  
State or other jurisdiction of incorporation or organization

**98-1341933**  
(I.R.S. Employer Identification No.)

**Block 10-1, Blanchardstown Corporate Park  
Ballycoolin  
Dublin 15, Ireland**  
(Address of principal executive offices)

**Not Applicable**  
(Zip Code)

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

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

American Depositary Shares\*  
Ordinary Shares\*\*  
Title of each class

**NASDAQ Stock Market LLC  
(NASDAQ Global Market)**  
Name of exchange on which registered

\* American Depositary Shares may be evidenced by American Depositary 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 \$434,848,871 based on the closing sale price of the registrant's American Depositary Shares as reported by the Nasdaq Global Market on June 30, 2017. Such market value excludes 659,963 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 9, 2018 was 37,952,119.

**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, 2017, 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 contains forward-looking statements. We may make additional written or oral forward-looking statements from time to time in filings with the Securities and Exchange Commission or otherwise. The words “will,” “may,” “believe,” “expect,” “anticipate,” “estimate,” “project” and similar expressions, and the negatives thereof, identify forward-looking statements, which speak only as of the date the statement is made. Such forward-looking statements are within the meaning of that term in Section 27A of the Securities Act of 1933 (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934 (the “Exchange Act”). Although we believe that our forward-looking statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results of our research, development and commercialization activities and our results of operations will not differ materially from our expectations. 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:

- Risks relating to our license agreement with Serenity Pharmaceuticals, LLC (“Serenity”) including:
  - consumer purchases of Noctiva are subject to risks related to reimbursement from government agencies and other third parties;
  - our internal analyses may overstate the market opportunity in the United States for the drug desmopressin acetate (the “Drug”) or we may not effectively exploit such market opportunity;
  - significant safety or drug interaction problems could arise with respect to the Drug;
  - we may not successfully increase awareness of nocturia and the potential benefits of the Drug;
  - patents and proprietary rights associated with the Drug may not provide adequate protection;
  - patents licensed to us under our license agreement with Serenity that cover the Drug are subject to litigation and if Serenity is unsuccessful in defending this litigation, we may lose its exclusive rights to such patents; and
  - the need for our management to focus attention on the development and commercialization of the Drug could cause our ongoing business operations to suffer.
- we depend on a small number of products and customers for the majority of our revenues and the loss of any one of these products or customers could reduce our revenues significantly.
- we may depend on partnership arrangements or strategic alliances for the commercialization of some of our products, and the failure of any third party to fulfill its duties under such an arrangement or alliance could have a material adverse effect on our financial condition and results of operation.
- our products may not reach the commercial market for a number of reasons, which would adversely affect our future revenues.
- we must invest substantial sums in research and development (“R&D”) in order to remain competitive, and we may not fully recover these investments.
- we depend upon a limited number of third parties to manufacture our products and to deliver certain raw materials used in our products and the failure of any such third party to efficiently manufacture such products or to timely deliver sufficient quantities of raw materials, as applicable, could have a material adverse effect on our business.
- if our competitors develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval for and market such technologies or products before we do, our commercial opportunity will be diminished or eliminated.
- if we cannot keep pace with the rapid technological change in our industry, we may lose business, and our products could become obsolete or noncompetitive.
- if we cannot adequately protect our intellectual property and proprietary information, we may be unable to sustain a competitive advantage.
- our effective tax rate could be highly volatile and could adversely affect our operating results.
- we depend on key personnel to execute our business plan and the loss of any one or more of these key personnel may limit our ability to effectively pursue our business plan.

Forward-looking statements are subject to inherent risks and uncertainties, some of which cannot be predicted or quantified. Future events and actual results could differ materially from those set forth in, contemplated by or underlying the forward-looking statements. We undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise. You should not place undue reliance on these forward-looking statements.

## **PART I**

### **Item 1. Business.**

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

#### **General Overview**

Avadel Pharmaceuticals plc (“Avadel,” the “Company,” “we,” “our,” or “us”) is a branded specialty pharmaceutical company. Avadel’s current revenues are primarily derived from products we market based on first-to-file New Drug Applications (“NDAs”) for pharmaceutical products previously sold in the U.S. without Food and Drug Administration (“FDA”) approval (“Unapproved Marketed Products” or “UMDs”). In addition, through the acquisition of patient-focused, innovative products or businesses in the commercial- and or late-stage of development, Avadel seeks to provide solutions for overlooked and unmet medical needs, including our urology product, Noctiva™, which we in-licensed in 2017 and will begin marketing in 2018. Avadel also seeks to develop products that utilize our Micropump® drug delivery technology, such as our narcolepsy product which is in clinical trials.

Avadel’s current commercial portfolio consists of three sterile injectable products, which were previously UMDs, used in the hospital setting, and Noctiva™, a urology product, which is the first and only FDA approved product for the treatment of nocturia due to nocturnal polyuria in adults. Avadel believes that nocturia, the condition of waking two or more times per night to void, represents a large unmet medical need affecting approximately 40 million Americans.

Avadel is actively developing a fourth sterile, injectable UMD product for which it expects to file an NDA and seek FDA approval. In addition, Avadel is currently enrolling patients in our REST-ON Phase III clinical trial to evaluate the safety and efficacy of FT 218, a once-nightly formulation of sodium oxybate using Micropump®, for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. Narcolepsy is a rare sleep disorder with few approved treatment options. Avadel will continue to strategically evaluate potential UMDs and Micropump® based product candidates for development and approval, and will also look for synergistic acquisition targets to grow our company.

#### **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](http://www.avadel.com), where we make available free of charge our reports (and any amendments thereto) on Forms 10-K, 10-Q and 8-K as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission (“SEC”). These filings are also available to the public at [www.sec.gov](http://www.sec.gov).

The Company is the successor to Flamel Technologies S.A., a French *société anonyme* (“Flamel”), as the result of the merger of Flamel with and into the Company which was completed 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, and elsewhere in this Item 1 under the caption “- The Flamel Merger.”

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.

The Company currently has five direct wholly owned subsidiaries: Avadel US Holdings, Inc., Flamel Ireland Limited, which conducts business under the name Avadel Ireland, Avadel Investment Company Limited, Avadel Finance Ireland Designated Activity Company and Avadel France Holding SAS. Avadel US Holdings, Inc. is a Delaware corporation, and is the holding entity of Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, FSC Holding Company and 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 a corporation organized under the laws of Ireland and is where all intellectual property was relocated on December 16, 2014. Avadel France Holding SAS is a *société par actions simplifiée*, organized under the laws of France and is the holding entity of Avadel Research SAS where Avadel’s R&D activities take place. 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

**FT 218 Orphan Drug Designation.** In January 2018 Avadel announced that the FDA granted Orphan Drug Designation to our proposed product, FT 218. FT 218, which is currently in a Phase III clinical trial, is intended for the treatment of EDS and cataplexy in patients suffering from narcolepsy. The designation has been granted on the plausible hypothesis that FT 218 may be clinically superior to the only other approved sodium oxybate product. FT 218 is a once-nightly formulation of sodium oxybate using Avadel’s Micropump® technology. Orphan Drug Designation is intended to advance drug development for rare diseases. The FDA provides Orphan Drug Designation to drugs and biologics that demonstrate promise or improvements for the diagnosis and/or treatment of rare diseases or conditions that affect fewer than 200,000 people in the U.S. Following the completion of the clinical trial, if FT 218 is able to adequately demonstrate clinical superiority over the current approved product, Orphan Drug Designation may provide development and commercial incentives for FT 218, including eligibility for a seven-year period of market exclusivity in the U.S., and an exemption from FDA user fees. Additional information regarding FT 218 is set forth elsewhere in this “Business of Avadel” under the caption “- Micropump® Based Products – FT 218.”

**Asset Purchase Agreement with Cerecor.** On February 12, 2018, Avadel Pharmaceuticals plc (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”). At the closing under the Purchase Agreement, on February 16, 2018, 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 Therapeutics and FSC Laboratories, Inc., which is also a subsidiary of the Company (collectively “FSC”). The Company acquired FSC in February 2016 from Deerfield CSF, LLC (“Deerfield CSF”) and certain of its affiliates. Pursuant to the Purchase Agreement, Cerecor assumed the Company’s remaining payment obligations to Deerfield CSF under the Membership Interest Purchase Agreement, dated as of February 5, 2016, between Holdings, Flamel Technologies SA (the predecessor of the Company) and Deerfield CSF and certain of its affiliates, which payment obligations consist 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.

#### *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.

#### *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 CSF, LLC and certain of its affiliates (“Deerfield”). Under the Deerfield Guarantee, the Company and Holdings guaranteed to Deerfield the payment by Cerecor of the obligations of the Company and certain of its subsidiaries (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”).

#### *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.

**Issuance of Exchangeable Notes.** On February 14, 2018 we announced that our wholly-owned subsidiary, Avadel Finance Cayman Limited (the “Issuer”), priced a \$125,000 aggregate principal amount of 4.50% exchangeable senior notes due 2023 (the “Notes”) in a private placement (the “Offering”) to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the “Securities Act”). The sale of the Notes closed on February 16, 2018. In connection with the Offering, the Issuer granted the initial purchasers of the Notes a 30-day option to purchase up to an additional \$18,750 aggregate principal amount of the Notes, which was fully exercised on February 16, 2018.

Net proceeds from the Notes were \$137,719 after deducting the initial purchasers’ discount and estimated offering expenses. We expect to use the net proceeds of the Offering for working capital and general corporate purposes. We also used cash on-hand to purchase approximately 2.0 million ADSs for \$18,000 concurrently with the pricing of the Offering in privately negotiated transactions effected with or through a representative of the initial purchasers or an affiliate of such representative. The Issuer agreed to purchase such ADSs at a purchase price per ADS equal to the \$8.99 per ADS closing price on The Nasdaq Global Market on February 13, 2018.

The Notes are general, unsecured obligations of the Issuer, and are fully and unconditionally guaranteed by Avadel on a senior unsecured basis. Interest on the Notes will be payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2018. The Notes will mature on February 1, 2023, unless earlier exchanged, repurchased or redeemed in accordance with their terms. The Notes will be issued in minimum denominations of \$200 and integral multiples of \$1 in excess thereof.

Subject to certain conditions and during certain periods, the Notes will be exchangeable at the option of the holders at an initial exchange rate of 92.6956 ADSs per \$1 principal amount of 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 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.

## Our Business Model

Avadel executes three primary strategies that allow us to develop and/or license or acquire differentiated branded products for FDA approval and commercialization, principally in the United States.

## Business Strengths and Strategies

Our business strengths and strategies include:

### **Unapproved Marketed Drug (“UMD”) Products**

In 2006 the FDA announced 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 NDA approval be granted 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.

*Additional UMD Products.* Avadel intends to develop and seek approval for our fourth NDA for a UMD, and intends to develop and seek approval for select other UMD products with large existing markets and limited competition.

Avadel believes our 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.

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 subsequent ANDA approvals that may occur.
- **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, and was granted approval for 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.

### ***Inorganic Growth Through Acquisitions, Licensing, Partnerships and/or Divestitures***

Avadel currently has a strong balance sheet and intends to explore and pursue appropriate inorganic growth opportunities that may enhance profitability and cash flow and would complement our urology and hospital products, or our sleep-focused product candidate, FT 218. Avadel in-licensed Noctiva™ in September 2017 from Serenity, and in February 2018 Avadel divested four pediatric products to, and entered into a LiquiTime® development agreement with, Cerecor. Avadel also has an ongoing LiquiTime® development partnership with Elan Pharma International Limited (“Elan Pharmaceuticals”) since 2015, described further in this Item 1 under the caption “– Other Products Under Development.” Avadel also owns two proprietary drug delivery technologies, Medusa™ and Trigger Lock™, which it has determined are no longer strategically viable for internal development due to the high cost of development and lengthy approval timelines. Avadel will continue to look for opportunities to out-license or divest our Medusa™ and Trigger Lock™ technologies.

Avadel’s most recent in-licensed product, Noctiva™, is urology focused. An outline of the licensing terms can be found in this Item 1 under the caption “– Noctiva™ (desmopressin acetate)” immediately below, and additional information regarding Noctiva may be found elsewhere in this Item 1 under the caption “– Competition and Market Opportunities.”

**Noctiva™ (desmopressin acetate).** On March 3, 2017, Noctiva™ was granted FDA approval and is the first and only product indicated for treatment of nocturia due to nocturnal polyuria (overproduction of urine during the night) in adults who awaken at least two times per night to void. Noctiva™ is an emulsified low-dose vasopressin analog administered through a preservative-free nasal spray 30 minutes before bedtime. Noctiva is approved in two dosage strengths of 0.83 mcg and 1.66 mcg.

On September 1, 2017, Avadel’s indirect wholly-owned subsidiary, Avadel Specialty Pharmaceuticals, LLC (the “Avadel Licensee”), entered into an Exclusive License and Assignment Agreement (the “Serenity License Agreement”) with Serenity. Under the terms of the Serenity License Agreement, Serenity granted to the Avadel Licensee an exclusive license, under certain rights of Serenity in and to certain intellectual property owned by Serenity (the “Serenity IP Rights”), to develop and commercialize the drug desmopressin acetate (the “Drug”) in the United States for the treatment of certain medical conditions characterized by abnormalities or disorders in voiding and other urinary functions of a subject to control urination (the “Field”). Such license includes a sublicense to certain intellectual property owned by CPEX Pharmaceuticals, Inc. (“CPEX”) and Reprise Biopharmaceutics, LLC. (“Reprise”). More specifically, (i) pursuant to a license agreement, effective as of May 28, 2017, Reprise granted Serenity a license to certain intellectual property held by Reprise relating to the Drug, including U.S. Patent Nos. 7,799,761, 7,579,321, and 7,405,203 (each of which is listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) for Noctiva™) as well as Canadian Patent No. 2,545,194 and (ii) pursuant to a Development and License Agreement, dated February 4, 2008 and as amended March 31, 2010, CPEX granted Serenity a license to certain intellectual property rights relating to the Drug. Accordingly, the Avadel Licensee’s sublicense to such intellectual property is subject to the foregoing agreements. In addition, under the Serenity License Agreement, Serenity granted to the Avadel Licensee certain rights of Serenity in the New Drug Application for the Drug approved by the U.S. Food and Drug Administration (the “NDA”), and certain supply agreements relating to the Drug.

The Serenity License Agreement further provides that:

The Avadel Licensee may sublicense the licensed rights in the U.S. beginning two years after the effective date of the license, subject to Serenity’s prior written consent which may not be unreasonably withheld, conditioned, or delayed.

The Avadel Licensee will use its commercially reasonable efforts to commercialize the rights licensed to it under the License Agreement. The Avadel Licensee is responsible for the costs associated with all regulatory activities, including development activities undertaken to support obtaining or maintaining regulatory approvals. Within 120 days following the effective date of the License Agreement, the Avadel Licensee was required to provide Serenity with a plan with respect to the commercialization of the Drug in the Field in the United States and Canada (“Territory”).

Within 180 days following the effective date of the License Agreement, the Avadel Licensee will notify Serenity of our decision to undertake development of the Drug for the “Nocturia Indication” (*i.e.*, adult night-time non-incontinent urination) in Canada and the “PNE Indication” (*i.e.*, bed-wetting) in the United States and/or Canada, each of which would require additional separate negotiated agreements with Serenity. Serenity will have the right to develop and commercialize the Drug for the Nocturia Indication in Canada and the PNE Indication in the Territory if the Avadel Licensee decides not to undertake such development.

The Avadel Licensee paid Serenity an up-front payment of \$50 million upon the effective date of the License Agreement. The Avadel Licensee will also pay Serenity \$20 million when the Drug first becomes available for commercial sale.



Serenity is eligible to receive milestone payments as follows: up to \$40 million (the “Cumulative Sales Milestone Payments”) in the aggregate based on achievement of cumulative sales milestones of \$50 million to \$200 million and up to \$180 million in the aggregate based on achievement of 12-month sales milestones of \$300 million to \$1.5 billion. Upon a change in control, Serenity will be eligible to receive a payment in the low to mid-double digit millions, reduced by portions of any Cumulative Sales Milestone Payments previously paid. In addition, Serenity is eligible to receive royalties of twenty-eight percent (28%) of annual net sales of up to \$500 million, thirty percent (30%) of annual net sales greater than \$500 million up to \$1 billion, and thirty-three percent (33%) of annual net sales over \$1 billion, subject to adjustment in certain circumstances.

Serenity has the sole discretion and responsibility to prosecute and maintain the patent applications and patents licensed to the Avadel Licensee under the Serenity License Agreement, however, Serenity may not abandon rights to such patent applications and patents without Serenity first giving the Avadel Licensee an opportunity to assume full responsibility for the continued prosecution and maintenance thereof. The Avadel Licensee is required to reimburse Serenity for all costs incurred by Serenity after the effective date of the Serenity License Agreement in the preparation, filing, prosecution, and maintenance of certain patents up to \$700,000.

The Avadel Licensee has the first right to enforce against third party infringement of intellectual property rights licensed to it under the Serenity License Agreement, however, if it elects to not do so, Serenity may step in and enforce against any such infringement. The Avadel Licensee has the first right to defend against claims by third parties that the Drug infringes any third party intellectual property rights, including the right to settle such claims unless they are indemnifiable by Serenity, in which case the Avadel Licensee must obtain Serenity’s prior written consent to enter into any such settlement. However, if the Avadel Licensee elects to not defend any such infringement claim, Serenity has the right to step in and do so.

Except with respect to pending litigation involving Ferring B.V., Ferring International Center S.A. and Ferring Pharmaceuticals Inc. (collectively, “Ferring”), the Avadel Licensee has the first right to defend against challenges to intellectual property licensed to it under the Serenity License Agreement, however, if the Avadel Licensee elects to not do so, Serenity may step in and defend against such challenges. With respect to pending litigation involving Ferring, Serenity has full control over such litigation at its own expense and may not settle such litigation in a manner that restricts the scope, or adversely affects the enforceability of the intellectual property rights licensed to the Avadel Licensee under the Serenity License Agreement without the Avadel Licensee’s consent, which may not be unreasonably withheld, delayed or conditioned. For more information regarding the pending litigation involving Ferring, please see the information set forth under the caption “– Risks Related to Avadel’s Exclusive License Agreement for Noctiva™” in the “Risk Factors” included in Part I, Item 1A of this Annual Report on Form 10-K.

The Serenity License Agreement remains in effect until it is terminated as specifically provided in the agreement. Both the Avadel Licensee and Serenity may terminate the agreement upon uncured, material breach of the agreement by or an insolvency-related event of the other party.

### ***Development of Micropump®-Based Products***

Avadel’s versatile Micropump® based technology allows us to select unique product development opportunities, representing either “life cycle” opportunities, whereby additional intellectual property can be added to a pharmaceutical to extend the commercial viability of a currently marketed product, or innovative formulation opportunities for new chemical entities (“NCEs”). Several products formulated using Avadel’s proprietary drug delivery technologies are currently under various stages of development. These products will be commercialized either by Avadel and/or by partners via licensing/distribution agreements. Additional information on products in development and detailed information regarding Avadel’s Micropump® based technologies is provided in this Item 1 under the caption “– Other Products Under Development” and the caption “– Avadel’s Drug Delivery Technologies.”

Because R&D costs for reformulating a drug are typically substantially lower than for developing NCEs, “reformulation approvals” provide an opportunity to extend the exclusivity period of already marketed drugs or create new market exclusivity for an off-patent drug. The Micropump® platform has successfully transitioned to commercial stage with Coreg CR® (a GlaxoSmithKline marketed product).

**FT 218 (Micropump® sodium oxybate):** Avadel is developing a product which uses our Micropump® drug-delivery technology for the treatment of EDS and cataplexy in patients suffering from narcolepsy. Avadel currently refers to this product as FT 218. FT 218 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 FT 218, Avadel reached an agreement with the FDA for the design and planned analysis of our study through a Special Protocol Assessment (“SPA”). An SPA is an acknowledgement 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 a Phase III clinical trial to assess the safety and efficacy of a once-nightly formulation of FT 218 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 50 to 60 clinical sites in the U.S., Canada and western Europe. In January 2018, Avadel announced that the FDA granted Orphan Drug Designation to FT 218. Avadel believes 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, for which the marketer estimates will generate revenues of between \$1.18 billion and \$1.2 billion in 2017.

#### Other Products Under Development

Avadel entered into an Exclusive License Agreement on September 30, 2015, with Elan, a subsidiary of Perrigo Company plc, for the right to use our LiquiTime® drug delivery technology for the U.S. (OTC) drug market. Under the multi-product license agreement, Avadel received an upfront payment of \$6 million and will be eligible for at least an additional \$50 million in approval and launch milestones. In addition, once commercialized Avadel will receive mid-single digit royalties on net sales of the 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 III trial ongoing
UMD #4	Sterile Injectable - Drug Undisclosed	Undisclosed	Development ongoing
LiquiTime®	Guaifenesin	Cough / Cold	Pivotal pharmacokinetics studies pending registration batches
LiquiTime®	Undisclosed	Pediatric	Proof of concept
Micropump®	Undisclosed	Pediatric	Proof of concept
LiquiTime®	Undisclosed	Pediatric	Proof of concept

#### 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, Endo Pharmaceuticals, Tris Pharma, Ferring, Astellas and others.

### *Potential competition for FT 218*

If FT 218 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 FT 218 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.

### *Noctiva™ Competition*

While there are no other approved treatment options for nocturia due to nocturnal polyuria, Avadel anticipates that Noctiva™ will compete with products that have been historically used off-label to treat nocturia, primarily medications indicated for overactive bladder and benign prostatic hyperplasia, and older forms of desmopressin.

### **Market Opportunities**

Because the pharmaceutical industry is highly competitive, participants seek ways to increase profitability by reducing competition through patent protection. Avadel, resulting from the combination of our existing proprietary drug delivery technologies with the established commercial capability of our unapproved to approved product strategy and with the acquisition of Noctiva™ 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)). Avadel's commercial capabilities also differentiate it from some competitors.

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.

The market opportunities for Noctiva and the proprietary pipeline products that Avadel intends to pursue independently are estimated by Avadel to be worth at least several hundred million dollars each.

### **Noctiva™**

Avadel believes that nocturia, the condition of waking two or more times per night to urinate, represents a substantial unmet medical need affecting approximately 40 million adults in the United States. Through claims analysis, it is estimated that only 27 percent, or approximately 11 million, of patients are diagnosed with the condition and only 3 million are on active pharmacological treatment. Noctiva™ is the first and only FDA approved product indicated to treat nocturia due to nocturnal polyuria, or the overproduction of urine at night, which is present in approximately 88 percent of patients with nocturia. With no approved or proven treatment options for nocturia due to nocturnal polyuria, Avadel believes that Noctiva™ may have the potential to address a very prevalent unmet need within a large patient population. Avadel further believes that Noctiva™ has the potential to provide Avadel with substantial revenue growth should we successfully execute our commercialization strategy, which will consist of condition-state awareness to prime the urology market with a full-scale product launch to follow in the second quarter of 2018. For a discussion of risks associated with Avadel's Noctiva™, please see the information set forth under the caption "-- Risks Related to Avadel's Exclusive License Agreement for Noctiva™" in the "Risk Factors" included in Part I, Item 1A of this Annual Report on Form 10-K.

### **FT 218**

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 FT 218 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 C<sub>max</sub> of FT 218 compared to the current approved product, and may provide other additional benefits related to quality of life. 2017 revenue estimates of the marketed twice-nightly sodium oxybate range from \$1.18 billion to \$1.2 billion and the number of patients actively on treatment as of November 2017 was approximately 13,000. Following the completion of Avadel's REST-ON clinical trial, if FT 218 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 FT 218, 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 and develops drug delivery technologies that address key formulation challenges, leading to 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) and that can be applied to a broad range of drugs (novel, already-marketed, or off-patent).

Avadel believes that our 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, Avadel believes that we have broad and versatile presentations to serve most markets from pediatric to geriatric. 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 C<sub>max</sub> 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.

Elan Pharmaceuticals has licensed the LiquiTime® technology in the U.S. for OTC products and Avadel is currently working on an extended release suspension formulation for guaifenesin (see "– Product Pipeline"). Avadel has maintained the prescription rights to LiquiTime®, as we view prescription products as higher-value opportunities. Avadel is currently conducting feasibility studies on two potential prescription products utilizing our LiquiTime® technology.

**Trigger Lock™.** *Trigger Lock™* allows development of abuse-resistant modified/controlled release formulations of narcotic/opioid analgesics and other drugs susceptible to abuse.

Medusa™. Medusa™ allows the development of extended/modified release of injectable dosage formulations of drugs (e.g., peptides, polypeptides, proteins, and small molecules).

### Proprietary Intellectual Property

Avadel's commercial success with respect to the development and commercialization of Noctiva™ is dependent on Avadel's and our licensor's ability to obtain and maintain patent protection for Noctiva™. In addition, 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.

Licensed Noctiva Patents. Avadel's licensed patent portfolio relating to Noctiva™ consists of four U.S. patents, one or more of which generally disclose pharmaceutical compositions that include desmopressin and a pharmaceutically acceptable carrier, methods for using those compositions, and/or intranasal spray devices for consistently achieving low desmopressin blood concentrations. The U.S. patents are expected to expire beginning in 2023 and ending in 2030. Avadel does not own any patents or patent applications relating to Noctiva™.

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 the UMDs 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.

Noctiva™ is manufactured pursuant to a manufacturing agreement between Serenity and a third party CMO, which was assigned to Avadel in connection with the Serenity License Agreement. The CMO manufactures Noctiva™ in a sterile one-of-a-kind manufacturing facility located in Lakewood, New Jersey that is in compliance with cGMP guidance and directives applicable to the manufacture of Noctiva™. This manufacturing facility was built expressly for the manufacture of Noctiva™, and allows for the product to be the only preservative free nasal spray for this prescription.

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 products using Avadel's Micropump® and LiquiTime® drug delivery technologies. 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 II, 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 III 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 I, II, and III 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 infringing 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 FT 218, please see the information set forth under the caption "- Risks Related to Regulatory and Legal Matters - If FT 218 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 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.

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.

**Employees**

As of December 31, 2017, we had approximately 180 employees, of which approximately 169 were full-time. None of the Company's employees are subject to a union or other collective bargaining agreement. Employees at our French subsidiaries (approximately 52 employees) are represented by a works' council in which employee representatives have the right to be consulted as to certain matters affecting the French entities. 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 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. Certain risks related specifically to the development and commercialization of Noctiva™ are included below under the subheading "- Risks Related to Avadel's Exclusive License Agreement for Noctiva™."*

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

*We depend on a small number of products and customers for the majority of our revenues and the loss of any one of these products or customers could reduce Avadel's revenues significantly.*

We derive a majority of our revenues from sales of three products, Bloxivert<sup>®</sup>, Vazculep<sup>®</sup> and Akovaz<sup>®</sup>. Additionally, we depend on a small number of customers for the majority of our revenues from these products. Four customers, accounted for approximately 93% of total revenues from sales of these products in 2017. These customers comprise a significant portion of the distribution network for pharmaceutical products in the U.S. Increased competition for any one of these products could result in significant downward pricing pressure and loss of market share by the Company resulting in lower revenues or loss of business. This distribution network is also 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 these products or the termination of our relationship with any of these customers or our failure to broaden our customer base could cause our revenues to decrease significantly and result in 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 expect to 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 will involve third-party collaboration partners for strategic alliances, licenses, product divestitures or other arrangements to commercialize these products, as we did with respect to the license to Elan for the OTC rights for LiquiTime<sup>®</sup> (see the discussion under the caption "Products in Development with Partners" in the "Business of Avadel" included in Part I, Item 1 of this Annual Report on Form 10-K). 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.

***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 additional previously Unapproved Marketed Drug (“UMD”) products, development of 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 cause harmful side effects, or may fail during any stage of pre-clinical testing or clinical trials;
- we or our partners may find 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, fail to achieve market acceptance, fail to be included within the pricing and reimbursement schemes of the U.S. or EU Member States, or be precluded from commercialization by proprietary rights of third parties.

***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 2017, we spent \$33,418 on R&D. Our ongoing investments in R&D for future products could result in higher costs without a proportionate increase, or any increase, in revenues. The R&D process is lengthy and carries a substantial risk of failure. If our R&D does not yield sufficient products that achieve commercial success, our future operating results will be adversely affected.

***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<sup>®</sup>, Vazculep<sup>®</sup> and Akovaz<sup>®</sup>, from which we derive a majority of our revenues and a single contract manufacturer for Noctiva<sup>™</sup>. 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 (“NCEs”) 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 could approve generic versions or previously filed NDAs of our marketed products.

Many of our competitors have substantially greater financial, technological, manufacturing, marketing, managerial and R&D resources and experience than we do. Furthermore, acquisitions of competing drug delivery companies by large pharmaceutical companies could enhance our competitors’ resources. Accordingly, our competitors may succeed in developing competing technologies and products, obtaining regulatory approval and gaining market share for their products more rapidly than we do.

***Our 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 commercially launch Noctiva™ during 2018, continue our UMD program, including by obtaining FDA approval for, and commercialize our fourth UMD product candidate as well as potentially additional future UMD product candidates, continue to seek FDA approval for FT 218 which is in Phase III clinical trial, continue to seek to develop and commercialize products using our drug delivery technologies, and develop and identify and acquire additional businesses or new product opportunities. 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.

In particular, we may be unable to successfully identify attractive acquisition candidates or complete any acquisitions, successfully integrate any acquired business, product or technology or retain any key employees of acquired businesses. Integrating any business,



product or technology we acquire could be expensive and time consuming, and could disrupt our ongoing business and distract our management. If we fail to complete these acquisitions or successfully integrate any acquired businesses, products or technologies, our business will suffer. In addition, any amortization or charges resulting from the costs of acquisitions could negatively impact our operating results.

***If we cannot adequately protect our intellectual property and proprietary information, we may be unable to sustain a competitive advantage.***

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 platforms, 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 to 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, 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, that the manufacture, use, import, offer for sale or sale of our drug delivery technologies or our other products infringes on their patent rights and other intellectual property rights. For example, in connection with us seeking regulatory approval for FT 218, companies that produce any branded pharmaceutical versions of such products may allege that FT 218 infringes their patents or other intellectual property rights and file suit against us to prevent it from commercializing FT 218. 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 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 proprietary data, including intellectual property, as well as our proprietary business information and that of our customers, suppliers and business partners, on our networks. 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 failure to do so 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 Mr. Anderson, our Chief Executive Officer, or other members of our senior executive team, we may have difficulty executing our business plan in the manner we currently anticipate. Further, because each of our key personnel is involved in numerous roles in various components of our business, the loss of any one or more of such individuals could have an adverse effect on our business.

***Risks Related to Our Exclusive License Agreement for Noctiva™***

***Consumer purchases of Noctiva™ are subject risks related to reimbursement from government agencies and other third parties.***

We anticipate that a substantial majority of Avadel's Noctiva™ sales will be reimbursed by third-party payors such as the Medicare Part D program in the U.S. and private health insurance companies. The commercial success of Noctiva™ will therefore depend substantially on the availability and levels of reimbursements by these payors. Government authorities and private health insurance companies decide which drugs they will cover and establish payment levels, and we cannot guaranty the availability or levels of any such reimbursements for Noctiva™. We do not anticipate that it will have material Medicare Part D reimbursement coverage until 2019. Patients in the Medicare Part D program make up at least 50% of the target patient population for Noctiva. The opportunity to target this patient population will therefore not be fully achievable until material Medicare Part D reimbursement coverage is achieved. If reimbursement for Noctiva™ is unavailable or limited by governmental or private insurance programs, our Noctiva™ business and its results of operations will suffer a material adverse effect.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for Noctiva™.

In recent years, government health programs such as Medicare and other third-party payors in the United States have increased their efforts to:

- limit the price of covered drugs, including by challenging the prices charged by manufacturers, or by seeking other cost saving measures such as mandatory discounts or rebates, stricter requirements for initial reimbursement approvals and other similar measures such as price increase restrictions;
- limit the use of covered drugs, including by shifting additional cost burden to patients, typically by requiring a co-payment or co-insurance percentage that increases significantly when the medicine is not covered or is not preferred; and
- limit the use of covered drugs by mandating treatment protocols that require additional healthcare administrative actions (in the form of a prior authorization for reimbursement) and or step edit therapy (requiring a patient to fail another therapy before getting access to the desired therapy).

Governmental agencies in the United States have enacted or adopted, are considering, and may in the future enact and adopt, various legislative and regulatory proposals to change the healthcare system, often with a particular focus on the pharmaceutical industry; and any changes resulting from such proposals may affect our ability to sell Noctiva™ profitably.

Any significant changes in the healthcare system in the United States would likely have a substantial impact on the manner in which we conduct our Noctiva™ business and could have a material adverse effect on our commercialization efforts for Noctiva™.

***We may have overestimated the market opportunity for Noctiva™ or we may not effectively exploit such market opportunity.***

Our internal analyses may overstate the market opportunity in the United States for the drug desmopressin acetate, which we have licensed from Serenity and which we intend to market under the brand name “Noctiva™”. If one or more of the assumptions underlying our internal analyses are incorrect, the benefits we anticipate from the Serenity License Agreement for Noctiva™ may not be realized or may be smaller than expected. We may also fail to effectively exploit the market opportunity for Noctiva™, and such failure could have a material adverse effect on our business, financial condition, operating results and liquidity.

***Significant safety or drug interaction problems could arise with respect to Noctiva™.***

Data supporting the marketing approvals and forming the basis for the safety warnings in the product labels were derived from controlled clinical trials of limited duration in limited patient populations with Noctiva™ and from existing scientific knowledge and previous clinical assessments of the active pharmaceutical ingredient (desmopressin Acetate). Specifically, Noctiva™’s prescribing information includes a black box warning stating that it can cause hyponatremia. As Noctiva™ is used over longer periods of time and by more patients, some of whom may have underlying health problems or may be taking other medicines, new issues relating to safety, tolerability, resistance or drug-interaction could arise, which may require Avadel to provide additional warnings or contraindications on product labels, or otherwise narrow approved indications for Noctiva™. Further, additional information from ongoing research or clinical trials of Noctiva™ may raise doubts or concerns about its efficacy. If serious safety, tolerability, resistance, drug-interaction, efficacy, or any other such concerns or issues arise with respect to Noctiva™, sales of Noctiva™ could be impaired, limited or abandoned.

***Patents covering Noctiva™ that we license from Serenity under the Serenity License Agreement are subject to litigation and if Serenity is unsuccessful in defending this litigation, we may lose our exclusive rights to such patents or be required to obtain licenses from third parties to continue to develop and commercialize Noctiva™, which would have a material adverse effect on our business.***

Patents covering Noctiva™ that we have in-licensed from Serenity and which are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations database published by the FDA’s Center for Drug Evaluation and Research (commonly known as the “Orange Book”) are subject to two pending litigation proceedings. In the first proceeding, which was initiated in April 2012 in the United States District Court for the Southern District of New York, Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc., which we collectively refer to as Ferring, filed suit against Serenity Pharmaceuticals Corporation, Serenity Pharmaceuticals, LLC, Reprise Biopharmaceutics, LLC, Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, Seymour H. Fein and Ronald V. Nardi, alleging a number of claims relating to U.S. Patent Nos. 7,799,761 (which is expected to expire in 2024), 7,579,321 (which is expected to expire in 2023), and 7,405,203 (which is expected to expire in 2023) (the “Patents-in-Suit”). In particular, Ferring has alleged that certain Ferring employees should be the sole named inventors of these patents or co-inventors with the current named inventors. In addition, Ferring has asserted related claims against the defendants for breach of common law duties, aiding and abetting breach of common law duties, breach of contract, intentional interference with contractual relations, trade secret misappropriation, unfair competition, conversion, fraudulent concealment and unjust enrichment. In March 2013, the district court dismissed all of Ferring’s allegations except for Ferring’s inventorship allegations. In April 2014, certain defendants filed certain counterclaims against Ferring. In September 2015, the district court granted the defendants’ motion for summary judgment on Ferring’s inventorship allegations, finding that Ferring was equitably estopped from asserting such allegations. Ferring may appeal the decisions dismissing its allegations. In the second proceeding, which was initiated in April 2017 in the United States District Court for the District of Delaware, Ferring filed suit against Serenity Pharmaceuticals, LLC, Reprise Biopharmaceutics, LLC and Allergan, Inc., seeking a declaratory judgment that the Patents-in-Suit are invalid and unenforceable and that Ferring’s Nocturna product does not infringe the Patents-in-Suit. No trial date has been set.

If Serenity is ultimately unsuccessful in defending Ferring’s allegations in these litigation proceedings, we may lose valuable patent rights covering Noctiva™. For example, if a court were to ultimately require that Ferring employees replace the current named inventors as the sole named inventors of the Patents-in-Suit or otherwise award ownership of the Patents-in-Suit to Ferring, then we would no longer have any rights to such patents and we would be required to obtain a license from Ferring to such patents to continue to develop and commercialize Noctiva™. Such a license may not be available on commercially reasonable terms or at all. If we were unable to obtain any license to any of the Patents-In-Suit, we may be required to cease our development and commercialization of Noctiva™. We could also be liable for damages to Ferring, which may be significant. Even if we were able to obtain such a license, we may only be non-exclusive and in such case we would not be able to enforce any of the Patents-in-

Suit against competitors or other third parties, which may materially impair our ability to prevent competitors and other third parties from developing and commercializing products that are the same as or similar to Noctiva™.

If a court were to ultimately find that Ferring employees should be added as named inventors to the Patents-in-Suit alongside the current named inventors or otherwise award Ferring co-ownership of the Patents-In-Suit, then we would no longer have exclusive rights to such patents. In such case, if we were unable to obtain an exclusive license to Ferring's co-ownership interest in the Patents-In-Suit, Ferring would be able to exploit such patents itself or license such rights to our competitors or other third parties. Moreover, we and Serenity would need the cooperation of Ferring as a co-owner of the Patents-In-Suit in order to enforce such patents against third parties, and such cooperation may not be provided.

If Ferring were ultimately successful in its challenges to the validity and enforceability of the Patents-In-Suit such that a court declares the Patents-in-Suit invalid or unenforceable, we would lose our ability to enforce such patents against third parties, which may materially impair our ability to prevent competitors and other third parties from developing and commercializing products that are the same as or similar to Noctiva™. In addition, if Ferring were ultimately successful in its request for a declaration that its Nocturna product does not infringe the Patents-in-Suit, then we would not be able to enforce the Patents-In-Suit to prevent the development and commercialization of Ferring's Nocturna product.

Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, liquidity or prospects.

***We may not successfully increase awareness of nocturia and or the potential benefits of Noctiva™.***

Our ability to establish effective marketing and advertising campaigns for Noctiva™ will be key to our success in commercializing the drug. If we are unable to increase awareness of nocturia (*i.e.*, adult night-time non-incontinent urination, which Noctiva™ is intended to reduce), the establishment of nocturnal polyuria as the critical etiology that must be treated despite any other co-morbidities and the potential benefits of Noctiva™, our effort to build a substantial customer base for the drug may not be successful. In addition, our overall marketing activities or pricing strategies may not be successful in promoting or selling Noctiva™. If our marketing and advertising programs are not adequate to support future growth of Noctiva™ sales, its expected results may experience a material adverse effect on our business, financial condition and results of operations.

***We depend on a third-party supplier to manufacture Noctiva™ and any failure of such supplier to deliver sufficient quantities of Noctiva™ would have a material adverse effect on our business.***

We will depend on a single CMO, Renaissance Lakewood, LLC, for the manufacturing and supply of Noctiva™. If the supplies of Noctiva™ are interrupted for any reason, our manufacturing and marketing of Noctiva™ could be delayed. These delays could be extensive and expensive, especially in situations where a substitute is not readily available, or where additional regulatory approval is required. Failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

***Our cost to commercialize Noctiva™ could exceed our estimates or such costs may not provide the intended results.***

Our past and future internal budgets, plans and projections may underestimate the costs it will incur to develop and commercialize Noctiva™, including transaction and integration costs and the costs of other financial, business and strategic initiatives related to the Serenity License Agreement. Even if we adequately control such costs, our expenditures in developing and commercializing Noctiva™ may not yield the desired results. Further, we may incur higher than expected operating costs, and we may encounter general economic and business conditions that adversely affect it relating to the Serenity License Agreement.

***The development and commercialization of Noctiva™ will likely require significant management attention, which could disrupt our business and adversely affect our financial results.***

We anticipate that our management will devote substantial time and attention to develop and commercialize Noctiva™. By diverting management's attention away from our other products, our ongoing operations could suffer, which could have a material adverse effect on our business, financial condition, results of operations or prospects.

## 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.***

Although Noctiva has FDA approval (as described in the “Business of Avadel” included in Part I, Item 1 of this Annual Report), our fourth UMD product and our FT 218 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 III 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 III 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 FT 218 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 FT 218 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. FT 218 would not be the first product with such FDA approval. However, in limited circumstances, including if the FDA concludes that FT 218 is safer, more effective or makes a major contribution to patient care, the FDA could award FT 218 with such marketing exclusivity. The orphan drug designation for FT 218 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 FT 218 Phase III 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 FT 218. 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**

***Our share price has been volatile and may continue to be volatile.***

The trading price of our shares has been, and is likely to continue to be, highly volatile. The market value of an investment in our shares may fall sharply at any time due to this volatility. During the year ended December 31, 2017, the closing sale price of our ADSs as reported on the Nasdaq Global ranged from \$8.03 to \$11.57. During the year ended December 31, 2016, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from \$7.85 to \$14.89. 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 securities we may issue.

***If we are not able to sustain profitability in the future, the value of our shares may fall.***

We reported net income of \$68.3 million for the year ended December 31, 2017 and net loss of \$41.3 million for the year ended December 31, 2016. We cannot predict if we will be able to sustain profitability. If we are unable to maintain 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 launch costs of Noctiva;
- 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 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.

***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 increase 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, to acquire assets or businesses that we may identify as potentially beneficial to our business strategies, and for working capital, capital expenditures and general corporate purposes. As in the past we expect to invest our 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 February 16, 2017, Deerfield Capital and certain of its affiliates beneficially owned approximately 9.98% of Avadel's outstanding shares (in the form of ADRs). As of February 6, 2018, Brandes Investment Partners, L.P. and certain of its affiliates beneficially owned 7.99% of Avadel's outstanding shares (in the form of ADRs). As of February 13, 2018, Broadfin Capital and certain of its affiliates beneficially owned approximately 6.59% of our outstanding shares (in the form of ADRs). As of November 1, 2017, Perceptive Advisors LLC and certain of its affiliates beneficially owned 5.4% of our 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 Notes**

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

In the event the conditional exchange feature of the Notes is triggered, holders of Notes will be entitled to exchange the 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 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 Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 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 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 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 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 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 Notes to their face amount over the term of the 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 Notes.

In addition, under certain circumstances, convertible or exchangeable debt instruments (such as the 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 Notes are not included in the calculation of diluted earnings per share except to the extent that the exchange value of the 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 Notes, then Avadel's diluted earnings per share would be adversely affected.

***Exchanges of the Notes will dilute the ownership interest of Avadel's existing shareholders and holders of the ADSs, including holders who had previously exchanged their Notes and received ADSs upon exchange, to the extent our exchange obligation includes ADSs.***

The exchange of some or all of the 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 Notes could adversely affect prevailing market prices of the ADSs and, in turn, the price of the Notes. In addition, the existence of the Notes may encourage short selling by market participants because the exchange of the Notes could depress the price of the ADS.

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

The indenture governing the Notes will require us to repurchase the 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 Notes in connection with a make-whole fundamental change. A takeover of Avadel may trigger the requirement that we repurchase the 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 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. While our analysis of the Tax Act’s impact on our cash tax liability and financial condition has not identified any overall material adverse effect, we are still evaluating the effects of the Tax Act on us and there are a number of uncertainties and ambiguities as to the interpretation and application of many of the provisions in the Tax Act. In the absence of guidance on these issues, we will use what it believes are reasonable interpretations and assumptions in interpreting and applying the Tax Act for purposes of determining our cash tax liabilities and results of operations, which may change as we receive additional clarification and implementation guidance and as the interpretation of the Tax Act evolves over time. It is possible that the Internal Revenue Service (“IRS”) could issue subsequent guidance or take positions on audit that differ from the interpretations and assumptions that we have previously made, which could have a material adverse effect on our cash tax liabilities, results of operations and financial condition.

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

Not applicable.

### **Item 2. Properties.**

*(Amounts in thousands, except per 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 2019. 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 2019. The third facility of approximately 26,000 square feet houses research and biochemistry (Medusa) laboratories and quality/regulatory affairs and the lease may be terminated by the end of 2018.

We have commercial and administrative activities located in Chesterfield, Missouri. Our current office space consists of 22,229 square feet, and the lease expires in 2023. We still maintain the lease on our former office space which expires in 2018. 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.**

With respect to pending litigation involving patents covering Noctiva™, please see the information set forth under the caption “— Risks Related to Avadel’s Exclusive License Agreement for Noctiva™” in the “Risk Factors” included in Part I, Item 1A of this Annual Report on Form 10-K. While we may be engaged in various other claims and legal proceedings in the ordinary course of business, we are not involved (whether as a defendant or otherwise) in, and, we have no knowledge of any threat of, any other litigation, arbitration or administrative or other proceeding that management believes would, if determined adversely, have a material adverse effect on our consolidated financial position, results of operations or liquidity.

### **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.

#### Issuance of Company Securities in Cross-Border Merger on December 31, 2016

As described in Item 1. of this Annual Report on Form 10-K under the caption "Business - General Overview," the Company is an Irish public limited company, or plc, and is the successor to Flamel Technologies S.A., a French *société anonyme* ("Flamel"), as the result of the merger of Flamel with and into the Company which was completed at 11:59:59 p.m., Central Europe Time, on December 31, 2016 (the "Merger") pursuant to the agreement between Flamel and the Company 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.

In addition, pursuant to the Merger, all outstanding ordinary shares of Flamel were canceled and exchanged on a one-for-one basis for newly issued ordinary shares of the Company, \$0.01 nominal value per share; and 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. These exchanges resulted in the issuance of approximately 41,370,804 ordinary shares of the Company, of which approximately 40,426,656 of such ordinary shares were issued to the Depository under the Company's ADS program. Such 40,426,656 ordinary shares issued to the Depository were thereupon represented by ADSs and issued to the former holders of Flamel ADSs. The issuances of these securities in connection with the Merger were sanctioned by the High Court of Ireland pursuant to an order issued on November 25, 2016 after a hearing upon the fairness of the terms and conditions of such issuances at which all holders of Flamel ordinary shares had a right to appear and of which notice had been given. The foregoing issuances of ordinary shares of the Company and ADSs representing such ordinary shares of the Company were exempt from the registration requirements of the Securities Act by virtue of the exemption provided under Section 3(a)(10) thereof.

#### 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 Depository for the ADRs.

As of March 9, 2018, there were 37,693,988 ADS outstanding, and the closing stock price of the Company was \$7.29 per share.

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

	2017 Price Range		2016 Price Range	
	High	Low	High	Low
First quarter	\$ 12.30	\$ 8.87	\$ 12.92	\$ 7.85
Second quarter	11.72	8.75	13.32	8.83
Third quarter	11.18	8.14	14.89	11.01
Fourth quarter	11.53	7.52	13.16	9.26

#### Holder

As of March 9, 2018, there were 87 holders of record of our ordinary shares and 19 accounts registered with The Bank of New York Mellon, the depository of our ADS program, as holders of ADSs, one of which ADS accounts is registered to the Depository 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

The following table summarizes the repurchase activity of our ordinary shares during the three months ended December 31, 2017. The repurchase activity presented below includes market repurchases of shares.

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.

### Issuer Purchases of Equity Securities

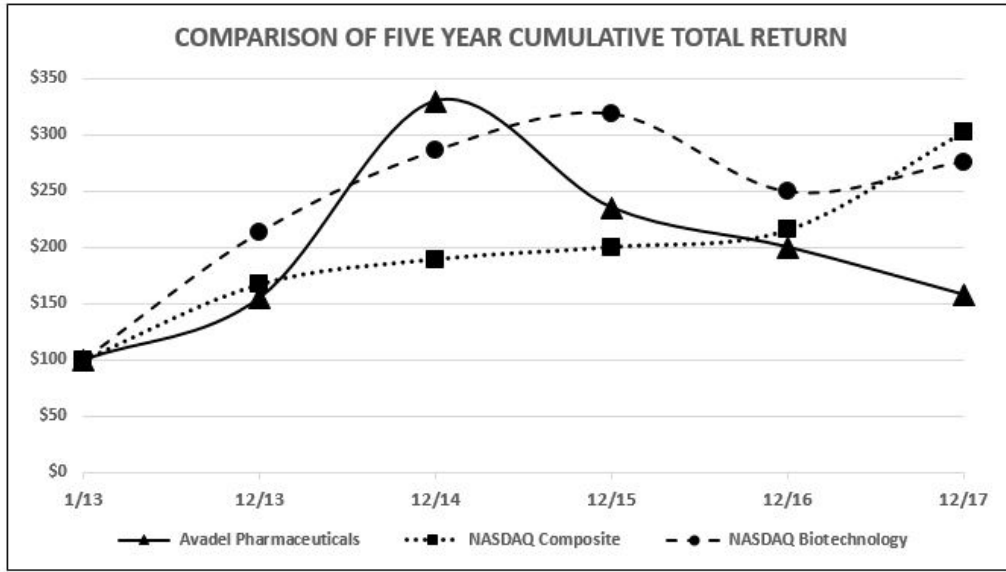
#### Fourth Quarter 2017

*(in thousands, except per share data)*

<b>Period</b>	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs</b>
October 1 - October 31, 2017	444	\$ 10.82	444	\$ 2,639
November 1, 2017 - November 30, 2017	—	—	—	2,639
December 1, 2017 - December 31, 2017	—	—	—	2,639
<b>Total</b>	<b>444</b>	<b>\$ 10.82</b>	<b>444</b>	<b>2,639</b>

## 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, 2017. 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.

<b>Statement of Income (Loss) Data:</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
Total revenue	\$ 173,245	\$ 150,246	\$ 173,009	\$ 14,975	\$ 4,179
Gross profit <sup>(a)</sup>	156,944	136,998	161,599	11,592	3,617
Operating income (loss)	89,505	(4,965)	70,758	(93,657)	(53,700)
Net income (loss) from continuing operations	68,271	(41,276)	41,798	(89,487)	(46,176)
Net income from discontinued operations	—	—	—	4,018	3,584
Net income (loss)	68,271	(41,276)	41,798	(85,469)	(42,592)
Net income (loss) per share - basic:					
Continuing operations	1.69	(1.00)	1.03	(2.47)	(1.81)
Discontinued operations	—	—	—	0.11	0.14
Net income (loss) per share - basic	1.69	(1.00)	1.03	(2.36)	(1.67)
Net income (loss) per share - diluted:					
Continuing operations	1.63	(1.00)	0.96	(2.47)	(1.81)
Discontinued operations	—	—	—	0.11	0.14
Net income (loss) per share - diluted	1.63	(1.00)	0.96	(2.36)	(1.67)

<b>Balance Sheet Data:</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
Cash and cash equivalents	\$ 16,564	\$ 39,215	\$ 65,064	\$ 39,760	\$ 6,636
Marketable securities	77,511	114,980	79,738	53,074	401
Goodwill	18,491	18,491	18,491	18,491	18,491
Intangible assets, net	92,289	22,837	15,825	28,389	40,139
Total assets	253,277	245,482	215,081	174,382	116,252
Long-term debt (incl. current portion)	267	815	1,118	3,717	30,249
Long-term related party payable (incl. current portion)	98,925	169,347	122,693	114,750	55,265

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

**Quarterly Financial Data (Unaudited):**

The following tables present certain unaudited consolidated quarterly financial information for each quarter of 2017 and 2016. Year-to-date net income (loss) per share amounts may be different than the sum of the applicable quarters due to differences in weighted average shares outstanding for the respective periods.

<b>2017:</b>	<b>March 31</b>		<b>June 30</b>		<b>September 30</b>		<b>December 31</b>	
Revenues	\$	52,507	\$	46,311	\$	39,675	\$	34,752
Gross profit <sup>(a)</sup>		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)

<b>2016:</b>	<b>March 31</b>		<b>June 30</b>		<b>September 30</b>		<b>December 31</b>	
Revenues	\$	36,216	\$	38,858	\$	32,087	\$	43,085
Gross profit <sup>(a)</sup>		32,310		34,951		29,243		40,494
Operating income (loss)		5,704		(11,543)		(16,190)		17,064
Net income (loss)		(6,058)		(19,958)		(19,994)		4,734
Net income (loss) per share - basic		(0.15)		(0.48)		(0.48)		0.11
Net income (loss) per share - diluted		(0.15)		(0.48)		(0.48)		0.11

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

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 (“Avadel,” the “Company,” “we,” “our,” or “us”) is a branded specialty pharmaceutical company. Avadel’s current revenues are primarily derived from products we market based on first-to-file New Drug Applications (“NDAs”) for pharmaceutical products previously sold in the U.S. without Food and Drug Administration (“FDA”) approval (“Unapproved Marketed Products” or “UMDs”). In addition, through the acquisition of patient-focused, innovative products or businesses in the commercial- and or late-stage of development, Avadel seeks to provide solutions for overlooked and unmet medical needs, including our urology product, Noctiva™, which we in-licensed in 2017 and will begin marketing in 2018. Avadel also seeks to develop products that utilize our Micropump® drug delivery technology, such as our narcolepsy product which is in clinical trials.

Avadel’s current commercial portfolio consists of three sterile injectable products, which were previously UMDs, used in the hospital setting, and Noctiva™, a urology product, which is the first and only FDA approved product for the treatment of nocturia due to nocturnal polyuria in adults. Avadel believes that nocturia, the condition of waking two or more times per night to void, represents a large unmet medical need affecting approximately 40 million Americans.

Avadel is actively developing a fourth sterile, injectable UMD product for which it expects to file an NDA and seek FDA approval. In addition, Avadel is currently enrolling patients in our REST-ON Phase III clinical trial to evaluate the safety and efficacy of FT 218, a once-nightly formulation of sodium oxybate using Micropump®, for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. Narcolepsy is a rare sleep disorder with few approved treatment options. Avadel will continue to strategically evaluate potential UMDs and Micropump® based product candidates for development and approval, and will also look for synergistic acquisition targets to grow our company.

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 an Irish public limited company, or plc, and is the successor to Flamel Technologies S.A., a French *société anonyme* (“Flamel”), as the result of the merger of Flamel with and into the Company which was completed 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. As a result of the Merger Agreement:

- 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.

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.

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 Securities and Exchange Commission on May 1, 2017.

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.

## **Our Business Model**

Avadel executes three primary strategies that allow us to develop and/or license or acquire differentiated branded products for FDA approval and commercialization, principally in the United States.

### **Unapproved Marketed Drug (“UMD”) Products**

In 2006 the FDA announced 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 NDA approval be granted for any such products via a 505(b)(2) process, the FDA will remove competing unapproved manufacturers until a generic application is approved. We believe 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, we have 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).

### **Inorganic Growth Through Acquisitions, Licensing, Divestitures and/or Partnerships**

We currently have a strong balance sheet and intend to explore and pursue appropriate inorganic growth opportunities that may enhance profitability and cash flow and would complement our urology and hospital products, or our sleep-focused product candidate, FT 218. We in-licensed Noctiva™ in September 2017 from Serenity Pharmaceuticals, and in February 2018 we divested four pediatric products to, and entered into a LiquiTime development agreement with, Cerecor.

## Development of Micropump®-Based Products

Our versatile Micropump-based technology allows us to select unique product development opportunities, representing either “life cycle” opportunities, whereby additional intellectual property can be added to a pharmaceutical to extend the commercial viability of a currently marketed product, or innovative formulation opportunities for new chemical entities (“NCE”). Several products formulated using our proprietary drug delivery technologies are currently under various stages of development. These products will be commercialized either by Avadel and/or by partners via licensing/distribution agreements. We are developing a product which uses our Micropump drug-delivery technology for the treatment of EDS and cataplexy in patients suffering from narcolepsy. We currently refer to this product as FT 218. FT 218 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.

## 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 and reimbursement 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.

## Recent Developments

### Asset Purchase Agreement with Cerecor.

On February 12, 2018, Avadel Pharmaceuticals plc (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”). At the closing under the Purchase Agreement, on February 16, 2018, 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 Therapeutics and FSC Laboratories, Inc., which is also a subsidiary of the Company (collectively “FSC”). The Company acquired FSC in February 2016 from Deerfield CSF, LLC (“Deerfield CSF”) and certain of its affiliates. Pursuant to the Purchase Agreement, Cerecor assumed the Company’s remaining payment obligations to Deerfield CSF under the Membership Interest Purchase Agreement, dated as of February 5, 2016, between Holdings, Flamel Technologies SA (the predecessor of the Company) and Deerfield CSF and certain of its affiliates, which payment obligations consist 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.

#### *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.

#### *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 CSF, LLC and certain of its affiliates (“Deerfield”). Under the Deerfield Guarantee, the Company and Holdings guaranteed to Deerfield the payment by Cerecor of the obligations of the Company and certain of its subsidiaries (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”).

#### *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.

#### *Issuance of Exchangeable Notes*

On February 14, 2018 we announced that our wholly-owned subsidiary, Avadel Finance Cayman Limited (the “Issuer”), priced a \$125,000 aggregate principal amount of 4.50% exchangeable senior notes due 2023 (the “Notes”) in a private placement (the “Offering”) to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the “Securities Act”). The sale of the Notes closed on February 16, 2018. In connection with the Offering, the Issuer granted the initial purchasers of the Notes a 30-day option to purchase up to an additional \$18,750 aggregate principal amount of the Notes, which was fully exercised on February 16, 2018.

Net proceeds from the Notes were \$137,719 after deducting the initial purchasers’ discount and estimated offering expenses. We expect to use the net proceeds of the Offering for working capital and general corporate purposes. We also used cash on-hand to purchase approximately 2.0 million ADSs for \$18,000 concurrently with the pricing of the Offering in privately negotiated transactions effected with or through a representative of the initial purchasers or an affiliate of such representative. The Issuer agreed to purchase such ADSs at a purchase price per ADS equal to the \$8.99 per ADS closing price on The Nasdaq Global Market on February 13, 2018.

The Notes are general, unsecured obligations of the Issuer, and are fully and unconditionally guaranteed by Avadel on a senior unsecured basis. Interest on the Notes will be payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2018. The Notes will mature on February 1, 2023, unless earlier exchanged, repurchased or redeemed in accordance with their terms. The Notes will be issued in minimum denominations of \$200 and integral multiples of \$1 in excess thereof.



Subject to certain conditions and during certain periods, the Notes will be exchangeable at the option of the holders at an initial exchange rate of 92.6956 ADSs per \$1 principal amount of 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 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.

### **Financial Highlights**

Highlights of our consolidated results for the year ended December 31, 2017 are as follows:

- Revenue was \$173,245 for the year ended December 31, 2017 compared to \$150,246 in the same period last year. This increase was primarily the result of having a full year's worth of Akovaz revenue in 2017, compared to the prior year which had revenue only from August 2016, the date Akovaz was launched. This increase was partially offset by declines in Bloxiverz unit volumes and net selling price as a result of additional competition.
- Operating income was \$89,505 for the year ended December 31, 2017 compared to operating loss of \$4,965 for the year ended December 31, 2016. The primary reasons for the increase in operating income were due to changes in the fair value of related party contingent considerations of \$80,325 (i.e., the Company recognized a \$31,040 gain resulting from the changes in fair value of related party contingent consideration for the year ended December 31, 2017, compared to a loss of \$49,285 in the same period last year), as well as increased gross margin of \$19,946 driven by higher revenue as described above and a decrease in intangible asset amortization expense of \$10,229. Higher SG&A of \$14,681 partially offset these increases.
- Net income was \$68,271 for the year ended December 31, 2017 compared to net loss of \$41,276 in the same period last year.
- Diluted net income per share was \$1.63 for the year ended December 31, 2017 compared to net loss per share of \$1.00 in the same period last year.
- Cash and marketable securities decreased \$60,120 to \$94,075 at December 31, 2017 from \$154,195 at December 31, 2016.

### **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, amortization of licensing fees, and, if any, milestone payments for R&D achievements.

#### *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 records revenue from product sales when title and risk of ownership have been transferred to the customer, which is typically upon delivery to the customer and when the selling price is determinable. As is customary in the pharmaceutical industry, the Company's gross product sales are subject to a variety of 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 based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

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 and Research Revenue*

Our license and research revenues consist of fees and/or milestone payments. Non-refundable fees where we have continuing performance obligations are deferred and are recognized ratably over our projected performance period. We recognize milestone payments, which are typically related to regulatory, commercial or other achievements by us or our licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. To the extent that the expected timelines for such milestone payments are changed from initial estimates, the Company will record cumulative adjustments to reflect the revised timeline. For the year ended December 31, 2017, we recognized \$404 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 grant-date fair value estimated in accordance with ASC 718. The fair value of stock options and warrants is estimated using Black-Scholes option-pricing valuation models (“Black-Scholes model”). As required by the Black-Scholes model, estimates are made of the underlying volatility of AVDL stock, a risk-free rate and an expected term of the option or warrant. We estimated the expected term using a simplified method, as we do not have enough historical exercise data for a majority of such options and warrants upon which to estimate an expected term. 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. ASC 740 states that 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 (1) record unrecognized tax benefits as liabilities in accordance with ASC 740 and (2) 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, 2017, the Company has unremitted earnings of \$3,038 outside of Ireland as measured on a US 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 2017, we performed our required annual impairment test of goodwill and have determined that no impairment of goodwill existed at December 31, 2017 or 2016.

**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 and FSC acquisitions. 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. The Company has determined that no impairment existed at December 31, 2017 or 2016.

**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) are accounted for at fair-value (see *Item 8. Financial Statements and Supplementary Data* and *Note 10: Long-Term Related Party Payable*). The fair value of the warrants issued in connection with the Éclat acquisition are estimated using a Black-Scholes option pricing model. The fair value of acquisition-related contingent consideration payable is estimated using a discounted cash flow model based on the long-term sales or gross profit forecasts of the specified hospital or pediatric products using an appropriate discount rate. There are a number of estimates used when determining the fair value of these earn-out payments. These estimates include, but are not limited to, the long-term pricing environment, market size, market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows. These estimates can and often do change based on changes in current market conditions, competition, management judgment and other factors. Changes to these estimates can have and have had a material impact on our consolidated statements of income (loss) and balance sheets. Changes in fair value of these liabilities are recorded in the consolidated statements of income (loss) within operating expenses as changes in fair value of 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 10: 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 income (loss) and balance sheets. Changes in the fair value of this liability are recorded in the consolidated statements of income (loss) 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):

Comparative Statements of Income (Loss):	Years Ended December 31,			Increase / (Decrease)			
	2017	2016	2015	2017 vs. 2016		2016 vs. 2015	
				\$	%	\$	%
Product sales and services	\$ 172,841	\$ 147,222	\$ 172,288	\$ 25,619	17.4 %	\$ (25,066)	(14.5)%
License and research revenue	404	3,024	721	(2,620)	(86.6)%	2,303	319.4 %
Total revenue	173,245	150,246	173,009	22,999	15.3 %	(22,763)	(13.2)%
Operating expenses:							
Cost of products and services sold	16,301	13,248	11,410	3,053	23.0 %	1,838	16.1 %
Research and development expenses	33,418	34,611	25,608	(1,193)	(3.4)%	9,003	35.2 %
Selling, general and administrative expenses	58,860	44,179	21,712	14,681	33.2 %	22,467	103.5 %
Intangible asset amortization	3,659	13,888	12,564	(10,229)	(73.7)%	1,324	10.5 %
(Gain) loss - changes in fair value of related party contingent consideration	(31,040)	49,285	30,957	(80,325)	(163.0)%	18,328	59.2 %
Restructuring costs	2,542	—	—	2,542	n/a	—	n/a
Total operating expenses	83,740	155,211	102,251	(71,471)	(46.0)%	52,960	51.8 %
Operating income (loss)	89,505	(4,965)	70,758	94,470	1,902.7 %	(75,723)	(107.0)%
Investment income, net	2,850	1,635	1,236	1,215	74.3 %	399	32.3 %
Interest expense, net	(1,052)	(963)	—	89	9.2 %	963	n/a
Other income (expense) - changes in fair value of related party payable	2,071	(6,548)	(4,883)	(8,619)	(131.6)%	1,665	34.1 %
Foreign exchange (loss) gain	(714)	1,123	10,594	(1,837)	(163.6)%	(9,471)	(89.4)%
Income (loss) before income taxes	92,660	(9,718)	77,705	102,378	1,053.5 %	(87,423)	(112.5)%
Income tax provision	24,389	31,558	35,907	(7,169)	(22.7)%	(4,349)	(12.1)%
Net income (loss)	\$ 68,271	\$ (41,276)	\$ 41,798	\$ 109,547	265.4 %	\$ (83,074)	(198.8)%
Net income (loss) per share - diluted	\$ 1.63	\$ (1.00)	\$ 0.96	\$ 2.63	263.0 %	\$ (1.96)	(204.2)%

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

Revenues	Years Ended December 31,			Increase / (Decrease)			
	2017	2016	2015	2017 vs. 2016		2016 vs. 2015	
				\$	%	\$	%
Bloxiverz	\$ 45,596	\$ 82,896	\$ 150,083	\$ (37,300)	(45.0)%	\$ (67,187)	(44.8)%
Vazculep	38,187	39,796	20,151	(1,609)	(4.0)%	19,645	97.5 %
Akovaz	80,617	16,831	—	63,786	379.0 %	16,831	n/a
Other	8,441	7,699	2,054	742	9.6 %	5,645	274.8 %
Total product sales and services	172,841	147,222	172,288	25,619	17.4 %	(25,066)	(14.5)%
License and research revenue	404	3,024	721	(2,620)	(86.6)%	2,303	319.4 %
Total revenue	\$ 173,245	\$ 150,246	\$ 173,009	\$ 22,999	15.3 %	\$ (22,763)	(13.2)%

### 2017 Compared to 2016

Product sales and services revenues were \$172,841 for the year ended December 31, 2017, compared to \$147,222 for the same prior year period. Revenues for the year ended December 31, 2016 include \$5,981 in additional non-recurring 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 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 were \$8,044 for the year ended December 31, 2017, compared to \$5,985 in the same prior year period.

License and research revenue was \$404 for the year ended December 31, 2017 compared to \$3,024 in the same period last 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.

#### 2016 Compared to 2015

Product sales and services revenues were \$147,222 for the year ended December 31, 2016, compared to \$172,288 for the same prior year period. 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 \$67,187 when compared to the same period last year, primarily due to a \$72,726 loss of market share and net selling price driven largely by two factors: a) lost business as a result of a new competitor in the neostigmine market who entered the market in the first quarter of 2016 and b) a new molecule approved by the FDA in late 2015 and launched in 2016 with a similar indicated use as Bloxiverz. The decline in Bloxiverz revenue was partially offset by an increase of \$4,597 related to the change in the revenue estimate noted above. Vazculep's revenue increased \$19,645 when compared to the same period last year due primarily to higher market share and a full year run rate in 2016 when compared to 2015 resulting from its launch in late 2014. Vazculep's sales were further increased by \$1,384 related to the change in revenue estimate noted above. The launch of Akovaz in August 2016 contributed \$16,831 to product sales for the year ended December 31, 2016. The increase in sales in Other was primarily driven from the February 2016 acquisition of FSC which contributed \$5,985 in revenues.

License and research revenues increased \$2,303 during the year ended December 31, 2016 compared to the same prior year period, driven primarily by a full year's accretion of the license payment we received from our entrance into an exclusive licensing agreement of the LiquiTime drug delivery platform for the U.S. OTC drug market during the third quarter of 2015.

Cost of Products and Services Sold	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
Cost of products and services sold	\$ 16,301	\$ 13,248	\$ 11,410	\$ 3,053	23.0%	\$ 1,838	16.1%
Percentage of sales	9.4%	8.8%	6.6%				

Cost of products and services sold increased \$3,053, or 23.0% during the year ended December 31, 2017 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 net selling prices.

Cost of products and services sold increased \$1,838 during the year ended December 31, 2016 as compared to the same period in 2015 primarily due to the consolidation of FSC which added \$2,929 in cost of products sold, offset partially by lower cost of products sold due to lower product sales in our Éclat portfolio of products. As a percentage of sales, cost of products sold increased to 8.8% in 2016 compared to 6.6% in 2015 due primarily to unfavorable product mix, largely related to the acquisition of FSC and lower net selling prices of Bloxiverz.

Research and Development Expenses	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
Research and development expenses	\$ 33,418	\$ 34,611	\$ 25,608	\$ (1,193)	(3.4)%	\$ 9,003	35.2%
Percentage of sales	19.3%	23.0%	14.8%				

R&D expenses were largely unchanged when compared to the same period last year. The Company continues to spend a substantial portion of our R&D spending on our FT 218 Phase 3 sodium oxybate clinical study.

R&D expenses increased \$9,003 or 35.2% and increased as a percentage of sales to 23.0% during the year ended December 31, 2016 as compared to the same period in 2015. These increases were primarily due to higher payroll and outside service costs related to feasibility studies and clinical program costs primarily associated with the sodium oxybate clinical trial.

Selling, General and Administrative Expenses	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
Selling, general and administrative expenses	\$ 58,860	\$ 44,179	\$ 21,712	\$ 14,681	33.2%	\$ 22,467	103.5%
Percentage of sales	34.0%	29.4%	12.5%				

Selling, general and administrative 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.

Selling, general and administrative expenses increased \$22,467 or 103.5% and increased as a percentage to sales to 29.4% during the year ended December 31, 2016 as compared to the same prior year period primarily due to increases resulting from the acquisition of FSC which added approximately \$9,700, increases in stock-based compensation of approximately \$5,000, increases in payroll and benefit costs to reinforce the Company's management team of approximately \$3,600, and higher professional fees, including legal, tax and audit of approximately \$3,500.

Intangibles Asset Amortization	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
Intangible asset amortization	\$ 3,659	\$ 13,888	\$ 12,564	\$ (10,229)	(73.7)%	\$ 1,324	10.5%
Percentage of sales	2.1%	9.2%	7.3%				

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.

Intangible asset amortization expense increased \$1,324 or 10.5% during the year ended December 31, 2016 as compared to the same prior year period, resulting from the commencement of amortization related to the acquired intangible assets of FSC.

Changes in Fair Value of Related Party Contingent Consideration	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
(Gain) loss - changes in fair value of related party contingent consideration	\$ (31,040)	\$ 49,285	\$ 30,957	\$ (80,325)	(163.0)%	\$ 18,328	59.2%
Percentage of sales	(17.9)%	32.8%	17.9%				

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.

As a result, changes in the estimates of the underlying assumptions used to determine the fair values of a) our acquisition-related contingent consideration earn-out payments - Éclat, b) acquisition related warrants and c) acquisition related FSC royalty liabilities we recorded a gain of \$31,040 to reduce the fair value of these liabilities for the year ended December 31, 2017 compared to an expense of \$49,285 to increase the fair value of these liabilities for the year ended December 31, 2016. As noted in our critical accounting estimates, there are numerous estimates we use when determining the fair value of the acquisition-related earn-out payments - Éclat. These estimates include the long-term pricing environment, market size, the market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows.

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.

For the year ended December 31, 2016, as a result of changes to these estimates when compared to the same estimates at December 31, 2015, we incurred a charge of \$57,609 to increase the fair value of acquisition related liabilities for Éclat primarily as a result of changes in market assumptions around our Akovaz product and a slightly better long-term sales and gross profit outlook for Bloxiverz. Additionally, we reduced the fair value of the acquisition related warrants which resulted in a gain of \$9,400, primarily due to a lower AVDL stock price at December 31, 2016 compared to December 31, 2015, changes in the volatility of AVDL stock during 2016 and a shorter remaining term. Further, we incurred a charge of \$1,076 to increase the fair value of acquisition related FSC royalty liabilities.

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 income (loss), balance sheet and cash flows.

Restructuring Costs	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
Restructuring costs	\$ 2,542	\$ —	\$ —	\$ 2,542	n/a	\$ —	n/a
Percentage of sales	1.5%	—%	—%				

Restructuring charges of \$2,542 were recognized during the year ended December 31, 2017. 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. In July 2017, the Company completed negotiations with the works council and received approval from the French Labor Commission to implement the plan. The reduction was substantially complete at the end of the year. The Company recorded a curtailment gain of \$717 during the year ended December 31, 2017 associated with the reduction of certain defined benefit retirement plan liabilities due to the reduction in force.

Investment Income, net	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
Investment income, net	\$ 2,850	\$ 1,635	\$ 1,236	\$ 1,215	74.3%	\$ 399	32.3%
Percentage of sales	1.6%	1.1%	0.7%				

Investment income increased \$1,215 during the year ended December 31, 2017 as compared to the same prior year period as gains were realized on a higher volume of sales of marketable securities year over year.

	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
<b>Interest Expense, net</b>							
Interest expense, net	\$ 1,052	\$ 963	\$ —	\$ 89	9.2%	\$ 963	n/a
Percentage of sales	(0.6)%	(0.6)%	—%				

Interest expense increased \$963 for the year ended December 31, 2016 when compared to the year ended December 31, 2015 as a result of interest on the long term related party note associated with the FSC acquisition.

	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
<b>Other Income (Expense) - Changes in Fair Value of Related Party Payable:</b>							
Other income (expense) - changes in fair value of related party payable	\$ 2,071	\$ (6,548)	\$ (4,883)	\$ (8,619)	(131.6)%	\$ 1,665	34.1%
Percentage of sales	1.2%	(4.4)%	(2.8)%				

We recorded a gain of \$2,071 and expense of \$6,548 to reduce and increase the fair value of these liabilities during the years ended December 31, 2017 and 2016, 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 estimates we use when determining the fair value of the related party payable payments. These estimates include the long-term pricing environment, 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 can and often do change based on changes in current market conditions, competition and other factors.

	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
<b>Foreign Exchange (Loss) Gain:</b>							
Foreign exchange (loss) gain	\$ (714)	\$ 1,123	\$ 10,594	\$ (1,837)	(163.6)%	\$ (9,471)	(89.4)%
Percentage of sales	(0.4)%	0.7%	6.1%				

We recorded a foreign exchange loss of \$714, for the year ended December 31, 2017 compared to a foreign exchange gain of \$1,123 for the year ended December 31, 2016. This decline was driven by an overall increase in the Euro foreign exchange rate during 2017 when compared to an overall decline in the Euro foreign exchange rate during 2016.

Foreign exchange gain declined \$9,471 or 89.4% for the year ended December 31, 2016 when compared to the year ended December 31, 2015. This decline was primarily due a foreign currency exchange gain recorded in 2015 associated with a USD denominated intercompany loan between Flamel SA, a Euro functional entity, and Éclat, a USD functional entity. This intercompany loan was settled in 2015.

	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
<b>Income Taxes:</b>							
Income tax provision	\$ 24,389	\$ 31,558	\$ 35,907	\$ (7,169)	(22.7)%	\$ (4,349)	(12.1)%
Percentage of income (loss) before income taxes	26.3%	(324.7)%	46.2%				



The items accounting for the difference between the income tax 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:	2017	2016	2015
Statutory tax rate <sup>(1)</sup>	12.5 %	12.5 %	33.3 %
Differences in international tax rates	22.2 %	(31.9)%	11.0 %
Nondeductible changes in fair value of contingent consideration	(11.6)%	(165.0)%	11.9 %
Income tax deferred charge	— %	(9.7)%	1.3 %
Change in valuation allowances	(0.7)%	11.8 %	(9.6)%
Nondeductible stock based compensation	(0.4)%	(14.8)%	1.3 %
Cross border merger	0.3 %	(100.6)%	— %
Unrealized tax benefits	1.4 %	(15.2)%	0.4 %
State and local taxes (net of federal)	0.3 %	(9.6)%	1.5 %
Change in U.S. tax law	3.8 %	— %	— %
Other	(1.5)%	(2.3)%	(4.9)%
Effective income tax rate	<u>26.3 %</u>	<u>(324.8)%</u>	<u>46.2 %</u>
Income tax provision (benefit) - at statutory tax rate <sup>(1)</sup>	\$ 11,582	\$ (1,215)	\$ 25,876
Differences in international tax rates	20,557	3,097	8,547
Nondeductible changes in fair value of contingent consideration	(10,779)	16,036	9,249
Income tax deferred charge	—	938	980
Change in valuation allowances	(610)	(1,143)	(7,425)
Nondeductible stock based compensation	(375)	1,436	1,004
Cross-border merger	265	9,773	—
Unrecognized tax benefits	1,296	1,475	290
State and local taxes (net of federal)	252	934	1,170
Change in U.S. tax law	3,513	—	—
Other	(1,312)	227	(3,784)
Income tax provision - at effective income tax rate	<u>\$ 24,389</u>	<u>\$ 31,558</u>	<u>\$ 35,907</u>

<sup>(1)</sup> The statutory rate reflects the Irish statutory tax rate of 12.5% for fiscal 2017 and 2016, and the French statutory tax rate of 33.3% for fiscal 2015.

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 United States 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 Tax Cuts and Jobs Act signed into law in the United States in December of 2017.

In 2016, the income tax provision decreased by \$4,349 when compared to the same period in 2015. The primary reason for the decrease in the income tax provision is a substantially lower level of pre-tax book income in the United States and France. Increases in the amount of nondeductible expenses due to changes in the fair value of contingent consideration and a reduced amount of income tax benefit from the release of valuation allowances partially offset the income tax benefit from the reduced amount of pre-tax book income in 2016, when compared to 2015. The Company also recorded \$9,773 of income tax provision in 2016 related to the cross-border merger.

## 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:

Net Cash Provided By (Used In):	Years Ended December 31,			Increase / (Decrease)			
				2017 vs. 2016		2016 vs. 2015	
	2017	2016	2015	\$	%	\$	%
Operating activities	\$ 16,662	\$ 18,901	\$ 84,293	\$ (2,239)	(11.8)%	\$ (65,392)	(77.6)%
Investing activities	(15,698)	(36,630)	(31,730)	20,932	57.1 %	(4,900)	(15.4)%
Financing activities	(23,318)	(7,954)	(23,751)	(15,364)	(193.2)%	15,797	66.5 %

### Operating Activities

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.

Net cash provided by operating activities of \$18,901 for the year ended December 31, 2016 decreased \$65,392 compared to the same prior year period. This decline in operating cash flow is primarily due to lower cash earnings (net loss adjusted for non-cash credits and charges) when compared to the same period last year, largely driven from lower revenues. Additionally, contributing to the lower operating cash flows was a shift in the classification of earn-out payments for related party contingent consideration and royalty payments for related party payables from financing activities to operating activities. During 2016, the cumulative life-to-date payments of such related party payables reached and exceeded the original fair value of the related liabilities established as part of the purchase price allocation of the Éclat acquisition and as such the Company began classifying all payments in excess of these original fair values within operating activities. Payments in excess of the original fair value totaling \$22,721 were classified within operating activities for the year ended December 31, 2016, compared to the same period in 2015 during which all such cash payments were classified as financing activities.

### Investing Activities

Cash used in investing activities of \$15,698 for the year ended December 31, 2017 decreased \$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.

Cash used in investing activities of \$36,630 for the year ended December 31, 2016 increased \$4,900 compared to the same prior year period. This increase was primarily driven by higher uses of cash of \$29,194 for purchases of marketable securities partially offset by the higher proceeds from sales of marketable securities of \$23,238.

### Financing Activities

Cash used in financing activities of \$23,318 for the year ended December 31, 2017 increased \$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.

Cash used in financing activities of \$7,954 for the year ended December 31, 2016 decreased \$15,797 compared to the same prior year period. The decrease in the usage of cash for financing activities was primarily related to lower earn-out payments for related party contingent consideration. As noted in the discussion of cash flows from operating activities, contributing to the lower uses of cash for financing activities was a shift in the classification of earn-out payments for related party contingent consideration and royalty payments for related party payables from financing activities to operating activities. During 2016, the cumulative life-to-date payments of such related party payables reached and exceeded the original fair value of the related liabilities established as part of the purchase price allocation of the Éclat acquisition and as such the Company began classifying all payments in excess of these original fair values within operating activities. Payments made before the Company exceeded the original fair value of the related liabilities are classified as financing activities and amounted to \$8,117 for the twelve months ended December 31, 2016 compared to \$27,897 in the same period last year, during which all such cash payments were classified as financing activities.

Additionally, the Company made \$4,911 in debt repayments during the twelve months ended December 31, 2015. No such payments were made in 2016 as the related debt was repaid in full in 2015. Cash proceeds from the issuance of ordinary shares and warrants were \$6,990 during the twelve months ended December 31, 2015, compared to \$440 during the twelve months ended December 31, 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 American Depositary Receipts in the open market with an indefinite duration. 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. As of December 31, 2017, the Company has used \$22,361 of our authorization.

#### ***Liquidity and Risk Management***

We believe that our existing cash and marketable securities balances and cash we expect to generate from operations will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product revenues and expenses, as well as the other factors set forth in "Risk Factors." To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business. Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash and marketable securities balances which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

To continue to grow our business over the longer term, we plan to commit substantial resources to the launch of Noctiva, product development and clinical trials of product candidates. In this regard, we have evaluated and expect to continue to evaluate a variety of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur indebtedness, seek equity capital or both. Raising additional capital could 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, 2017 and December 31, 2016, there were no contingent liabilities with respect to any threat of 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.

##### ***Material Commitments***

At December 31, 2017, the Company has a commitment to purchase services for a total of \$22,500 for a five-year period commencing January 1, 2015. The minimum amount of services for the remaining two years is \$4,875 for both 2018 and 2019. See *Item 8. Financial Statements and Supplementary Data* and *Note 14: Contingent Liabilities* for more discussion.

The Company also has two commitments to purchase finished product from two different contract manufacturers for a twenty-year period commencing August 1, 2015 and for a six-year period commencing in 2017. For the twenty-year commitment, the commitment for any individual year is contractually waived if the Company's net customer sales for that product exceed certain amounts in that same year. This commitment, which amounts to \$19,705, has been assumed by Cerecor as part of the divestiture of the pediatric assets. See *Item 8. Financial Statements and Supplementary Data and Note 21: Subsequent Events*. Commitments for these arrangements, at maximum quantities and at contractual prices over the remaining life of the contract, and excluding any waived commitments, are as follows for the years ended December 31:

<b>Purchase Commitments:</b>	<b>Balance</b>
2018	\$ 10,512
2019	9,406
2020	4,531
2021	4,531
2022	4,531
Thereafter	14,169
<b>Total</b>	<b>\$ 47,680</b>

The Company and our subsidiaries lease office facilities under noncancelable operating leases expiring at various dates. Rent expense, net of rental income, was \$1,146, \$970 and \$752 in 2017, 2016, and 2015, respectively. Minimum rental commitments for non-cancelable leases in effect at December 31, 2017 are as follows:

<b>Lease Commitment:</b>	<b>Balance</b>
2018	\$ 1,417
2019	919
2020	812
2021	548
2022	559
Thereafter	188
<b>Total</b>	<b>\$ 4,443</b>

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 9: Long-Term Debt, Note 10: Long-Term Related Party Payable, and Note 12: Post-Retirement Benefit Plans*, respectively.

#### **Aggregate Contractual Obligations**

The following table presents contractual obligations of the Company at December 31, 2017:

<b>Contractual Obligations:</b>	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1 to 3 Years</b>	<b>3 to 5 Years</b>	<b>More than 5 Years</b>
Long-term debt	\$ 267	\$ 111	\$ 156	\$ —	\$ —
Long-term related party payable (undiscounted) <sup>(1)</sup>	163,100	22,173	26,080	37,822	77,025
Purchase commitments <sup>(2)</sup>	47,680	10,512	13,937	9,062	14,169
Operating leases	4,957	1,721	1,912	1,136	188
<b>Total contractual cash obligations</b>	<b>\$ 216,004</b>	<b>\$ 34,517</b>	<b>\$ 42,085</b>	<b>\$ 48,020</b>	<b>\$ 91,382</b>

(1) On February 12, 2018, Avadel Pharmaceuticals plc (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"). At the closing under the Purchase Agreement, on February 16, 2018, 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 Therapeutics and FSC Laboratories, Inc., which is also a subsidiary of the Company (collectively “FSC”). The Company acquired FSC in February 2016 from Deerfield CSF, LLC (“Deerfield CSF”) and certain of its affiliates. Pursuant to the Purchase Agreement, Cerecor assumed the Company’s remaining payment obligations to Deerfield CSF under the Membership Interest Purchase Agreement dated February 5, 2016, between Holdings, Flamel Technologies SA (the predecessor of the Company) and Deerfield CSF and certain of its affiliates, which payment obligations consist 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. All three of these amounts, which total approximately \$29,000, are included within the Long-term related party payable line above. See *Item 8. Financial Statements and Supplementary Data* and *Note 21: Subsequent Events* for a further discussion.

(2) This line includes the twenty-year commitment, which amounts to \$19,705 and has been assumed by Cerecor as part of the Purchase Agreement. See *Note 21: Subsequent Events* for a further discussion.

See *Note 9: Long-Term Debt* and *Note 10: 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. Obligations relative to the Deerfield warrant-based contingent consideration of \$2,479 are not included within the above table. The Company’s long-term debt does not bear interest and therefore no interest is included in the above table.

See *Note 12: 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 \$1,303 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 have significant operations in Europe as well as in the U.S. Prior to December 31, 2016 each of the Company’s non-U.S. subsidiaries and the parent entity, Flamel Technologies S.A., used the Euro as its functional currency. At December 31, 2016, in conjunction with the cross-border merger, the surviving entity in the merger and our new public holding company, Avelo Pharmaceuticals plc or the “Company,” determined the U.S. dollar is our functional currency. The functional currency of certain foreign subsidiaries is the local currency. We are exposed to foreign currency exchange risk as the functional currency financial statements of foreign subsidiaries are translated to U.S. dollars. The assets and liabilities of our foreign subsidiaries having a functional currency other than the U.S. dollar are 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 our foreign subsidiaries 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 our subsidiaries that have 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, 2017 would have had an immaterial impact on net income for the year ended December 31, 2017.

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 income (loss). As of December 31, 2017, our primary exposure 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 losses resulting from transactional exposure were \$714 for the year ended December 31, 2017.

Item 8. Financial Statements and Supplementary Data.

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

	Years ended December 31,		
	2017	2016	2015
<b>Revenues:</b>			
Product sales and services	\$ 172,841	\$ 147,222	\$ 172,288
License and research revenue	404	3,024	721
Total revenue	173,245	150,246	173,009
<b>Operating expenses:</b>			
Cost of products and services sold	16,301	13,248	11,410
Research and development expenses	33,418	34,611	25,608
Selling, general and administrative expenses	58,860	44,179	21,712
Intangible asset amortization	3,659	13,888	12,564
(Gain) loss - changes in fair value of related party contingent consideration	(31,040)	49,285	30,957
Restructuring costs	2,542	—	—
Total operating expenses	83,740	155,211	102,251
Operating income (loss)	89,505	(4,965)	70,758
Investment income, net	2,850	1,635	1,236
Interest expense, net	(1,052)	(963)	—
Other income (expense) - changes in fair value of related party payable	2,071	(6,548)	(4,883)
Foreign exchange (loss) gain	(714)	1,123	10,594
Income (loss) before income taxes	92,660	(9,718)	77,705
Income tax provision	24,389	31,558	35,907
Net income (loss)	\$ 68,271	\$ (41,276)	\$ 41,798
<b>Net income (loss) per share - basic</b>			
	\$ 1.69	\$ (1.00)	\$ 1.03
<b>Net income (loss) per share - diluted</b>			
	\$ 1.63	\$ (1.00)	\$ 0.96
<b>Weighted average number of shares outstanding - basic</b>			
	40,465	41,248	40,580
<b>Weighted average number of shares outstanding - diluted</b>			
	41,765	41,248	43,619

*See accompanying notes to consolidated financial statements.*

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

	Years ended December 31,		
	2017	2016	2015
Net income (loss)	\$ 68,271	\$ (41,276)	\$ 41,798
Other comprehensive income (loss), net of tax:			
Foreign currency translation gain (loss)	134	(1,024)	(15,087)
Net other comprehensive income (loss), net of \$28, \$16, (\$20) tax, respectively	165	116	(147)
<b>Total other comprehensive income (loss), net of tax</b>	<b>299</b>	<b>(908)</b>	<b>(15,234)</b>
<b>Total comprehensive income (loss)</b>	<b>\$ 68,570</b>	<b>\$ (42,184)</b>	<b>\$ 26,564</b>

*See accompanying notes to consolidated financial statements.*



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

	December 31,	
	2017	2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 16,564	\$ 39,215
Marketable securities	77,511	114,980
Accounts receivable	14,785	17,839
Inventories, net	6,157	3,258
Prepaid expenses and other current assets	8,958	5,894
<b>Total current assets</b>	<b>123,975</b>	<b>181,186</b>
Property and equipment, net	3,001	3,320
Goodwill	18,491	18,491
Intangible assets, net	92,289	22,837
Research and development tax credit receivable	5,272	1,775
Income tax deferred charge	—	10,342
Other non-current assets	10,249	7,531
<b>Total assets</b>	<b>\$ 253,277</b>	<b>\$ 245,482</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ 111	\$ 268
Current portion of long-term related party payable	25,007	34,177
Accounts payable	7,477	7,105
Deferred revenue	2,007	2,223
Accrued expenses	50,926	17,222
Income taxes	414	1,200
Other current liabilities	597	226
<b>Total current liabilities</b>	<b>86,539</b>	<b>62,421</b>
Long-term debt, less current portion	156	547
Long-term related party payable, less current portion	73,918	135,170
Other non-current liabilities	7,084	5,275
<b>Total liabilities</b>	<b>167,697</b>	<b>203,413</b>
Shareholders' equity:		
Preferred shares, \$0.01 nominal value; 50,000 shares authorized; none issued or outstanding at December 31, 2017 and December 31, 2016, respectively	—	—
Ordinary shares, nominal value of \$0.01; 500,000 shares authorized; 41,463 issued and 39,346 outstanding at December 31, 2017, and 41,371 issued and outstanding at December 31, 2016	414	414
Treasury shares, at cost, 2,117 and 0 shares held at December 31, 2017 and December 31, 2016, respectively	(22,361)	—
Additional paid-in capital	393,478	385,020
Accumulated deficit	(262,685)	(319,800)
Accumulated other comprehensive loss	(23,266)	(23,565)
<b>Total shareholders' equity</b>	<b>85,580</b>	<b>42,069</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 253,277</b>	<b>\$ 245,482</b>

*See accompanying notes to consolidated financial statements.*

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

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Treasury Shares		Total shareholders' equity
	Shares	Amount				Shares	Amount	
Balance, December 31, 2014	40,191	\$ 6,188	\$ 346,582	\$ (320,322)	\$ (7,423)	\$ —	\$ —	\$ 25,025
Net income	—	—	—	41,798	—	—	—	41,798
Other comprehensive loss	—	—	—	—	(15,234)	—	—	(15,234)
Subscription of warrants	—	—	601	—	—	—	—	601
Exercise of stock options or warrants	899	123	6,266	—	—	—	—	6,389
Vesting of restricted shares	151	20	(20)	—	—	—	—	—
Stock-based compensation expense	—	—	7,741	—	—	—	—	7,741
Excess tax benefit from stock-based comp	—	—	2,814	—	—	—	—	2,814
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 2: Effect of New Accounting Standards)	—	—	—	(11,156)	—	\$ —	—	(11,156)
Balance, December 31, 2017	41,463	\$ 414	\$ 393,478	\$ (262,685)	\$ (23,266)	\$ 2,117	\$ (22,361)	\$ 85,580

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2017	2016	2015
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 68,271	\$ (41,276)	\$ 41,798
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	4,883	14,489	13,132
Loss on disposal of property and equipment	—	110	—
(Gain) loss on sale of marketable securities	(411)	826	779
Foreign exchange loss (gain)	714	(349)	(8,969)
Grants recognized in research and development expenses	(539)	—	(1,498)
Remeasurement of related party acquisition-related contingent consideration	(31,040)	49,285	30,957
Remeasurement of related party financing-related contingent consideration	(2,071)	6,548	4,883
Change in deferred tax and income tax deferred charge	3,556	(4,000)	69
Stock-based compensation expense	8,072	14,679	7,741
Net changes in assets and liabilities			
Accounts receivable	3,054	(10,050)	(8,440)
Inventories	(2,899)	1,831	3,036
Prepaid expenses and other current assets	(3,741)	3,412	(684)
Research and development tax credit receivable	(3,141)	397	2,975
Accounts payable & other current liabilities	595	(434)	(8,533)
Deferred revenue	(216)	(2,923)	3,815
Accrued expenses	13,187	6,764	3,376
Accrued income taxes	(786)	1,778	(393)
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(31,636)	(20,252)	—
Royalty payments for related party payable in excess of original fair value	(4,429)	(2,469)	—
Other long-term assets and liabilities	(4,761)	535	249
Net cash provided by operating activities	<u>16,662</u>	<u>18,901</u>	<u>84,293</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(591)	(1,201)	(1,629)
Acquisitions of businesses, including cash acquired and other adjustments	—	628	—
Purchase of intangible assets	(53,111)	—	—
Proceeds from sales of marketable securities	189,009	71,546	48,308
Purchases of marketable securities	(151,005)	(107,603)	(78,409)
Net cash used in investing activities	<u>(15,698)</u>	<u>(36,630)</u>	<u>(31,730)</u>
<b>Cash flows from financing activities:</b>			
Reimbursement of loans	—	—	(4,911)
Reimbursement of conditional R&D grants	(115)	(277)	(747)
Earn-out payments for related party contingent consideration	(1,246)	(6,892)	(24,526)
Royalty payments for related party payable	—	(1,225)	(3,371)
Excess tax benefit from stock-based compensation	—	—	2,814
Cash proceeds from issuance of ordinary shares and warrants	404	440	6,990
Share repurchases	(22,361)	—	—
Net cash used in financing activities	<u>(23,318)</u>	<u>(7,954)</u>	<u>(23,751)</u>
Effect of foreign currency exchange rate changes on cash and cash equivalents	(297)	(166)	(3,508)
Net (decrease) increase in cash and cash equivalents	(22,651)	(25,849)	25,304
Cash and cash equivalents at January 1	39,215	65,064	39,760
Cash and cash equivalents at December 31	<u>\$ 16,564</u>	<u>\$ 39,215</u>	<u>\$ 65,064</u>
Supplemental disclosures of cash flow information:			
Income tax paid	\$ 19,143	\$ 27,180	\$ 42,121
Interest paid	1,050	788	4,738

See accompanying notes to consolidated financial statements.

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

**NOTE 1 : Summary of Significant Accounting Policies**

**Nature of Operations.** Avadel Pharmaceuticals plc (“Avadel,” the “Company,” “we,” “our,” or “us”) is a branded specialty pharmaceutical company. Avadel’s current revenues are primarily derived from products we market based on first-to-file New Drug Applications (“NDAs”) for pharmaceutical products previously sold in the U.S. without FDA approval (“Unapproved Marketed Products” or “UMDs”). In addition, through the acquisition of patient-focused, innovative products or businesses in the commercial- and or late-stage of development, Avadel seeks to provide solutions for overlooked and unmet medical needs, including our urology product, Noctiva™, which we in-licensed in 2017 and will begin marketing in 2018. Avadel also seeks to develop products that utilize our Micropump® drug delivery technology, such as our narcolepsy product which is in clinical trials.

Avadel’s current commercial portfolio consists of three sterile injectable products, which were previously UMDs, used in the hospital setting, and Noctiva™, a urology product, which is the first and only FDA approved product for the treatment of nocturia due to nocturnal polyuria in adults. Nocturia is the condition of waking two or more times per night to void.

Avadel is actively developing a fourth sterile, injectable UMD product for which it expects to file an NDA and seek FDA approval. In addition, Avadel is currently enrolling patients in our REST-ON Phase III clinical trial to evaluate the safety and efficacy of FT 218, a once-nightly formulation of sodium oxybate using Micropump®, for the treatment of EDS and cataplexy in patients suffering from narcolepsy. Narcolepsy is a rare sleep disorder with few approved treatment options. Avadel will continue to strategically evaluate potential UMDs and Micropump® based product candidates for development and approval, and will also look for synergistic acquisition targets to grow our company.

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 an Irish public limited company, or plc, and is the successor to Flamel Technologies S.A., a French *société anonyme* (“Flamel”), as the result of the merger of Flamel with and into the Company which was completed 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. As a result of the Merger Agreement:

- 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 Securities and Exchange Commission on May 1, 2017.

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.

**Revenue.** Revenue includes sales of pharmaceutical products, amortization of licensing fees, and, if any, milestone payments for R&D achievements.

#### *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 records revenue from product sales when title and risk of ownership have been transferred to the customer, which is typically upon delivery to the customer and when the selling price is determinable. As is customary in the pharmaceutical industry, the Company's gross product sales are subject to a variety of 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 based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

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 and Research Revenue*

Our license and research revenues consist of fees and/or milestone payments. Non-refundable fees where we have continuing performance obligations are deferred and are recognized ratably over our projected performance period. We recognize milestone payments, which are typically related to regulatory, commercial or other achievements by us or our licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. To the extent that the expected timelines for such milestone payments are changed from initial estimates, the Company will record cumulative adjustments to reflect the revised timeline. For the year ended December 31, 2017, we recognized \$404 of revenue from license agreements.

**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 income (loss) 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 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 grant-date fair value estimated in accordance with ASC 718. The fair value of stock options and warrants is estimated using Black-Scholes option-pricing valuation models ("Black-Scholes model"). As required by the Black-Scholes model, estimates are made of the underlying volatility of AVDL stock, a risk-free rate and an expected term of the option or warrant. We estimated the expected term using a simplified method, as we do not have enough historical exercise data for a majority of such options and warrants upon which to estimate an expected term. 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 income (loss). Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheets.

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

**Marketable Securities.** The Company's marketable securities are considered to be available for sale and are carried at fair value, with unrealized gains and losses, net of taxes, reported as a component of accumulated other comprehensive 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 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 three significant customers. See *Note 19: Company Operations by Product, Customer and Geographic Area*.

**Inventories.** Inventories consist of raw materials and finished products, which are stated at lower of cost or market determined under 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 2017, we performed our required annual impairment test of goodwill and have determined that no impairment of goodwill existed at December 31, 2017 or 2016.

**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 and FSC acquisitions. 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. The Company has determined that no impairment existed at December 31, 2017 or 2016.

**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) are accounted for at fair-value (see *Item 8. Financial Statements and Supplementary Data* and *Note 10: Long-Term Related Party Payable*). The fair value of the warrants issued in connection with the Éclat acquisition are estimated using a Black-Scholes option pricing model. The fair value of acquisition-related contingent consideration payable is estimated using a discounted cash flow model based on the long-term sales or gross profit forecasts of the specified hospital or pediatric products using an appropriate discount rate. There are a number of estimates used when determining the fair value of these earn-out payments. These estimates include, but are not limited to, the long-term pricing environment, market size, market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows. These estimates can and often do change based on changes in current market conditions, competition, management judgment and other factors. Changes to these estimates can have and have had a material impact on our consolidated statements of income (loss) and balance sheets. Changes in fair value of these liabilities are recorded in the consolidated statements of income (loss) within operating expenses as changes in fair value of 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 10: 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 income (loss) and balance sheets. Changes in the fair value of this liability are recorded in the consolidated statements of income (loss) as other income (expense) - changes in fair value of related party payable.

**Foreign Currency Translation.** At December 31, 2017, 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 income (loss). 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 comprehensive income (loss).

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

#### **NOTE 2 : Effect of New Accounting Standards**

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 standard is effective starting in 2018, with early adoption permitted. Retrospective application is required for the guidance on the statement of income presentation. Prospective application is required for the guidance on the cost capitalization in assets. The Company does not believe this standard will materially impact our consolidated financial statements.

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 January 2017, the FASB issued ASU 2017-01, "*Business Combinations (Topic 805): Clarifying the Definition of a Business.*" This update provides a screen to determine whether or not a set of assets is a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set of assets is not a business. If the screen is not met, the amendments in this update (1) require that to be considered a business, a set of assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. This guidance is effective for the Company in the first quarter of fiscal 2018. Early adoption is permitted for transactions not previously reported in the Company's consolidated financial statements. In September 2017, the Company entered into an Exclusive License and Assignment Agreement ("ELAA") to acquire from Serenity Pharmaceuticals, LLC intellectual property rights to further develop and commercialize Noctiva in the United States. The Company elected to early adopt ASU 2017-01 and determined the intangible assets acquired as part of the ELAA should be accounted for as an acquisition of a single group of assets and not as a business combination.

In October 2016, the FASB issued ASU 2016-16, "*Income Taxes (Topic 740), Intra-Entity Transfers of Assets Other Than Inventory,*" which requires companies to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. ASU 2016-16 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. The Company elected to early adopt ASU 2016-16 on a modified-retrospective basis as of January 1, 2017. Adoption of ASU 2016-16 eliminated the \$11,156 income tax deferred charge recorded within the consolidated balance sheet as of December 31, 2016 and such elimination is reflected as an adjustment to accumulated deficit as of January 1, 2017.



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 does not believe this standard will materially impact 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. These ASUs will be effective for annual and interim periods beginning after December 15, 2017, with early adoption for annual and interim periods beginning after December 15, 2016 permitted and should be applied retrospectively to each prior reporting period presented or as a modified retrospective adjustment as of the date of adoption.

The Company has completed our evaluation and assessment of the potential impacts of adopting this pronouncement on our consolidated financial statements and related disclosures. Based on this assessment, we will adopt the pronouncement under the modified retrospective method of transition in the first quarter of 2018. The Company does not expect adoption of the new standard will 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.

In March 2016, the FASB issued ASU 2016-09, “*Improvements to Employee Share-Based Payment Accounting*” which amends Accounting Standards Codification (“ASC”) Topic 718 “*Compensation – Stock Compensation*”. This update simplifies several aspects of accounting for share-based payment awards to employees, including the accounting for income taxes, classification of awards as either equity or liabilities, forfeitures and classification in the statement of cash flows. We adopted the standard on a prospective basis with the effect of adoption reflected for the interim periods after the year beginning January 1, 2017 as required by the standard. The primary effects of adoption were immaterial to the Company’s consolidated financial statements for the year ended December 31, 2017.

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. This update will be applied using a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the effect of this update on our consolidated financial statements.

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 ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2017, and requires a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. Early adoption is not permitted. The new guidance will require 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 will be recognized in our consolidated statement of income (loss) rather than as a component of our consolidated statement of comprehensive income (loss). The Company cannot reasonably estimate at this time the impact ASU 2016-01 will have on its financial statements and related disclosures.

### **NOTE 3 : FAIR VALUE MEASUREMENTS**

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

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

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

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

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

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

Fair Value Measurements:	As of December 31, 2017			As of December 31, 2016		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<b>Marketable securities (see Note 4: Marketable Securities)</b>						
Equity securities	\$ 468	\$ —	\$ —	\$ 4,033	\$ —	\$ —
Money market funds	44,481	—	—	—	—	—
Corporate bonds	—	9,262	—	—	57,348	—
Government securities - U.S.	—	19,050	—	—	42,814	—
Government securities - Non-U.S.	—	—	—	—	233	—
Other fixed-income securities	—	4,250	—	—	10,471	—
Other securities	—	—	—	—	81	—
<b>Total assets</b>	<b>\$ 44,949</b>	<b>\$ 32,562</b>	<b>\$ —</b>	<b>\$ 4,033</b>	<b>\$ 110,947</b>	<b>\$ —</b>
<b>Related party payable (see Note 10: Long-Term Related Party Payable)</b>						
	—	—	98,925	—	—	169,347
<b>Total liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 98,925</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 169,347</b>

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, 2017, there were no transfers in and out of Level 1, 2, or 3. During the twelve months ended December 31, 2017, 2016 and 2015, 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. Additionally, the Company's long-term 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.

#### NOTE 4 : Marketable Securities

The Company has investments in available-for-sale marketable securities which are recorded at fair market value. Unrealized gains and losses are recorded as other comprehensive income (loss) in shareholders' equity, net of income tax effects.

The following tables show the Company's available-for-sale securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category as of December 31, 2017 and 2016, respectively:

Marketable Securities:	2017			
	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

Marketable Securities:	2016			
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value
Equity securities	\$ 3,689	\$ 409	\$ (65)	\$ 4,033
Corporate bonds	57,871	89	(612)	57,348
Government securities - U.S.	43,049	515	(750)	42,814
Government securities - Non-U.S.	247	—	(14)	233
Other fixed-income securities	10,281	221	(31)	10,471
Other securities	81	—	—	81
Total	\$ 115,218	\$ 1,234	\$ (1,472)	\$ 114,980

We determine realized gains or losses on the sale of marketable securities on a specific identification method. We recognized gross realized gains of \$1,677, \$1,265, and \$241 for the twelve months ended December 31, 2017, 2016, and 2015, respectively. These realized gains were offset by realized losses of \$1,390, \$586, and \$677 for the twelve-months ended December 31, 2017, 2016, and 2015, respectively. We reflect these gains and losses as a component of investment income in the accompanying consolidated statements of income (loss).

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, 2017:

Marketable Debt Securities:	Maturities				Total
	Less than 1 Year	1-5 Years	5-10 Years	Greater than 10 Years	
Corporate bonds	1,033	6,826	1,403	—	9,262
Government securities - U.S.	50	17,509	977	514	19,050
Other fixed-income securities	—	4,250	—	—	4,250
Total	\$ 1,083	\$ 28,585	\$ 2,380	\$ 514	\$ 32,562

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 5 : Inventories**

The principal categories of inventories, net reserves of \$1,039 and \$3,223 at December 31, 2017 and 2016, respectively, are comprised of the following:

Inventory:	2017	2016
Finished goods	\$ 4,774	\$ 2,429
Raw materials	1,383	829
Total	<u>\$ 6,157</u>	<u>\$ 3,258</u>

**NOTE 6 : Property and Equipment, net**

The principal categories of property and equipment, net at December 31, 2017 and 2016, respectively, are as follows:

Property and Equipment, net:	2017	2016
Laboratory equipment	\$ 10,135	\$ 9,019
Software, office and computer equipment	3,115	2,519
Furniture, fixtures and fittings	4,779	4,239
Less - accumulated depreciation	(15,028)	(12,457)
Total	<u>\$ 3,001</u>	<u>\$ 3,320</u>

Depreciation expense for the years ended December 31, 2017, 2016 and 2015 was \$1,224, \$601 and \$568, respectively.

**NOTE 7 : 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 21: Subsequent Events*.

This acquisition has been accounted for using the acquisition method of accounting and, accordingly, its results are included in the Company's consolidated financial statements from the date of acquisition. 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 are reported in related party payable within the Company's consolidated balance sheet, and is further disclosed in *Note 10: Long-Term Related Party Payable*.

The fair values assigned to the acquired assets and liabilities have been 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	<u>\$ 21,192</u>

A portion of the transaction attributable to certain intangible assets was taxable for income tax purposes resulting 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 range 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 2015, the Company's unaudited pro forma net revenue and net income (loss) for the twelve months ended December 31, 2016 and 2015 would have been as follows:

Pro Forma Net Revenue and Income (Loss):	2016		2015	
Net revenues	\$	150,721	\$	178,104
Net income (loss)		(42,290)		30,965

#### NOTE 8 : Goodwill and Intangible Assets

The Company's amortizable and unamortizable intangible assets at December 31, 2017 and 2016, respectively, are as follows:

Goodwill and Intangible Assets:	2017			2016		
	Gross Value	Accumulated Amortization	Net Carrying Amount	Gross Value	Accumulated Amortization	Net Carrying Amount
Amortizable intangible assets:						
Acquired developed technology - Noctiva	\$ 73,111	\$ (1,401)	\$ 71,710	\$ —	\$ —	\$ —
Acquired developed technology - Vazculep	12,061	(9,616)	2,445	12,061	(8,801)	3,260
Acquired product marketing rights	16,600	(2,132)	14,468	16,600	(1,019)	15,581
Acquired developed technology	4,300	(634)	3,666	4,300	(304)	3,996
Total amortizable intangible assets	<u>\$ 106,072</u>	<u>\$ (13,783)</u>	<u>\$ 92,289</u>	<u>\$ 32,961</u>	<u>\$ (10,124)</u>	<u>\$ 22,837</u>
Unamortizable intangible assets:						
Goodwill	\$ 18,491	\$ —	\$ 18,491	\$ 18,491	\$ —	\$ 18,491
Total unamortizable intangible assets	<u>\$ 18,491</u>	<u>\$ —</u>	<u>\$ 18,491</u>	<u>\$ 18,491</u>	<u>\$ —</u>	<u>\$ 18,491</u>

The Company recorded amortization expense related to amortizable intangible assets of \$3,659, \$13,888 and \$12,564 for the years ended December 31, 2017, 2016 and 2015, respectively.

During the period, the Company acquired \$73,111 in developed technology as part of the ELAA with Serenity Pharmaceuticals, LLC. The aggregate cost was composed of an upfront payment of \$50,000, an accrued payment of \$20,000 due within one year, and \$3,111 of transaction costs. The Company will amortize the developed technology over a 13 year period beginning October 1, 2017.

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, 2017, total future amortization of intangible assets for the next five years is as follows:

Estimated Amortization Expense:	Amount
2018	\$ 7,882
2019	7,882
2020	7,882
2021	7,067
2022	7,067

#### NOTE 9 : Long-Term Debt

French government agencies provide financing to French companies for R&D. At December 31, 2017 and 2016, the Company had outstanding loans of \$267 and \$815, 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, 2017, 2016 and 2015, the Company repaid \$115, \$277 and \$747, of loans associated with specific research projects, respectively. In addition, during 2017 and 2015 the Company received waivers of repayment for the remaining portion of certain loans of \$539 and \$1,498, respectively, 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 income (loss). No such waivers were received during 2016.

#### NOTE 10 : 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, 2017 and 2016, respectively:

	Activity during the Twelve Months Ended December 31, 2017					Balance, December 31, 2017
	Balance, December 31, 2016	Payments to Related Parties	Changes in Fair Value of Related Party Payable		Operating Income	
			Other Income	Other Income		
<b>Acquisition-related contingent consideration:</b>						
Warrants - Éclat Pharmaceuticals <sup>(a)</sup>	\$ 11,217	\$ —	\$ (8,738)	\$ —	\$ —	\$ 2,479
Earn-out payments - Éclat Pharmaceuticals <sup>(b)</sup>	121,377	(31,636)	(21,997)	—	—	67,744
Royalty agreement - FSC <sup>(c)</sup>	7,291	(1,246)	(305)	—	—	5,740
<b>Financing-related:</b>						
Royalty agreement - Deerfield <sup>(d)</sup>	9,794	(2,999)	—	(1,403)	—	5,392
Royalty agreement - Broadfin <sup>(e)</sup>	4,668	(1,430)	—	(668)	—	2,570
Long-term liability - FSC <sup>(f)</sup>	15,000	—	—	—	—	15,000
<b>Total related party payable</b>	<b>169,347</b>	<b>\$ (37,311)</b>	<b>\$ (31,040)</b>	<b>\$ (2,071)</b>	<b>\$ —</b>	<b>98,925</b>
Less: Current portion	(34,177)	—	—	—	—	(25,007)
<b>Total long-term related party payable</b>	<b>\$ 135,170</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 73,918</b>

Each of the above items is associated with related parties as further described in Note 20: 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 is exercisable for 2,200 ordinary shares at an exercise price of \$7.44 per share, and the other warrant is 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. See *Note 21: Subsequent Events*.

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

<b>Assumptions for the Warrant Valuation:</b>	<b>2017</b>		<b>2016</b>	
Stock price	\$	8.20	\$	10.39
Weighted average exercise price per share		8.63		8.63
Expected term (years)		0.25		1.25
Expected volatility		37.90%		54.20%
Risk-free interest rate		1.39%		0.94%
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 as to whether the Company would ultimately fulfill our obligation under these warrants using Company 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 stock, 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 the Company's CEO, and certain other current and former employees. As part of the consideration, the Company committed to provide quarterly earn-out payments equal to 20% of any gross profit generated by certain Éclat products. These payments will continue in perpetuity, to the extent gross profit of the related products also continue in perpetuity.
- (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 21: Subsequent Events*.
- (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 consists 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 are 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 21: Subsequent Events.

At December 31, 2017, the fair value of each related party payable listed in (b) through (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 and FSC products. 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. The most significant of these inputs are the Company's estimates of future market share and the risk-adjusted discount rate. New entrants into the markets for any of the Company's products can put downward pressure on volume and price. To the extent that these factors reduce the Company's expectations of future market share or selling price, the estimated future earn-out payments and the respective fair value of contingent consideration would be reduced. The Company uses an appropriate risk-adjusted discount rate within the discounted cash flow models ranging from 15% to 22%. Decreases in the discount rate would increase the calculated fair value of contingent consideration.

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 income (loss) in the line items entitled "(Gain) loss - changes in fair value of related party contingent consideration" for items noted in (b) and (c) above and in "Other income (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 fair value of these liabilities.

The Company has chosen to make a fair value election pursuant to ASC 825, "Financial Instruments" for our 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 income (loss).

The following table summarizes changes to the related party payables, a recurring Level 3 measurement, for the twelve-month periods ended December 31, 2017, 2016 and 2015:

Related Party Payable:	Balance
Balance at December 31, 2014	114,750
Payment of related party payable	(27,897)
Fair value adjustments <sup>(1)</sup>	35,840
Balance at December 31, 2015	122,693
Additions <sup>(2)</sup>	21,659
Payment of related party payable	(30,838)
Fair value adjustments <sup>(1)</sup>	55,833
Balance at December 31, 2016	169,347
Payment of related party payable	(37,311)
Fair value adjustments <sup>(1)</sup>	(33,111)
Balance at December 31, 2017	98,925

<sup>(1)</sup> 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 Income (Loss).

<sup>(2)</sup> Relates to the acquisition of FSC. See items (c) and (f) above.



**NOTE 11 : Income Taxes**

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. Accordingly, beginning in 2016, the Company reports the Irish tax jurisdiction as our Domestic jurisdiction. For periods prior to 2016, the French tax jurisdiction was the Domestic jurisdiction.

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

<b>Income (Loss) Before Income Taxes:</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>
Ireland	\$ (3,123)	\$ (22,866)	\$ (29,469)
United States	92,754	32,786	100,552
France	3,029	(19,638)	6,622
Total income (loss) before income taxes	<u>\$ 92,660</u>	<u>\$ (9,718)</u>	<u>\$ 77,705</u>

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

<b>Income Tax Provision:</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>
<b>Current:</b>			
United States - Federal	\$ 18,064	\$ 30,738	\$ 33,289
United States - State	331	1,081	970
France	265	5,267	1,657
Total current	<u>18,660</u>	<u>37,086</u>	<u>35,916</u>
<b>Deferred:</b>			
United States - Federal	4,686	(6,443)	504
United States - State	1,043	(23)	1,234
France	—	938	(1,747)
Total deferred	<u>5,729</u>	<u>(5,528)</u>	<u>(9)</u>
Income tax provision	<u>\$ 24,389</u>	<u>\$ 31,558</u>	<u>\$ 35,907</u>

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

<b>Reconciliation to Effective Income Tax Rate:</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>
Statutory tax rate <sup>(1)</sup>	12.5 %	12.5 %	33.3 %
Differences in international tax rates	22.2 %	(31.9)%	11.0 %
Nondeductible changes in fair value of contingent consideration	(11.6)%	(165.0)%	11.9 %
Income tax deferred charge	— %	(9.7)%	1.3 %
Change in valuation allowances	(0.7)%	11.8 %	(9.6)%
Nondeductible stock based compensation	(0.4)%	(14.8)%	1.3 %
Cross border merger	0.3 %	(100.6)%	— %
Unrealized tax benefits	1.4 %	(15.2)%	0.4 %
State and local taxes (net of federal)	0.3 %	(9.6)%	1.5 %
Change in U.S. tax law	3.8 %	— %	— %
Other	(1.5)%	(2.3)%	(4.9)%
Effective income tax rate	<u>26.3 %</u>	<u>(324.8)%</u>	<u>46.2 %</u>
Income tax provision (benefit) - at statutory tax rate <sup>(1)</sup>	\$ 11,582	\$ (1,215)	\$ 25,876
Differences in international tax rates	20,557	3,097	8,547
Nondeductible changes in fair value of contingent consideration	(10,779)	16,036	9,249
Income tax deferred charge	—	938	980
Change in valuation allowances	(610)	(1,143)	(7,425)
Nondeductible stock based compensation	(375)	1,436	1,004
Cross-border merger	265	9,773	—
Unrecognized tax benefits	1,296	1,475	290
State and local taxes (net of federal)	252	934	1,170
Change in U.S. tax law	3,513	—	—
Other	(1,312)	227	(3,784)
Income tax provision - at effective income tax rate	<u>\$ 24,389</u>	<u>\$ 31,558</u>	<u>\$ 35,907</u>

<sup>(1)</sup> The statutory rate reflects the Irish statutory tax rate of 12.5% for fiscal 2017 and 2016, and the French statutory tax rate of 33.3% for fiscal 2015.

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 United States 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 Tax Cuts and Jobs Act signed into law in the United States in December of 2017.

In 2016, the income tax provision decreased by \$4,349 when compared to the same period in 2015. The primary reason for the decrease in the income tax provision is a substantially lower level of pre-tax book income in the United States and France. Increases in the amount of nondeductible expenses due to changes in the fair value of contingent consideration and a reduced amount of income tax benefit from the release of valuation allowances partially offset the income tax benefit from the reduced amount of pre-tax book income in 2016, when compared to 2015. The Company also recorded \$9,773 of income tax provision in 2016 related to the cross-border merger.

#### **Unrecognized Tax Benefits**

The Company or one of our subsidiaries files income tax returns in Ireland, France, United States and various states. With few exceptions, the Company is no longer subject to Irish, French, US Federal, and state and local examinations for years before 2013. The Internal Revenue Service (IRS) commenced an examination of the Company's US income tax return for 2015 in the 4th quarter of 2016 that is anticipated to be completed by the end of 2018.

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	2017		2016		2015	
Balance at January 1:	\$	1,686	\$	448	\$	—
Additions based on tax positions related to the current year		2,268		1,578		448
Reductions for tax positions of prior years		—		(340)		—
Balance at December 31:	\$	3,954	\$	1,686	\$	448

It is reasonably possible that within the next twelve months, as a result of activities performed in various jurisdictions, that the unrecognized tax benefits could change by up to \$600. Interest and penalties could change by up to \$500.

At December 31, 2017, 2016, and 2015, there are \$3,349, \$1,565, and \$291 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, 2017, 2016, and 2015, the Company recognized approximately \$304, \$26, and \$0 in interest and penalties. The Company had approximately \$331, and \$26 for the payment of interest and penalties accrued at December 31, 2017, and 2016, 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, 2017 and 2016 resulted from the following temporary differences:

Net Deferred Tax Assets and Liabilities:	2017		2016	
Deferred tax assets:				
Net operating loss carryforwards	\$		9,831	\$ 11,566
Amortization			7,563	—
Stock based compensation			4,375	5,012
Fair value royalty agreements			635	3,386
Fair value contingent consideration			870	2,152
Other			406	583
Gross deferred tax assets			23,680	22,699
Deferred tax liabilities:				
Amortization			(2,419)	(4,349)
Accounts receivable			(936)	(3,319)
Prepaid expenses			(1,094)	—
Gross deferred tax liabilities			(4,449)	(7,668)
Less: valuation allowances			(15,354)	(7,599)
Net deferred tax assets	\$		3,877	\$ 7,432

At December 31, 2017, the Company had \$39,574 of net operating losses in Ireland and \$698 of net operating losses in France that do not have an expiration date and \$11,190 of net operating losses in the United States that expire 2034 through 2035. The US net operating losses were acquired as part of the acquisition of FSC. A valuation allowance is recorded if, based on the weight of available evidence, it is more likely than not that a deferred tax asset will not be realized. This assessment is based on an evaluation of the level of historical taxable income and projections for future taxable income. For the year ended December 31, 2017 the Company recorded \$4,963 of valuation allowances related to Irish net operating losses, \$233 of valuation allowances related to French net operating losses and \$309 of valuation allowances on U.S. net operating losses. The U.S. net operating losses are subject to an annual limitation as a result of the FSC acquisition under Internal Revenue Code Section 382 and will not be fully utilized before they expire.

We recorded a valuation allowance against all of our net operating losses in Ireland and France as of both December 31, 2017, and December 31, 2016. 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, 2017, the Company has unremitted earnings of \$3,038 outside of Ireland as measured on a US 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, 2017, the Company's net Research tax credit receivable amounts to \$5,272 and represents a French gross research tax credit of \$4,754 and an Irish gross research tax credit of \$518. As of December 31, 2016, the Company's net research tax credit receivable amounted to \$1,775 and represented a French gross research tax credit of \$3,376, partially offset by current income tax payable of \$1,601. The Company utilized \$4,001 of research tax credits in 2016 to offset the tax cost of the cross-border merger.

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

On December 16, 2014, the Company transferred all of our intangible intellectual property from its 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"), a new minimum tax. As a result of the Act being signed into law, the Company recognized a provisional charge of \$3,513 in the fourth quarter of 2017 related to the re-measurement of its U.S. net deferred tax assets and certain unrecognized tax benefits based on the lower enacted corporate tax rates. A majority of the provisions in the Tax Act are effective January 1, 2018. In response to the Tax Act, the SEC staff issued guidance on accounting for the tax effects of the Tax Act. The guidance provides a one-year measurement period for companies to complete the accounting. We reflected the income tax effects of those aspects of the Tax

Act for which the accounting is complete. To the extent our accounting for certain income tax effects of the Tax Act is incomplete but we are able to determine a reasonable estimate, we recorded a provisional estimate in the financial statements. If a company cannot determine a provisional estimate to be included in the financial statements, it should continue to apply the provisions of the tax laws that were in effect immediately before the enactment of the Tax Act. We have not completed our accounting for the income tax effects of certain elements of the Tax Act. Because of the complexity of the new BEAT rules, we are continuing to evaluate these provisions of the Tax Act and whether taxes due on future U.S. inclusions related to BEAT should be recorded as a current-period expense when incurred, or factored into the Company's measurement of its deferred taxes. As a result, we have not included an estimate of the tax expense or benefit related to these items for the period ended December 31, 2017.

## NOTE 12 : 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. Expenses recognized for these plans were \$123 in 2017, \$348 in 2016, and \$573 in 2015. The 2017 pension expense does not include the retirement indemnity curtailment gain of \$717 which was recorded in the third and fourth quarters of 2017 associated with the reduction of certain defined benefit retirement plan liabilities due to the reduction in force. See *Note 15: Restructuring Costs* 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 income (loss) 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:	2017	2016	2015
Compensation rate increase	3.00%	3.00%	3.00%
Discount rate	1.25%	1.31%	2.03%
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:	2017		2016	
Retirement indemnity benefit obligation, beginning of year	\$	2,431	\$	2,170
Service cost		132		123
Interest cost		21		29
Plan amendment		(829)		—
Curtailment gain		(717)		—
Actuarial (loss) gain		(25)		203
Exchange rate changes		290		(94)
Retirement indemnity benefit obligation, end of year	\$	1,303	\$	2,431

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:

<b>Future Retirement Indemnity Benefit Obligation:</b>	<b>Balance</b>
2018	\$ —
2019	12
2020	—
2021	—
2022	—
Next five years	198
<b>Total</b>	<b>210</b>

**NOTE 13 : Other Assets and Liabilities**

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

<b>Prepaid Expenses and Other Current Assets:</b>	<b>2017</b>	<b>2016</b>
Valued-added tax recoverable	\$ 1,206	\$ 736
Prepaid expenses	7,106	3,442
Advance to suppliers and other current assets	128	1,265
Income tax receivable	518	451
<b>Total</b>	<b>\$ 8,958</b>	<b>\$ 5,894</b>

<b>Other Non-Current Assets:</b>	<b>2017</b>	<b>2016</b>
Deferred tax assets	\$ 3,877	\$ 7,432
Long-term deposit	3,350	—
Other	3,022	99
<b>Total</b>	<b>\$ 10,249</b>	<b>\$ 7,531</b>

<b>Accrued Expenses:</b>	<b>2017</b>	<b>2016</b>
Accrued compensation	\$ 3,157	\$ 3,291
Accrued social charges	1,204	794
Accrued employee severance (see Note 15: Restructuring Costs)	1,000	—
Customer allowances	10,613	7,981
Accrued ELAA payment	20,000	—
Accrued CMO charges	2,327	936
Accrued contract sales organization and marketing costs	7,641	—
Other	4,984	4,220
<b>Total</b>	<b>\$ 50,926</b>	<b>\$ 17,222</b>

<b>Other Non-Current Liabilities:</b>	<b>2017</b>	<b>2016</b>
Provision for retirement indemnity	\$ 1,303	\$ 2,431
Customer allowances	1,636	905
Unrecognized tax benefits	3,954	1,565
Other	191	374
<b>Total</b>	<b>\$ 7,084</b>	<b>\$ 5,275</b>

**NOTE 14 : 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, 2017 and December 31, 2016, there were no contingent liabilities with respect to any threat of 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.

**Material Commitments**

At December 31, 2017, the Company has a commitment to purchase services for a total of \$22,500 for a five-year period commencing January 1, 2015. The minimum amount of services for the remaining two years is \$4,875 for both 2018 and 2019.

The Company also has two commitments to purchase finished product from two different contract manufacturers for a twenty-year period commencing August 1, 2015 and for a six-year period commencing in 2017. For the twenty-year commitment, the commitment for any individual year is contractually waived if the Company's net customer sales for that product exceed certain amounts in that same year. This commitment, which amounts to \$19,705, has been assumed by Cerecor as part of the divestiture of the pediatric assets. See Note 21: Subsequent Events. Commitments for these arrangements, at maximum quantities and at contractual prices over the remaining life of the contract, and excluding any waived commitments, are as follows for the years ended December 31:

<b>Purchase Commitments:</b>	<b>Balance</b>
2018	\$ 10,512
2019	9,406
2020	4,531
2021	4,531
2022	4,531
Thereafter	14,169
Total	\$ 47,680

For the year ended December 31, 2017, the Company paid \$6,898 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 \$1,146, \$970 and \$752 in 2017, 2016, and 2015, respectively. Minimum rental commitments for non-cancelable leases in effect at December 31, 2017 are as follows:

<b>Lease Commitment:</b>	<b>Balance</b>
2018	\$ 1,417
2019	919
2020	812
2021	548
2022	559
Thereafter	188
Total	\$ 4,443

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 9: Long-Term Debt, Note 10: Long-Term Related Party Payable, and Note 12: Post-Retirement Benefit Plans, respectively.

## Contractual Obligations

The following table presents contractual obligations of the Company at December 31, 2017:

Contractual Obligations:	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
Long-term debt	\$ 267	\$ 111	\$ 156	\$ —	\$ —
Long-term related party payable (undiscounted) <sup>(1)</sup>	163,100	22,173	26,080	37,822	77,025
Purchase commitments <sup>(2)</sup>	47,680	10,512	13,937	9,062	14,169
Operating leases	4,957	1,721	1,912	1,136	188
Total contractual cash obligations	\$ 216,004	\$ 34,517	\$ 42,085	\$ 48,020	\$ 91,382

(1) On February 12, 2018, Avadel Pharmaceuticals plc (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”). At the closing under the Purchase Agreement, on February 16, 2018, 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 Therapeutics and FSC Laboratories, Inc., which is also a subsidiary of the Company (collectively “FSC”). The Company acquired FSC in February 2016 from Deerfield CSF, LLC (“Deerfield CSF”) and certain of its affiliates. Pursuant to the Purchase Agreement, Cerecor assumed the Company’s remaining payment obligations to Deerfield CSF under the Membership Interest Purchase Agreement dated February 5, 2016, between Holdings, Flamel Technologies SA (the predecessor of the Company) and Deerfield CSF and certain of its affiliates, which payment obligations consist 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. All three of these amounts, which total approximately \$29,000, are included within the Long-term related party payable line above. See Note 21: Subsequent Events for a further discussion.

(2) This line includes the twenty-year commitment, which amounts to \$19,705 and has been assumed by Cerecor as part of the Purchase Agreement. See Note 21: Subsequent Events for a further discussion.

## NOTE 15 : Restructuring Costs

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, 2017. Restructuring charges of \$2,542, which are net of the curtailment gain of \$717, were recognized during the year ended December 31, 2017. No similar amounts were recorded during the prior year. The following table sets forth activities for the Company’s cost reduction plan obligations for the year ended December 31, 2017:

Severance Obligation:	2017
Balance of restructuring accrual at January 1,	\$ —
Charges for employee severance, benefits and other	3,259
Payments	(2,600)
Foreign currency impact	341
Balance of restructuring accrual at December 31,	\$ 1,000

The restructuring accrual at December 31, 2017 is included in the consolidated balance sheet in Accrued expenses.



## NOTE 16 : 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, 2017, we had 41,463 and 39,346 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. As of December 31, 2017, the Company had repurchased 2,117 ordinary shares for \$22,361. Additionally, on February 12, 2018, the Board of Directors approved an authorization to repurchase up to \$20,000 of Avadel ordinary shares represented by American Depository Shares in connection with our Convertible Notes Offering completed on February 16, 2018. See Note 21: Subsequent Events.

### Stock-Based Compensation

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

Stock-based Compensation Expense:	2017	2016	2015
Research and development	\$ 672	\$ 3,523	\$ 1,587
Selling, general and administrative	7,400	11,156	6,154
Total stock-based compensation expense	\$ 8,072	\$ 14,679	\$ 7,741

As of December 31, 2017, the Company expects \$13,101 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 3.1 years.

The excess tax benefit related to stock-based compensation recorded by the Company was not material in for the years ended December 31, 2017 and 2016 and \$1,767, for the year ended December 31, 2015.

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

At December 31, 2017, there were 2,290,147 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, 2017, 2016 and 2015, are as follows:

<b>Stock Option and Warrant Assumptions:</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>
<b>Stock option grants:</b>			
Expected term (years)	6.25	6.25	6.25
Expected volatility	58.82%	58.39%	58.59%
Risk-free interest rate	2.20%	2.04%	1.89%
Expected dividend yield	—	—	—
<b>Warrant grants:</b>			
Expected term (years)	—	2.50	2.50
Expected volatility	—%	60.57%	55.00%
Risk-free interest rate	—%	0.82%	0.89%
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, 2017 is as follows:

<b>Stock Option Activity and Other Data:</b>	<b>Number of Stock Options</b>	<b>Weighted Average Exercise Price per Share</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Aggregate Intrinsic Value</b>
Stock options outstanding, January 1, 2017	3,732	\$ 12.07		
Granted	1,477	9.24		
Exercised	(14)	4.99		
Forfeited	(46)	12.88		
Expired	(108)	13.47		
Stock options outstanding, December 31, 2017	5,041	\$ 11.34	8.19 years	\$ 1,187
Stock options exercisable, December 31, 2017	1,917	\$ 11.79	6.68 years	\$ 1,161

The aggregate intrinsic value of options exercised during the years ended December 31, 2017, 2016 and 2015 was \$1,161, \$58, and \$10,063, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2017, 2016 and 2015 was \$9.24, \$6.14 and \$9.38 per share, respectively.

## Warrants

A summary of the combined warrant activity and other data for the year ended December 31, 2017 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, 2017	959	\$ 16.05		
Granted	—	—		
Exercised	(55)	6.14		
Forfeited	—	—		
Expired	(10)	6.14		
Warrants outstanding, December 31, 2017	894	\$ 16.77	1.51 years	\$ —
Warrants exercisable, December 31, 2017	894	\$ 16.77	1.51 years	\$ —

Each of the above warrants is convertible into one ordinary share. The aggregate intrinsic value of warrants exercised during the years ended December 31, 2017, 2016 and 2015 was \$0, \$0 and \$2,698, respectively.

The weighted average grant date fair value of warrants granted during the years ended December 31, 2016 and 2015 was \$2.99 and \$5.92 per share, respectively. There were no warrants granted during the year ended December 31, 2017.

At December 31, 2017, 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 10: Long-Term Related Party Payable*.

## 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 and after 2016 are fully expensed at the date of grant as they contain no service requirement. Employees, however, are not free to trade these awards until the end of a two-year holding period.

A summary of the Company's restricted share awards as of December 31, 2017, 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, 2017	573	\$ 12.57
Granted	271	8.95
Vested	(23)	7.31
Forfeited	(2)	16.27
Non-vested restricted share awards outstanding, December 31, 2017	819	\$ 11.51

The weighted average grant date fair value of restricted share awards granted during the years ended December 31, 2017 and 2016 was \$8.95 and \$12.11, respectively. There were no restricted share awards granted in 2015.

## 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, 2017, there were no shares issued to employees as the program was launched in January 2018.

#### NOTE 17 : Net Income (Loss) Per Share

Basic net income (loss) per share is calculated using the weighted average number of shares outstanding during each period. The diluted net income (loss) per share calculation includes the impact of dilutive equity compensation awards and contingent consideration warrants.

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

Net Income (Loss) Per Share:	2017	2016	2015
Net income (loss)	\$ 68,271	\$ (41,276)	\$ 41,798
Weighted average shares:			
Basic shares	40,465	41,248	40,580
Effect of dilutive securities—options and warrants outstanding	1,300	—	3,039
Diluted shares	41,765	41,248	43,619
Net income (loss) per share - basic	\$ 1.69	\$ (1.00)	\$ 1.03
Net income (loss) per share - diluted	\$ 1.63	\$ (1.00)	\$ 0.96

Potential common shares of 6,368, 8,564, and 635 were excluded from the calculation of weighted average shares for the years ended December 31, 2017, 2016 and 2015, because their effect was considered to be anti-dilutive. For the year ended December 31, 2016, the effects of dilutive securities were entirely excluded from the calculation of net income (loss) per share as a net loss was reported in this period.

#### NOTE 18 : Comprehensive Income (Loss)

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

Accumulated Other Comprehensive Income (Loss):	2017	2016	2015
Foreign currency translation adjustment:			
Beginning balance	\$ (23,336)	\$ (22,312)	\$ (7,225)
Net other comprehensive income (loss)	134	(1,024)	(15,087)
Balance at December 31,	(23,202)	(23,336)	(22,312)
Unrealized gain (loss) on marketable securities, net			
Beginning balance	(229)	(345)	(198)
Net other comprehensive income (loss), net of \$28, \$16, (\$20), tax, respectively	165	116	(147)
Balance at December 31,	(64)	(229)	(345)
Accumulated other comprehensive loss at December 31,	\$ (23,266)	\$ (23,565)	\$ (22,657)

**NOTE 19 : 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 CEO. The CEO and the Board review 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, 2017, 2016, and 2015:

<b>Revenue by Product:</b>	<b>2017</b>		<b>2016</b>		<b>2015</b>	
Bloxiverz	\$	45,596	\$	82,896	\$	150,083
Vazculep		38,187		39,796		20,151
Akovaz		80,617		16,831		—
Other		8,441		7,699		2,054
Total product sales and services		172,841		147,222		172,288
License and research revenue		404		3,024		721
Total revenue	\$	173,245	\$	150,246	\$	173,009

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, 2017, 2016, and 2015:

<b>Revenue by Significant Customer:</b>	<b>2017</b>		<b>2016</b>		<b>2015</b>	
Customer A	\$	53,342	\$	17,728	\$	—
Customer B		44,762		51,648		53,988
Customer C		37,965		39,359		60,420
Customer D		25,691		30,916		43,434
Others		11,081		7,571		14,446
Total product sales and services		172,841		147,222		172,288
License and research revenue		404		3,024		721
Total revenue	\$	173,245	\$	150,246	\$	173,009

As of December 31, 2017, the Company had three customers, each of which are substantial wholesale distributors, and accounted for 10% or more of the accounts receivable balance. One customer accounted for 31%, or \$4,550, a second customer accounted for 26% or \$3,772, and a third customer accounted for 23% or \$3,395. As of December 31, 2017, 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, 2017, 2016, and 2015:

<b>Revenue by Geographic Region:</b>	<b>2017</b>		<b>2016</b>		<b>2015</b>	
United States	\$	172,841	\$	147,283	\$	172,179
France		—		—		89
Ireland		404		2,963		741
Total revenues	\$	173,245	\$	150,246	\$	173,009

Currently we depend on a single contract manufacturing organization for the manufacture of Bloxiverz, Vazculep and Akovaz, and to deliver certain raw materials used in their production, 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, 2017, 2016, and 2015:

<b>Long-lived Assets by Geographic Region:</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>
United States	\$ 116,536	\$ 42,021	\$ 34,515
France	2,257	2,524	2,317
Ireland	1,360	202	258
Total	<u>\$ 120,153</u>	<u>\$ 44,747</u>	<u>\$ 37,090</u>

#### **NOTE 20 : 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. As of December 31, 2016 and 2015, the remaining consideration obligations for this transaction consisted of two warrants to purchase a total of 3,300 shares of Avadel and 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 the Company’s CEO and certain other 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 will 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. See Note 21: Subsequent Events.

## NOTE 21 : Subsequent Events

### *Asset Purchase Agreement with Cerecor.*

On February 12, 2018, Avadel Pharmaceuticals plc (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”). At the closing under the Purchase Agreement, on February 16, 2018, 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 Therapeutics and FSC Laboratories, Inc., which is also a subsidiary of the Company (collectively “FSC”). The Company acquired FSC in February 2016 from Deerfield CSF, LLC (“Deerfield CSF”) and certain of its affiliates. Pursuant to the Purchase Agreement, Cerecor assumed the Company’s remaining payment obligations to Deerfield CSF under the Membership Interest Purchase Agreement, dated as of February 5, 2016, between Holdings, Flamel Technologies SA (the predecessor of the Company) and Deerfield CSF and certain of its affiliates, which payment obligations consist 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.

### *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.

### *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 CSF, LLC and certain of its affiliates (“Deerfield”). Under the Deerfield Guarantee, the Company and Holdings guaranteed to Deerfield the payment by Cerecor of the obligations of the Company and certain of its subsidiaries (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”).

### *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.

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.

The Company does not expect to record a significant gain or loss on the disposition of these assets.

### **Issuance of Exchangeable Notes**

On February 14, 2018 we announced that our wholly-owned subsidiary, Avadel Finance Cayman Limited (the "Issuer"), priced a \$125,000 aggregate principal amount of 4.50% exchangeable senior notes due 2023 (the "Notes") in a private placement (the "Offering") to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"). The sale of the Notes closed on February 16, 2018. In connection with the Offering, the Issuer granted the initial purchasers of the Notes a 30-day option to purchase up to an additional \$18,750 aggregate principal amount of the Notes, which was fully exercised on February 16, 2018.

Net proceeds from the Notes were \$137,719 after deducting the initial purchasers' discount and estimated offering expenses. We expect to use the net proceeds of the Offering for working capital and general corporate purposes. We also used cash on-hand to purchase approximately 2.0 million ADSs for \$18,000 concurrently with the pricing of the Offering in privately negotiated transactions effected with or through a representative of the initial purchasers or an affiliate of such representative. The Issuer agreed to purchase such ADSs at a purchase price per ADS equal to the \$8.99 per ADS closing price on The Nasdaq Global Market on February 13, 2018.

The Notes are general, unsecured obligations of the Issuer, and are fully and unconditionally guaranteed by Avadel on a senior unsecured basis. Interest on the Notes will be payable semi-annually in cash in arrears on February 1 and August 1 of each year, beginning on August 1, 2018. The Notes will mature on February 1, 2023, unless earlier exchanged, repurchased or redeemed in accordance with their terms. The Notes will be issued in minimum denominations of \$200 and integral multiples of \$1 in excess thereof.

Subject to certain conditions and during certain periods, the Notes will be exchangeable at the option of the holders at an initial exchange rate of 92.6956 ADSs per \$1 principal amount of 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 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.

The Company is evaluating the impacts of ASC 470-20 and the ASC 815 exception regarding conventional convertible notes that may be settled entirely or partially in cash upon conversion. Should these Notes be deemed as conventional per the exception allowed under ASC 815, the rules under ASC 470-20 would require the Company to separate the Notes into a liability and equity component, such that interest expense reflects our economic interest cost. The original issue discount would be recognized as a decrease in debt and an increase in equity. The debt component would accrete up to the principal amount over the expected term of the debt.

In addition, under certain circumstances, convertible or exchangeable debt instruments 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 Notes are not included in the calculation of diluted earnings per share except to the extent that the exchange value of the 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.

### **Related Party Exercise of Warrants**

On February 22, 2018, the Company was notified by the related party holding 2,200 warrants (*See Note 10: Long-term Related Party Payable*) of its intent to exercise these warrants in full. As a result, the Company settled these warrants for a combination of cash of \$2,911 and the issuance of approximately 603 ADS. The remaining 1,100 warrants held by this same related party, with an exercise price of \$11.00 expired worthless on March 12, 2018.



## 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, 2017 and 2016, the related consolidated statements of income (loss), comprehensive income (loss), shareholders’ equity, and cash flows for each of the years then ended, and the related notes and financial statement schedule listed in Item 15 (collectively referred to 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, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity 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, 2017, based on criteria established in Internal Control— Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2018, expressed an unqualified opinion on the Company’s internal control over financial reporting.

The financial statements of the Company as of and for the year ended December 31, 2015, were audited by other auditors whose report dated March 15, 2016, except for the effects of previously disclosed revisions as to which the date is March 28, 2017, expressed an unqualified opinion on those statements.

### Basis for Opinion

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

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

/s/ Deloitte and Touche LLP

St. Louis, Missouri  
March 16, 2018

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, 2017, 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 has maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, 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, 2017, of the Company and our report dated March 16, 2018, expressed an unqualified opinion on those financial statements.

### Basis for Opinion

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

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

### Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ Deloitte and Touche LLP

St. Louis, Missouri  
March 16, 2018

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Avadel Pharmaceuticals PLC (formerly Flamel Technologies S.A.),

In our opinion, the consolidated statement of income (loss), the related consolidated comprehensive income (loss), shareholders' equity and cash flows for the year ended December 31, 2015 present fairly, in all material respects, the results of operations and cash flows of Avadel Pharmaceuticals PLC (formerly Flamel Technologies S.A.) and its subsidiaries for the year ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule for the year ended December 31, 2015, presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

Lyon, France,  
March 15, 2016 except for the effects of the revisions discussed in Note 1 (not presented herein) to the consolidated financial statements appearing under Item 8 of the Company's 2016 annual report on Form 10-K, as to which the date is March 28, 2017.

/s/ PricewaterhouseCoopers Audit

Represented by  
/s/ Frédéric Charcosset

**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, 2017. 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, 2017, the Company's internal control over financial reporting is effective based on those criteria.

**Changes in Internal Control over Financial Reporting**

**Remediation of Previously Reported Material Weaknesses**

The Company previously reported material weaknesses in its December 31, 2016 Form 10-K. As more fully described below, we have identified and implemented additional processes, procedures and controls to improve the effectiveness of our internal control over financial reporting and disclosure controls and procedures. We regularly reviewed our progress toward remediating these material weaknesses with our audit committee during 2017. Leading this remediation process was our Senior Vice President and Chief Financial Officer and our Chief Accounting Officer. Assisting management with the remediation process was a nationally recognized consulting firm who, under the direction of management, created and enhanced controls documentation, assisted management in the implementation of improvements or changes to the existing internal control structure and tested such processes, procedures and controls to support management's conclusions surrounding the design and operating effectiveness of management's internal controls over financial reporting.

**Personnel**

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2016, as of December 31, 2015, management had identified a material weakness in our internal controls over financial reporting related to personnel. Specifically, the Company did not maintain a sufficient number of personnel with an appropriate level of knowledge, experience and training in internal control over financial reporting commensurate with our financial reporting requirements. As the result of management's internal control design and operational assessments as of December 31, 2016, management noted additional time in role and training of our personnel was needed in order to have an impact on the system of internal control over financial reporting, in order to gain an appropriate level of knowledge to execute controls consistent with the risk assessment and the

required level of precision for management review controls associated with the review of inputs used in the controls, key assumptions utilized in accounting estimates and accounting for significant non-routine and complex transactions.

In an effort to remediate the identified material weakness, we initiated and implemented the following corrective actions:

- Senior Accounting and Finance Management personnel that were added to the organization in prior years have had additional time in role in order to have an impact on the system of controls. This includes the company's Chief Financial Officer, Chief Accounting Officer, and Tax Director.
- Supplemented our U.S. based Accounting and Finance organization through adding appropriate levels of subject matter knowledge and training, including establishing a Revenue accounting function, a centralized Accounts Payable Shared Services function, and supplementing the accounting staff with additional personnel to support appropriate control.
- Retained an outside consultant to assist the Company in documenting and testing the internal controls over financial reporting that are in place at the Company and the serve in the role of the Company's internal audit function. We have assessed the qualifications of the third-party provider and determined that they have the appropriate experience, certification education and training in internal audit and controls to serve in this role. This firm was responsible for assisting in the training of internal personnel relative to the various aspects and requirements of internal control within the current reporting environment.

As of December 31, 2017, management evaluated the design and operational effectiveness of the remediation activities and concluded that we have sufficient evidence that the previously reported material weakness pertaining to personnel has been remediated as of December 31, 2017.

#### *Financial Close*

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2016, management had identified a material weakness in our internal controls over financial reporting related to the financial close process. Specifically, we had not designed or maintained effective and precise controls over the data and assumptions utilized in accounting for non-routine and complex transactions.

In an effort to remediate the identified material weakness, we initiated and implemented the following corrective actions:

- Supplemented our U.S. based Accounting and Finance organizations through adding appropriate levels of subject matter knowledge and training.
- Refined precision levels of management reviews and enhanced review of key assumptions and inputs within existing controls over non-routine and complex transactions.
- Developed, formalized and implemented additional management review controls across the organization in order to add more comprehensive levels of review and approval for significant transactions having complex U.S. GAAP and SEC reporting implications and non-routine transaction processing.
- Developed new quantitative and qualitative analytical analysis as part of our financial close process to help in the early detection of potential material misstatements to our financial statements.
- Enhanced and refined our quarterly and annual financial analysis and procedures to allow for more timely and substantive review of financial results before the filing of the quarterly reports of Form 10-Q and Annual Report on Form 10-K.

As of December 31, 2017, management evaluated the design and operational effectiveness of the remediation activities and concluded that we have sufficient evidence that the Financial Close processes and controls have been adequately designed and were operating effectively. As a result, management has concluded that the previously reported material weakness has been remediated as of December 31, 2017.

#### *Rebates and Expired Products Reserves*

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2016, management had identified a material weakness in our internal controls over financial reporting related to Rebates and Expired Product reserves. Specifically, we concluded additional time is necessary to ensure that controls regarding assumptions using historical data for the setting of rebate and expired product reserves are operating with an appropriate level of precision.

In an effort to remediate the identified material weakness, we initiated and implemented the following corrective actions:

- Enhanced our documentation and support around product pricing approvals and subsequent changes to customer pricing and contractual obligations.
- Enhanced the information supporting the accounting and review process for gross to net accruals related to revenue.
- Reassessed and improved the estimates, calculations, and the precision level of reviews underlying all gross to net accruals, including rebates and expired product return accruals.
- Performed of a comprehensive review of service provider reporting and end user considerations as well as more comprehensive periodic reviews of activities performed by third parties and validation of financial information received from third parties.
- Expanded the communication protocols between our Sales and Accounting functions to identify rebate arrangements and appropriately account for these arrangements.

As of December 31, 2017, management evaluated the design and operational effectiveness of the remediation activities and concluded that we have sufficient evidence that the Rebates and Expired Product Reserves processes and controls have been adequately designed and were operating effectively. As a result, management has concluded that the previously reported material weakness has been remediated as of December 31, 2017.

***Other Changes in Internal Control***

Other than those actions described above, 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, 2017 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 2018 annual general meeting of shareholders pursuant to Regulation 14A of the Securities Exchange Act of 1934 (our "Definitive 2018 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 2018 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 2018 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2017.

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

Information regarding Executive Compensation is hereby incorporated by reference to our Definitive 2018 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2017.

#### **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 2018 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2017.

#### **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 2018 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2017.

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

Information regarding Principal Accountant Fees and Services is hereby incorporated by reference to our Definitive 2018 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2017.

**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
2017	\$ 7,599	\$ 391	\$ (664)	\$ 8,028	\$ 15,354
2016	\$ 45,516	\$ 6,873	\$ (42,417)	\$ (2,373)	\$ 7,599
2015	57,980	4,312	(11,737)	(5,039)	45,516

- 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	<a href="#">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)</a>
4.1	<a href="#">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)</a>



- 4.2 [Warrant to purchase 1,100,000 American Depositary Shares, each representing one ordinary share of Avadel Pharmaceuticals plc \(incorporated by reference to Exhibit 4.1 to the registrant's Post-Effective Amendment No. 2 to Form F-3 registration statement \(No. 333-183961\) on Form S-3, filed on January 6, 2017\)](#)
- 4.3 [Warrant to purchase 2,200,000 American Depositary Shares, each representing one ordinary share of Avadel Pharmaceuticals plc \(incorporated by reference to Exhibit 4.2 to the registrant's Post-Effective Amendment No. 2 to Form F-3 registration statement \(No. 333-183961\) on Form S-3, filed on January 6, 2017\)](#)
- 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 Channon 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	<a href="#"><u>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)</u></a>
10.42	<a href="#"><u>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)</u></a>
10.43*	<a href="#"><u>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 (filed herewith)</u></a>
10.44*	<a href="#"><u>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 (filed herewith)</u></a>
10.45*	<a href="#"><u>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 (filed herewith)</u></a>
10.46*	<a href="#"><u>Guarantee by Armistice Capital Master Fund, Ltd. in favor of Avadel US Holdings, Inc. dated as of February 16, 2018 (filed herewith)</u></a>
14.1	<a href="#"><u>Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 to the registrant's current report on Form 8-K, filed on March 7, 2017)</u></a>
14.2	<a href="#"><u>Financial Integrity Policy (incorporated by reference to Exhibit 14.2 to the registrant's current report on Form 8-K, filed on March 7, 2017)</u></a>
21.1	<a href="#"><u>List of Subsidiaries (filed herewith)</u></a>
23.1	<a href="#"><u>Consent of PricewaterhouseCoopers Audit (filed herewith)</u></a>
23.2	<a href="#"><u>Consent of Deloitte &amp; Touche, LLP (filed herewith)</u></a>
31.1	<a href="#"><u>Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)</u></a>
31.2	<a href="#"><u>Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)</u></a>
32.1	<a href="#"><u>Certification of the Chief Executive Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith),(1)</u></a>
32.2	<a href="#"><u>Certification of the Principal Financial Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith),(1)</u></a>
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 16, 2018

By: /s/ Michael S. Anderson  
Name: Michael S. Anderson  
Title: Chief Executive Officer

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

## POWER OF ATTORNEY

**KNOW ALL PERSONS BY THESE PRESENTS**, that each of each of Craig R. Stapleton, Peter Thornton, Francis J.T. Fildes, Benoit Van Assche and Christophe Navarre, by their respective signatures below, irrevocably constitutes and appoints Michael S. Anderson and Phillandas T. Thompson, and each of them individually acting alone without the other, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Michael S. Anderson</u> Michael S. Anderson	Chief Executive Office (Principal Executive Officer) and Director	March 16, 2018
<u>/s/ Michael F. Kanan</u> Michael F. Kanan	Chief Financial Officer (Principal Financial Officer)	March 16, 2018
<u>/s/ David P. Gusky</u> David P. Gusky	Corporate Controller (Principal Accounting Officer)	March 16, 2018
<u>/s/ Craig R. Stapleton</u> Craig R. Stapleton	Non-Executive Chairman of the Board and Director	March 16, 2018
<u>/s/ Peter Thornton</u> Peter Thornton	Director	March 16, 2018
<u>/s/ Francis J.T. Fildes</u> Francis J.T. Fildes	Director	March 16, 2018
<u>/s/ Benoit Van Assche</u> Benoit Van Assche	Director	March 16, 2018
<u>/s/ Christophe Navarre</u> Christophe Navarre	Director	March 16, 2018

**CONFIDENTIAL TREATMENT REQUESTED**

**THE PORTIONS OF THIS AGREEMENT MARKED WITH ASTERISKS WITHIN BRACKETS (“[\*\*\*]”) HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER 17 C.F.R. SECTIONS 200.80(B)(4), 200.83 AND 230.406. A COMPLETE COPY OF THIS AGREEMENT HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

ASSET PURCHASE AGREEMENT

Dated as of February 12, 2018

between

CERECOR, INC.

and

AVADEL PHARMACEUTICALS (USA), INC.,

AVADEL PEDIATRICS, INC.,

FSC THERAPEUTICS, LLC,

AVADEL US HOLDINGS, INC.

AND

AVADEL PHARMACEUTICALS PLC

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

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## Exhibits

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## ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement (this “Agreement”) dated as of February 12, 2018 is entered into between Cerecor, Inc., a Delaware corporation (“Buyer”), Avadel Pharmaceuticals (USA), Inc., a Delaware corporation (“Pharma”), Avadel Pediatrics, Inc., a Delaware corporation (“Pediatrics”), FSC Therapeutics, LLC, a Delaware limited liability company (“Therapeutics”), Avadel US Holdings, Inc., a Delaware corporation (“US Holdings”), and Avadel Pharmaceuticals plc, an Irish corporation (“Parent”). Each of Pharma, Pediatrics, Therapeutics, US Holdings and Parent are individually referred to herein as a “Seller” and are collectively referred to as “Sellers”. Buyer and Sellers are sometimes individually referred to herein as a “Party” and are sometimes collectively referred to herein as the “Parties”. Certain capitalized terms used herein have the meanings ascribed to them in Section 1.1.

### RECITALS

WHEREAS, Sellers desire to sell all of each Seller’s right, title and interest in, to and under the Purchased Assets and transfer the Assumed Liabilities to Buyer, and Buyer wishes to purchase from the Sellers all of each Seller’s right, title and interest in, to and under the Purchased Assets and to assume the Assumed Liabilities, upon the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual benefits to be derived from this Agreement, and of the representations, warranties, conditions, agreements and promises contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

### ARTICLE I.

#### DEFINITIONS; INTERPRETATION

Section 1.1. Definitions. For purposes of this Agreement, the following terms shall have the corresponding meanings set forth below:

“Act” means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules, regulations, guidelines, guidance documents and requirements promulgated thereunder, as may be in effect from time to time.

“Action” means any claim, action, suit, arbitration, audit, proceeding, or formal investigation, in each case by or before a Governmental Authority.

“Acquisition” has the meaning set forth in Section 2.1(a).

“Affiliate” of any Person means another Person that directly or indirectly, through one or more intermediaries, Controls, is Controlled by or is under common Control with, such first Person.

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

“Agreement” has the meaning set forth in the preamble hereof.

“Apportioned Obligations” has the meaning set forth in Section 5.2(b).

“Assumed Contracts” has the meaning set forth in Section 2.2(a)(i).

“Assumed Liabilities” means (a) all Liabilities arising out of or related to the Assumed Contracts and Purchased Assets following the Closing, (b) all Liabilities arising out of or related to the operation of the Business by Buyer following the Closing and (c) all Liabilities set forth on Schedule 2.3.

“Bill of Sale, Assignment and Assumption Agreement” has the meaning set forth in Section 2.4(b)(iii).

“Books and Records” means all books, records, files and documents related to a Product, the Compound or any other Purchased Asset (including sales, pricing, promotional, research and development, data (including Data), customer and supplier lists, marketing studies, consultant reports, physician databases and correspondence (excluding invoices), complaint files and adverse drug experience files, correspondence with Governmental Authorities and, to the extent not originals, true and complete copies of all files relating to the filing, prosecution, issuance, maintenance, enforcement or defense of any Business Intellectual Property, including written Third Party correspondence, records and documents related to research and pre-clinical and clinical testing and studies for a Product or the Compound conducted by or on behalf of any Seller, including laboratory and engineering notebooks, procedures, tests, dosage, criteria for patient selection, safety and efficacy and study protocols, investigators brochures and all vigilance and other safety records) in all forms, including electronic, in which they are stored or maintained, and all data and information included or referenced therein, in each case that are licensed, owned or controlled by or otherwise in the possession of any Seller in respect of a Product or Compound, but in all cases excluding the Excluded Books and Records.

“Business” means the business of licensing and selling the Compound and the Products and the outsourcing of services in respect of the Compound or Products. For the avoidance of doubt, Sellers make no representations or warranties or any other statements with regard to the services performed by the third-parties to which the Company outsources such activities.

“Business Day” means any day other than (a) a Saturday or Sunday or (b) a day on which banking institutions located in New York City are permitted or required by applicable Law to remain closed.

“Business Employee” has the meaning set forth in Section 5.11(a).

“Business Intellectual Property” means, other than the items set forth on Schedule 1.1(a), all Patents, Trademarks, Copyrights, Software, Trade Secrets and other Intellectual Property Rights, in each case Controlled by any Seller and that (i) relate to the Compounds or the

Products or (ii) were acquired, conceived, or reduced to practice by Sellers in connection with Exploiting the Products, and the right to recover for past infringement of any of the foregoing.

“Buyer” has the meaning set forth in the preamble hereof.

“Buyer Indemnified Party” has the meaning set forth in Section 6.1(a).

“Cap” has the meaning set forth in Section 6.3(a)(iii).

“Closing” has the meaning set forth in Section 2.4(a).

“Closing Date” has the meaning set forth in Section 2.4(a).

“Code” means the Internal Revenue Code of 1986, as amended.

“Competing Product” has the meaning set forth in Section 5.1(b).

“Compound” means the compounds set forth in Schedule 1.1(b).

“Confidential Information” has the meaning set forth in Section 5.1(a)(ii).

“Confidentiality Agreement” means the Confidential Disclosure Agreement, dated January 2, 2018 between Pharma and Buyer.

“Contemplated Transactions” means the transactions contemplated by this Agreement and any Related Document.

“Contracts” means any legally binding loan or credit agreement, bond, debenture, note, mortgage, indenture, lease, supply agreement, license agreement, development agreement, distribution agreement or other legally binding contract, agreement, obligation, commitment, arrangement, understanding, instrument, permit, franchise or license, whether written or oral.

“Control” including its various tenses and derivatives (such as “controlled” and “controlling”) means (a) when used with respect to any Person, the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such entity, whether through the ownership of voting securities, by Contract or otherwise, (b) when used with respect to any security, the possession, directly or indirectly, of the power to vote, or to direct the voting of, such security or the power to dispose of, or to direct the disposition of, such security and (c) when used with respect to any Intellectual Property Rights, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign or grant a license, sublicense or other right to or under such Intellectual Property Rights or to compel another to do so.

“Data” means all databases and data, including all compilations thereof, and all rights therein, Controlled by any Seller that (i) were collected, compiled, generated or used in connection with the Business between February 5, 2016 (including all that were acquired by any

Seller on that date) and the Closing Date, or (ii) otherwise are related to the Business and has been in Sellers' Control since February 5, 2016.

“Data Room” has the meaning set forth in Section 1.2.

“Deerfield Agreement” means the Membership Interest Purchase Agreement, dated as of February 5, 2016 by and among certain parties affiliated with the Sellers and Deerfield CSF, LLC.

“Deerfield Obligation” means the interest payment to be made on April 30, 2018 under the Deerfield Agreement.

“Development Agreement” means the License and Development Agreement in the form attached hereto as Exhibit 2.4(b)(ii).

“Disclosure Letter” means the disclosure letter delivered to Buyer by Sellers simultaneously with the execution of this Agreement; all references to Schedules shall refer to Schedules to the Disclosure Letter.

“Drop Dead Date” has the meaning set forth in Section 9.1.

“Dollars” or “\$” means United States dollars.

“Excluded Assets” has the meaning set forth in Section 2.2(b).

“Excluded Books and Records” means Books and Records relating to the Excluded Assets.

“Excluded Contracts” means all Contracts of any Seller other than the Assumed Contracts.

“Excluded Liabilities” has the meaning set forth in Section 2.3(b).

“Exploit” means to make, have made, import, use, sell, offer for sale, and otherwise dispose of, including to research, develop, register, modify, enhance, improve, manufacture, have manufactured, store, formulate, optimize, export, transport, distribute, commercialize, promote, market, have sold and otherwise dispose of. “Exploitation” means the act of Exploiting a compound, product or process.

“FCPA” has the meaning set forth in Section 3.17(a).

“FDA” has the meaning set forth in Section 3.10(b).

“First Restricted Period” has the meaning set forth in Section 5.1(b)(i).

“GAAP” means the United States generally accepted accounting principles in effect at the time relevant to the context in which such term is used herein.

“Governmental Authority” means any Federal, state, local or foreign government, any court, tribunal, administrative, regulatory or other governmental agency, department, commission or authority or any non-governmental self-regulatory agency, commission or authority.

“Indemnified Party” has the meaning set forth in Section 6.4(a).

“Indemnifying Party” has the meaning set forth in Section 6.4(a).

“Indemnity Threshold” has the meaning set forth in Section 6.3(a)(i).

“Independent Accountant” has the meaning set forth in Section 2.6(a).

“Intellectual Property Rights” means any (a) patents, patent applications (including in each case any continuation, continuation-in-part, division, renewal, patent term extension (including any supplemental protection certificate), reexamination or reissue thereof) (collectively, “Patents”); (b) registered and unregistered trademarks, trade dress, trade names, logos, design rights, service marks, together with the goodwill pertaining to the foregoing, and all applications, registrations and renewals therefor (collectively, “Trademarks”); (c) registered and unregistered copyrights, works of authorship, copyrightable works (published or unpublished) and all applications, registrations and renewals therefor (collectively, “Copyrights”); (d) domain names; (e) software, computer programs and applications (whether in source code, object code or other form) algorithms, databases, documentation and technology supporting the foregoing (excluding off the shelf software) (collectively, “Software”); and (f) trade secrets (“Trade Secrets”), know-how (including all ideas, concepts, research and development, composition information and embodiments, manufacturing and production processes, techniques and information, specifications, technical and business data, Data, designs, drawings, suppliers lists, pricing and cost information, and data and know-how embodied in business and marketing plans and proposals), other proprietary information and other proprietary intellectual property rights, and all copies and tangible embodiments of the foregoing in whatever form or medium.

“Inventory” means all inventories of the Product, including all drug substances, drug product, clinical lots, reference standards, reserve samples, patient samples, patient images and scans, vials, reagents, vectors, DNA constructs, inventories of active pharmaceutical ingredients, intermediates, raw materials, components, consumables, work-in- process, finished goods, supplies, parts, labels and packaging (including rights and interests in goods in transit, consigned inventory, inventory sold on approval and rental inventory).

“Labeling” shall be as defined in Section 201(m) of the Act (21 U.S.C. § 321(m)) and other comparable foreign Law relating to the subject matter thereof, including a Product’s label, packaging and instructions for use accompanying a Product, and any other written, printed, or graphic materials accompanying a Product, including patient instructions or patient indication guides.

“Law” means any federal, state, local or foreign constitution, treaty, law, statute, ordinance, rule, regulation, interpretation, guidance document, directive, policy, award, Order and any other ruling or decision of any applicable Governmental Authority.

“Liabilities” means liabilities, obligations and commitments, whether accrued or fixed, absolute or contingent, known or unknown, determined or determinable, due or to become due, or otherwise.

“Lien” means any lien (statutory or otherwise), security interest, pledge, hypothecation, mortgage, assessment, lease, claim, levy, license, defect in title, charge, or any other Third Party right, license or property interest of any kind, or any conditional sale or other title retention agreement, right of first option, right of first refusal or similar restriction, any covenant not to sue, or any restriction on use, transfer, receipt of income or exercise of any other attribute of ownership or any agreement to give any of the foregoing in the future or similar encumbrance of any kind or nature whatsoever.

“Losses” has the meaning set forth in Section 6.1(a).

“Marketing Authorization” means the receipt of all approvals from the relevant Regulatory Authority necessary to market and sell a Product in the United States (including all applicable approvals or determinations by a Regulatory Authority for the pricing or pricing reimbursement for a pharmaceutical product even if not legally required to sell the Product in the United States).

“Material Adverse Effect” means any change, effect, event, occurrence or fact that, individually or in the aggregate, would reasonably be expected to result in, or has resulted in, a materially adverse change or effect to (a) the assets, liabilities or condition of the Purchased Assets, taken as a whole, or (b) any Seller’s ability to consummate the Contemplated Transactions; provided, however, that, for purposes of clause (a), none of the following shall be deemed, either alone or in combination, to constitute, and none of the following shall be taken into account in determining whether there has been or will be, a Material Adverse Effect: (i) any change, effect, event, occurrence, state of facts or development relating to the economy in general in the United States or in any other jurisdiction in which any Seller has operations or conducts business, or conditions generally affecting the industries in which the Sellers operate the Business, so long as the effects do not have a materially disproportionate effect and adversely impact the Purchased Assets, taken as a whole, (ii) any change, effect, event, occurrence, state of facts or development reasonably attributable to conditions affecting the pharmaceutical industry (other than as may arise or result from regulatory action by a Regulatory Authority), so long as the effects do not have a materially disproportionate effect and adversely impact the Purchased Assets, taken as a whole (iii) the announcement, pendency or completion of the Contemplated Transactions, including losses or threatened losses of employees, customers, suppliers, distributors or others having relationships with any Seller and the Business, (iv) earthquakes, hurricanes, tornadoes, natural disasters or global, national or regional political conditions, including hostilities, military actions, political instability, acts of terrorism or war or any escalation or material worsening of any such hostilities, military actions, political instability, acts of terrorism or war existing or underway as of the date hereof (other than any of the foregoing



that causes any material damage or destruction to or renders unusable any material Purchased Assets and so long as the effects do not have a materially disproportionate effect and adversely impact the Purchased Assets, taken as a whole), (v) any effect that results from any action taken at the express prior written request of Buyer or with Buyer's prior written consent, (vi) any failure by the Business to meet any internal or published projections, forecasts or revenue or earnings predictions (provided that the underlying causes of such failures may nevertheless constitute a Material Adverse Effect, subject to the other provisions of this definition) or (vii) changes in Law or GAAP or any interpretation thereof (so long as the effects do not have a materially disproportionate effect and adversely impact the Purchased Assets, taken as a whole and it being understood that this clause (vii) shall not apply with respect to any representation or warranty contained in this Agreement the purpose of which is to address compliance with Law or GAAP or any interpretation thereof).

"Measurement Date" has the meaning set forth in Section 3.3.

"NDA" means a New Drug Application, filing pursuant to Section 510(k) of the Act, or similar application or submission for Marketing Authorization of a Product filed with the relevant Regulatory Authority to obtain Marketing Authorization for a pharmaceutical or diagnostic product in the United States.

"Order" means any writ, judgment, decree, injunction or similar order, including consent orders, of any Governmental Authority (in each such case whether preliminary or final).

"Ordinary Course of Business" means the ordinary course of business of the Business and Sellers consistent with Sellers' practices of operating the Business since February 5, 2016.

"Party" or "Parties" has the meaning set forth in the preamble hereof.

"Permitted Liens" means, (i) statutory liens for Taxes, assessments and governmental charges not yet due and payable or that are being contested in good faith by appropriate proceedings and, if required under GAAP, for which appropriate reserves have been created; (ii) statutory Liens of landlords and Liens of carriers, warehousemen, mechanics, material men and other Liens imposed by law arising or incurred in the ordinary course of business for amounts that are not yet due and payable and, if required under GAAP, for which appropriate reserves have been created or that are being contested in good faith by appropriate proceedings and that are not resulting from any breach, violation or default by any Seller of any Contract or applicable Law; or (iii) other Liens that do not materially impair the usage, disposition, pledging or operation of the respective asset.

"Person" means an individual, corporation, partnership, limited liability company, joint venture, association, trust, unincorporated organization or other entity or any Governmental Authority.

“Post-Closing Tax Period” means (i) any Tax period beginning after the Closing Date, and (ii) with respect to any Straddle Period, the portion of such period beginning after the Closing Date.

“Pre-Closing Tax Period” means (i) any Tax period ending on or before the Closing Date, and (ii) with respect to any Straddle Period, the portion of such period up to and including the Closing Date.

“Product” means the products set forth on Schedule 1.1(c).

“Purchase Price” means an amount equal to \$1.00.

“Purchase Price Allocation” has the meaning set forth in Section 2.6(a).

“Purchased Assets” has the meaning set forth in Section 2.2(a).

“Regulatory Authority” means any applicable Governmental Authority with responsibility for granting licenses or approvals, including Marketing Authorizations, necessary for the marketing and sale of a Product in any jurisdiction, or that is concerned with the research, development, marketing, sale, use, handling and control, safety, efficacy, reliability or manufacturing of drug or biological products.

“Regulatory Authorizations” means (a) all licenses, permits, certificates, clearances, exemptions, approvals, consents and other authorizations that any Seller owns, holds or possesses, including those prepared for submission to or issued by any Regulatory Authority or research ethics committee (including pre-market notification clearances, pre-market approvals, investigational device exemptions, non-clinical and clinical study authorizations, product re-certifications, manufacturing approvals and authorizations, CE Mark certifications, pricing and reimbursement approvals, Labeling approvals, registration notifications or their foreign equivalent), that are required for or relate to the Purchased Assets or the Exploitation of the Purchased Assets, including those set forth on Schedule 3.10(a); and (b) all applications, supporting files, writings, data, studies and reports, and all correspondence to, with, or from the FDA or any other Regulatory Authority or research ethics committee, relating to any license, permit, certificate, clearance, exemption, approval, consent or other authorization described in clause (a).

“Related Documents” means, other than this Agreement, the Development Agreement, and all other agreements, certificates and documents signed and delivered by any Party in connection with this Agreement or the transactions contemplated hereby.

“Representatives” means, with respect to any Person, such Person’s directors, officers, managers, employees, counsel, consultants, accountants, financial advisors, lenders and other agents and representatives (in each case, acting in such Person’s capacity as such).

“Second Restricted Period” has the meaning set forth in Section 5.1(b)(ii).

“Seller” and “Sellers” has the meaning set forth in the preamble hereof.

“Seller Indemnified Party” has the meaning set forth in Section 6.2(a).

“Sellers’ Organizational Documents” has the meaning set forth in Section 3.1.

“Sellers’ Knowledge” (and similar phrases) means, with respect to any matter in question, the actual knowledge of the following individuals: Michael Anderson, Gregory Divis, Sandra Hatten, Michael Kanan and Phil Thompson.

“Social Security Act” has the meaning set forth in Section 3.10(e).

“Specified Representations” has the meaning set forth in Section 6.3(a).

“Straddle Period” means any taxable period that includes (but does not end on) the Closing Date.

“Subsidiary” of any Person means another Person, an amount of the voting securities, other voting rights or voting partnership interests of which is sufficient to elect at least a majority of its board of directors or other governing body (or, if there are no such voting interests, 50% or more of the equity interests of which) is owned directly or indirectly by such first Person.

“Tax” or “Taxes” means (whether disputed or not) all (a) Federal, state, local and foreign income, property, sales, use, excise, withholding, payroll, employment, social security, capital gain, alternative minimum, transfer and other taxes and similar governmental charges, in each case in the nature of a tax, including any interest, penalties and additions with respect thereto, (b) liability for the payment of any amounts of the type described in clause (a) as a result of being a member of an affiliated, consolidated, combined, unitary or aggregate group or as a transferee or successor and (c) liability for the payment of any amounts as a result of being party to any tax sharing agreement or as a result of any express or implied obligation to indemnify any other Person with respect to the payment of any amounts of the type described in clause (a) or (b).

“Tax Benefit” has the meaning set forth in Section 6.3(d).

“Tax Refunds” has the meaning set forth in Section 2.2(b)(vi).

“Tax Return” means all returns (including amended returns), requests for extensions of time, claims for refund, declarations of estimated Tax payments, reports, estimates, information returns and statements, including any related or supporting information with respect to any of the foregoing, filed or required to be filed with any Taxing Authority in connection with the determination, assessment, collection or administration of any Taxes.

“Taxing Authority” means any Federal, state, local or foreign government, any subdivision, agency, commission or authority thereof, or any quasi-governmental body exercising tax regulatory authority.

“Third Party” means any Person other than: (a) any Seller or Buyer or (b) any Affiliates of any Seller or Buyer.

“Third Party Claim” has the meaning set forth in Section 6.4(a).

“Transfer Taxes” has the meaning set forth in Section 5.2(a).

“Treasury Regulations” means the final and temporary Regulations promulgated under the Code by the United States Department of the Treasury.

“Written Report” has the meaning set forth in Section 5.9(a).

Section 1.2. Interpretation. When a reference is made in this Agreement to an Article, a Section or an Exhibit, such reference shall be to an Article of, a Section of, or an Exhibit to, this Agreement unless otherwise indicated. When a reference is made in this Agreement to a Schedule, such reference shall be to a Schedule of the Disclosure Letter. The table of contents and headings contained in this Agreement, any Related Document or in any Exhibit or Schedule to the Disclosure Letter hereto are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement, such Related Document or such Exhibit or Schedule to the Disclosure Letter. Whenever the words “include”, “includes” or “including” are used in this Agreement or any Related Document, they shall be deemed to be followed by the words “without limitation”. The word “or,” when used in this Agreement, has the inclusive meaning represented by the phrase “and/or.” The words “hereof”, “herein” and “hereunder” and words of similar import when used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. References to the “date hereof” refer to the date of this Agreement. “Extent” in the phrase “to the extent” means the degree to which a subject or other thing extends, and such phrase does not mean simply “if”. For purposes of this Agreement and the Related Documents, the phrases “delivered or made available to Buyer prior to the date hereof”, “delivered or made available to Buyer in the data room prior to the date hereof”, “has made available to Buyer prior to the date hereof” or “has made available to Buyer in the data room prior to the date hereof” and similar expressions in respect of any document or information will be construed for all purposes of this Agreement and the Related Documents as meaning that a copy of such document or information was filed and made available for viewing by Buyer in the electronic data rooms hosted by Sellers’ SharePoint site (the “Data Room”) in each case no later than three Business Days prior to the date hereof (or, if after such third Business Day, then delivered directly to Buyer and its legal counsel). All terms defined in this Agreement shall have the defined meanings when used in any certificate or other document made or delivered pursuant hereto unless otherwise defined therein. The definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms and to the masculine as well as to the feminine and neuter genders of such term. Any Contract or statute defined or referred to herein or in any Contract that is referred to herein means (a) in the case of any statute, such statute and any comparable statute that from time to time replaces such statute by succession and (b) in the case of any Contract, such Contract and

all amendments, modifications and attachments thereto and instruments incorporated therein. References to a Person are also to its permitted successors and assigns. Any reference contained in this Agreement to specific governmental regulatory provisions or to any specific Governmental Authority shall include any successor regulation or regulatory provisions, or successor Governmental Authority, as the case may be.

## ARTICLE II. PURCHASE AND SALE

### Section 2.1. Purchase and Sale of Purchased Assets; Purchase Price.

(a) Pursuant to the terms and subject to the conditions of this Agreement, at the Closing, Sellers shall sell, convey, deliver, transfer and assign to Buyer (or its designated Affiliate), free and clear of all Liens, other than Permitted Liens, and Buyer (or its designated Affiliate) shall purchase, take delivery of and acquire from Sellers all of each Seller's right, title and interest in, to and under all of the Purchased Assets. The purchase and sale of the Purchased Assets hereunder is referred to herein as the "Acquisition".

(b) In consideration of the sale, conveyance, delivery, transfer and assignment of the Purchased Assets to Buyer and Sellers' other covenants and obligations hereunder, at the Closing, upon the terms and subject to the conditions hereof:

(i) Buyer shall pay Sellers, by wire transfer of immediately available funds to the account set forth on Schedule 2.1(b)(i), the Purchase Price; and

(ii) Buyer shall assume the Assumed Liabilities.

### Section 2.2. Purchased Assets; Excluded Assets.

(a) The term "Purchased Assets" means all of the assets primarily used or held for use in the Business, including each Seller's right, title and interest in, to and under the following properties and assets (tangible or intangible), in each case to the extent used in the Business and in each case other than the Excluded Assets:

(i) the Contracts set forth on Schedule 2.2(a)(i) (collectively, the "Assumed Contracts"), including all rights thereunder;

(ii) all Regulatory Authorizations, including as set forth on Schedule 2.2(a)(ii);

(iii) all Business Intellectual Property, including the registrations and applications set forth on Schedule 2.2(a)(iii);

(iv) all Books and Records, other than the Excluded Books and Records;

(v) all Inventory, including as set forth on Schedule 2.2(a)(v), to be delivered to Buyer as set forth on such Schedule; and

(vi) all claims, counterclaims, credits, causes of action, choses in action, rights of recovery, and rights of indemnification or setoff against Third Parties and other claims arising out of or relating to the Purchased Assets or the Assumed Liabilities after the Closing and all other intangible property rights that relate to the Purchased Assets or the Assumed Liabilities.

(b) Other than the Purchased Assets, Buyer expressly understands and agrees that it is not purchasing or acquiring, and the Sellers are not selling or assigning, any other assets or properties of any Seller or any of their Affiliates, and all such other assets and properties shall be excluded from the Purchased Assets (collectively, the "Excluded Assets"). The Excluded Assets shall include, but not be limited to, the following:

(i) all cash and cash equivalents, bank accounts and securities of Sellers, and all accounts receivable generated prior to the Closing Date;

(ii) all Contracts other than the Assumed Contracts (it being understood that, for the avoidance of doubt, all Excluded Contracts are Excluded Assets);

(iii) all statements of work, proposals or other similar documents executed pursuant to any Contract (including the Assumed Contracts) that are not related to the Business, a Product, the Compound or the Purchased Assets;

(iv) all rights, claims and credits of Sellers to the extent relating to any Excluded Asset or any Excluded Liability;

(v) all land, buildings, improvements and fixtures thereon owned or leased by Sellers;

(vi) any refunds, credits or other assets or rights (including interest thereon or claims therefor) with respect to any Taxes (the "Tax Refunds") relating to the Purchased Assets and attributable to any Pre-Closing Tax Period;

(vii) all Intellectual Property Rights of Sellers other than the Business Intellectual Property;

(viii) the corporate seals, organizational documents, minute books, stock books, Tax Returns, books of account or other records having to do with the corporate organization of any Seller, and all Excluded Books and Records;

- (ix) all insurance policies of Sellers and all rights to applicable claims and proceeds thereunder;
- (x) all Tax assets (including duty and Tax refunds and prepayments) of Sellers or any of their Affiliates;
- (xi) all assets, properties and rights used by Sellers in their businesses other than the Business;
- (xii) except to the extent included in the Purchased Assets, all other properties, assets, goodwill and rights of Sellers of whatever kind and nature, real, personal or mixed, tangible or intangible; and
- (xiii) the assets set forth on Schedule 2.2(b)(xiii).

Section 2.3. Assumed Liabilities; Excluded Liabilities.

(a) Pursuant to the terms and subject to the conditions of this Agreement, at the Closing, Sellers shall sell, convey, deliver, transfer and assign to Buyer (or its designated Affiliate), and Buyer (or its designated Affiliate) shall assume from Sellers the Assumed Liabilities.

(b) Notwithstanding anything in this Agreement or the Related Documents to the contrary, other than the Assumed Liabilities: (i) Buyer shall not be the successor to any Seller or any Affiliates of any Seller, and (ii) Buyer expressly does not assume, and shall not become liable to pay, perform or discharge, any Liability whatsoever of any Seller or any Affiliates of any Seller, to the extent arising out of or otherwise relating in any way to the Purchased Assets. All such Liabilities are referred to herein as the "Excluded Liabilities". Without limitation of the foregoing, the Excluded Liabilities shall include the following Liabilities:

- (i) any Liabilities to the extent relating to or arising out of the Excluded Assets;
- (ii) any Liabilities of any Seller, or any member of any consolidated, affiliated, combined or unitary group of which any Seller is or has been a member, for Taxes (excluding, for the avoidance of doubt, any Taxes imposed with respect to any Post-Closing Tax Period that relate to the ownership or operation of the Purchased Assets; provided, that the Transfer Taxes and the Apportioned Obligations shall be paid in the manner set forth in Section 5.2;
- (iii) any Liabilities of any Seller or any Affiliates of any Seller under this Agreement, the Related Documents or in connection with the Contemplated Transactions;

(iv) all Liabilities under Excluded Contracts (other than the Deerfield Obligation);

(v) any Liabilities (including all Actions relating to such Liabilities) of any Seller or any Affiliates of any Seller to any Person and claims from any Person to the extent relating to or arising out of circumstances existing on or prior to the Closing, including those to the extent relating to or arising out of any product liability, patent infringement, breach of warranty or similar claim for injury to person or property that resulted from the use, operation, ownership or misuse of the Purchased Assets or the operation of the business of Seller or any Affiliates of any Seller, to the extent such conduct occurred on or prior to the Closing;

(vi) any Liabilities (including all Actions relating to such Liabilities) to the extent relating to or arising out of the Intellectual Property Rights of any Person on or prior to the Closing, including any Liability for any loss or infringement, misappropriation, other violation thereof or for violation of privacy, personal information or data protection rights; and

(vii) any other Liabilities arising out of the Purchased Assets or the operation of the business of any Seller or any Affiliates of any Seller on or prior to the Closing, whether or not any such Liabilities are claimed prior to or after the Closing (other than the Assumed Liabilities).

Section 2.4. Closing; Closing Deliverables.

(a) Closing. The closing of the Acquisition (the "Closing") shall take place remotely by exchange of electronic copies of the agreements, documents, certificates and other instruments set forth in this Section 2.4 on the second Business Day after all of the conditions to Closing set forth in Article VIII are either satisfied or waived (other than conditions which, by their nature, are to be satisfied on the Closing Date), or at such other time, date or place as Sellers and Buyer may mutually agree upon in writing. The date on which the Closing occurs is referred to herein as the "Closing Date" and, for all purposes of this Agreement, the Closing shall be deemed effective as of open of business on the Closing Date.

(b) Seller Closing Deliverables. At the Closing, Sellers shall deliver or cause to be delivered to Buyer:

(i) a certificate, dated as of the Closing Date, duly executed by the secretary of Parent, certifying that:

(A) all documents to be executed by Sellers and delivered at the Closing have been executed by a duly authorized officer of the applicable Seller;



(B) the resolutions adopted by the Board of Directors or other similar body of each Seller (the “Seller Boards”) authorizing the execution, delivery and performance of this Agreement, as attached to the certificate, were duly adopted by the respective Seller Board and remain in full force and effect, and have not been amended, rescinded or modified, except to the extent attached thereto; and

(C) Sellers’ officer(s) executing this Agreement, and each of the other documents necessary for consummation of the Contemplated Transactions, is an incumbent officer, and the specimen signature on such certificate is a genuine signature;

(ii) the Development Agreement, duly executed by Parent and Flamel Ireland Limited;

(iii) the Bill of Sale, Assignment and Assumption Agreement, in the form of Exhibit 2.4(b)(iii) (the “Bill of Sale, Assignment and Assumption”), duly executed by each Seller;

(iv) a certificate of each Seller other than Parent, in compliance with Section 1.1445-2(b)(2) of the Treasury Regulations, listing such Seller’s name, address and U.S. employer identification number and stating that such Seller is not a foreign person; provided, however, that if any Seller is treated as a disregarded entity under the Treasury Regulations issued under Code Section 7701, such Seller will not be required to provide a certificate, but rather, the “owner of the disregarded entity” (within the meaning of Treasury Regulations Section 1.445-2(b)(2)(iii)) shall provide such a certificate and identify thereon the disregarded entity that it owns;

(v) a duly completed and accurate Internal Revenue Service Form W-8 or W-9 for each Seller;

(vi) a fully executed waiver, pursuant to which Deerfield CSF, LLC, on behalf of itself and all its Affiliates, (a) waives its right to accelerate the Deferred Payments (as defined in the Deerfield Agreement) as a result of the Contemplated Transactions and (b) acknowledges that the Contemplated Transactions are not an Acceleration Trigger Event (as defined in the Deerfield Agreement); and

(vii) all forecasts since the Measurement Date that are required to be delivered pursuant to or in accordance with any of the Assumed Contracts.

(c) Buyer Closing Deliverables. At the Closing, Buyer shall deliver or cause to be delivered to Parent:

(i) the payments required pursuant to Section 2.1(b)(i);

(ii) a certificate, dated as of the Closing Date, duly executed by an authorized officer of Buyer, certifying that:

(A) all documents to be executed by Buyer and delivered at the Closing have been executed by a duly authorized signatory of Buyer;

(B) the resolutions adopted by the Board of Directors of Buyer authorizing the execution, delivery and performance of this Agreement, as attached to the certificate, were duly adopted and remain in full force and effect, and have not been amended, rescinded or modified, except to the extent attached thereto; and

(C) Buyer's officer executing this Agreement, and each of the other documents necessary for consummation of the Contemplated Transactions, is an incumbent officer, and the specimen signature on such certificate is a genuine signature;

(iii) the Development Agreement, duly executed by Buyer;

(iv) the Bill of Sale, Assignment and Assumption, duly executed by Buyer; and

(v) a guaranty, duly executed by Buyer's majority stockholder, Armistice Capital Master Fund, Ltd., in form and substance reasonably acceptable to the Sellers.

Section 2.5. Non-assignable Assets.

(a) Notwithstanding anything to the contrary in this Agreement, and subject to the provisions of this Section 2.5, to the extent that the sale, assignment, transfer, conveyance or delivery, or attempted sale, assignment, transfer, conveyance or delivery, to Buyer of any Purchased Asset would result in a violation of applicable Law, or would require the consent, authorization, approval or waiver of a Person who is not a party to this Agreement or an Affiliate of a party to this Agreement (including any Governmental Authority), and such consent, authorization, approval or waiver has not been obtained prior to the Closing, this Agreement shall not constitute a sale, assignment, transfer, conveyance or delivery, or an attempted sale, assignment, transfer, conveyance or delivery, thereof; provided, however, that, subject to Sellers' compliance with this Section 2.5, the Closing shall occur notwithstanding the foregoing without any adjustment to the Purchase Price on account thereof. Following the Closing, Sellers and Buyer shall use, each at its own cost and expense, commercially reasonable efforts, and shall cooperate with each other, to obtain any such required consent, authorization, approval or waiver,

or any release, substitution or amendment required to novate all liabilities and obligations under any and all Assigned Contracts or other liabilities that constitute Assumed Liabilities or to obtain in writing the unconditional release of all parties to such arrangements, so that, in any case, Buyer shall be solely responsible for such liabilities and obligations from and after the Closing Date; provided, however, that neither Sellers nor Buyer shall be required to pay any consideration therefor. Once such consent, authorization, approval, waiver, release, substitution or amendment is obtained, Sellers shall sell, assign, transfer, convey and deliver to Buyer the relevant Purchased Asset to which such consent, authorization, approval, waiver, release, substitution or amendment relates for no additional consideration. Applicable Transfer Taxes in connection with such sale, assignment, transfer, conveyance or license shall be paid by Buyer in accordance with Section 5.2(a) of this Agreement.

(b) To the extent that any Purchased Asset and/or Assumed Liability cannot be transferred to Buyer following the Closing pursuant to this Section 2.5, Buyer and Sellers shall use, each at its own cost and expense, commercially reasonable efforts to enter into such arrangements (such as subleasing, sublicensing or subcontracting) to provide to the parties the economic and, to the extent permitted under applicable Law, operational equivalent of the transfer of such Purchased Asset and/or Assumed Liability to Buyer as of the Closing and the performance by Buyer of its obligations with respect thereto. To the extent permitted under applicable Law, Sellers shall hold in trust for and pay to Buyer promptly upon receipt thereof, such Purchased Asset and all income, proceeds and other monies received by Sellers to the extent related to such Purchased Asset in connection with the arrangements under this Section 2.5. Notwithstanding anything herein to the contrary, the provisions of this Section 2.5 shall not apply to any consent or approval required under any antitrust, competition or trade regulation Law.

#### Section 2.6. Purchase Price Allocation.

(a) The Purchase Price and other relevant items for Tax purposes shall be allocated among the Purchased Assets in accordance with the principles set forth in Section 1060 of the Code (and the Treasury Regulations promulgated thereunder). Buyer shall prepare a draft allocation statement in accordance with the aforementioned principles and provide a copy to Parent no later than sixty (60) calendar days after the Closing Date. Parent shall inform Buyer in writing within fifteen (15) calendar days of the receipt of such draft of any objection by Sellers to the draft allocation. To the extent that any such objection is received, the Buyer and Sellers shall attempt in good faith to resolve any dispute. If Buyer and Sellers are unable to reach such agreement within fifteen (15) days after receipt by Buyer of such notice, the disputed items shall be resolved by a nationally recognized accounting firm that is mutually acceptable to Buyer and Sellers (the "Independent Accountant"), and any determination by the Independent Accountant shall be final. The Independent Accountant shall resolve any disputed items within fifteen (15) days of having the item referred to it pursuant to such procedures as it may require. The costs, fees and expenses of the Independent Accountant shall be borne equally by Buyer and Sellers.

The allocation as determined by agreement of the Parties or by the Independent Accountant, as the case may be (the “Purchase Price Allocation”) shall be binding on the Parties.

(b) Each Seller and Buyer agree to act in accordance with the Purchase Price Allocation, as adjusted in accordance with Section 2.6(a) if applicable, in any Tax Return, including any forms or reports required to be filed pursuant to Section 1060 of the Code or any provisions of any comparable Law, unless otherwise required by a change in Law after the date hereof, or a final “determination,” as defined in Section 1313(a) of the Code. Buyer and each Seller shall cooperate in the preparation of such Tax Returns and file such forms as required by applicable Law. Neither Buyer nor any Seller shall take a position inconsistent therewith upon examination of any Tax Return, in any refund claim, or in any litigation or investigation, without the prior written consent of the other Party (which consent, in the case of the Sellers, will be deemed to be given by all Sellers upon consent of Parent), except as required by applicable Law. In the event that the Purchase Price Allocation is disputed by any Taxing Authority, the Party receiving notice of the dispute shall promptly notify the other Party in writing of such notice and resolution of the dispute.

### ARTICLE III.

#### REPRESENTATIONS AND WARRANTIES OF SELLERS

Except as set forth in the Schedules to the Disclosure Letter attached hereto (to the extent any such Schedule to the Disclosure Letter is numbered to correspond to a representation or warranty, such Schedule to the Disclosure Letter includes a cross reference to a Schedule to the Disclosure Letter corresponding to another representation or warranty, or the applicability of disclosure on a Schedule to the Disclosure Letter to another representation is reasonably apparent based on the face of such disclosure), Sellers jointly and severally represent and warrant to Buyer that the statements contained in this Article III are true and correct for the period between February 5, 2016 and the date hereof.

Section 3.1. Organization, Standing and Power. Each Seller is duly organized, validly existing and in good standing under the laws of its jurisdiction of organization, and has all requisite corporate power and authority to own, lease or otherwise hold and operate the Purchased Assets and the Business, except where the failure to be in good standing or have such power or authority, individually or in the aggregate, has not been and would not reasonably be expected to be material and adverse to the Business or the Purchased Assets, taken as a whole. Each Seller is duly qualified or licensed to do business and is in good standing (in jurisdictions that recognize the concept of good standing) in each jurisdiction in which the Business operates, other than in such jurisdictions where the failure to be so qualified or licensed or to be in good standing individually or in the aggregate has not been and would not reasonably be expected to have a Material Adverse Effect. Sellers have made available to Buyer, prior to the execution of this Agreement, complete and accurate copies of each Seller’s certificate of incorporation, bylaws, certificate of organization, operating agreement, and any other applicable formation or

organizational documents, in each case as amended to the date hereof (collectively, the “Sellers’ Organizational Documents”). No Seller is in violation of any of the provisions of the Sellers’ Organizational Documents.

Section 3.2. Authority; Noncontravention. (a) Each Seller has all requisite corporate power and authority to execute and deliver this Agreement and the Related Documents and to consummate the Contemplated Transactions. The execution and delivery of this Agreement and the Related Documents by Sellers and the consummation by Sellers of the Contemplated Transactions have been duly authorized by all necessary corporate action on the part of Sellers and no other corporate proceedings on the part of Sellers are necessary to authorize this Agreement, the Related Documents or to consummate the Contemplated Transactions. Each of this Agreement and the Related Documents has been duly executed and delivered by each Seller and, assuming the due authorization, execution and delivery by Buyer, constitutes a legal, valid and binding obligation of each Seller, enforceable against each Seller in accordance with its terms, subject to bankruptcy, insolvency, moratorium, reorganization or similar Laws affecting the rights of creditors generally and the availability of equitable remedies. The Seller Boards duly and unanimously adopted resolutions (a) approving and declaring advisable this Agreement, the other Related Documents, the Acquisition and the other Contemplated Transactions and (b) declaring that it is in the best interests of the stockholder(s) or member(s), as applicable, of each Seller that Sellers enter into this Agreement and the Related Documents and consummate the Contemplated Transactions on the terms and subject to the conditions set forth in this Agreement or such Related Documents, which resolutions have not been subsequently rescinded, modified or withdrawn in any way. No stockholder, member, or other equity holder approval is required on behalf of any Seller for the execution, delivery or performance of this Agreement or any Related Document.

(b) The execution and delivery of this Agreement and the Related Documents by each Seller do not, and the consummation of the Contemplated Transactions and compliance by each Seller with the provisions of this Agreement and the Related Documents will not, conflict with, or result in any violation or breach of, or default under (with or without notice or lapse of time, or both), or give rise to a right of, or result in, termination, cancellation or acceleration of any obligation or to the loss of a benefit under, or result in the creation of any Lien in or upon the Purchased Assets under, (i) Sellers’ Organizational Documents, (ii) any Contract to which a Seller is a party in respect of the Business, or to which any of the Purchased Assets is subject or (iii) any (A) statute, ordinance, rule, regulation or other Law applicable to the Business or the Purchased Assets or (B) Order applicable to the Business or the Purchased Assets, except in the cases of clauses (ii) and (iii), where the conflict, violation, breach, default, termination, cancellation, acceleration or creation of a Lien, individually or in the aggregate, has not had a Material Adverse Effect.

(c) Except as set forth on Schedule 3.2(c), no consent, approval, order or authorization of, action by or in respect of, or registration, declaration or filing with, any

Governmental Authority is required by or with respect to any Seller or the Purchased Assets in connection with the execution and delivery of this Agreement or any Related Document by any Seller, the transfer of the Purchased Assets to Buyer or the consummation of the Contemplated Transactions.

Section 3.3. Absence of Certain Changes or Events. Since February 5, 2016 (the "Measurement Date") (a) no event has occurred which would reasonably be expected to result in, individually or in the aggregate, a Material Adverse Effect and (b) there has been no material loss, destruction or damage (in each case, whether or not insured) affecting the Purchased Assets or any rights thereunder.

Section 3.4. Good Title; Sufficiency of Assets.

(a) Except for the Business Intellectual Property (which is addressed in Section 3.5), (i) Sellers have good and marketable title to, or valid contract rights to or other valid rights to use, as applicable, all of the Purchased Assets free and clear of all Liens (other than Permitted Liens), and have complete power and rights to sell, assign, transfer and deliver to Buyer, as applicable, the Purchased Assets, (ii) there are no adverse claims of ownership to the Purchased Assets and no Seller has received written notice that any Person has asserted a claim of ownership or right of possession or use in or to any of the Purchased Assets, and (iii) at the Closing, Buyer will acquire from Sellers good title to, or valid contract rights to or other valid rights to use, as applicable, all of the Purchased Assets, free and clear of all Liens (other than Permitted Liens).

(b) Except for the Excluded Assets, the Purchased Assets constitute (i) all of the interests, assets and rights of any Seller or any Affiliates of any Seller acquired, conceived, collected, compiled, generated, reduced to practice or otherwise made or used in connection with the Business and (ii) all of the interests, assets and rights of any Seller or any Affiliates of any Seller used, held for use or intended to be used in connection with a Product, the Compound or the Business.

(c) The Purchased Assets include all assets required for Buyer to conduct the Business substantially as conducted by Sellers prior to the Closing, it being acknowledged by Buyer that the foregoing does not take into account cash and trademarks of Sellers that are Excluded Assets as well as certain other Excluded Assets, the absence of which would not have a material effect on Buyer's ability to operate the Business following the Closing.

Section 3.5. Intellectual Property.

(a) Subject to Sections 3.5(b) and 3.5(f), Sellers exclusively own, or validly Control, all Business Intellectual Property (including all Intellectual Property Rights set forth on Schedule 2.2(a)(iii)), in each case free and clear of all Liens (other than Permitted Liens). All Business Intellectual Property will, immediately subsequent to the Closing, be transferred to, and

Controlled by, Buyer on substantially the same terms with which Sellers, immediately prior to the Closing, Controlled such Business Intellectual Property. For the avoidance of doubt, this Section 3.5(a) does not constitute a representation or warranty of Sellers relating to infringement, misappropriation or other violation of the Intellectual Property Rights of any Person.

(b) To Sellers' Knowledge, (i) no Seller has infringed, misappropriated or otherwise violated and (ii) no Seller is infringing, misappropriating or otherwise violating (including with respect to the discovery, development, clinical testing, manufacture, distribution, advertising, use, Exploitation or sale by any Seller of a Product or the Compound) the rights of any other Person with regard to any Seller's possession or use of any Business Intellectual Property for the Business as presently conducted. To Sellers' Knowledge, no other Person or Persons has infringed, misappropriated or otherwise violated or is or are infringing, misappropriating or otherwise violating the Business Intellectual Property.

(c) No claims against any Seller are pending or, to Sellers' Knowledge, threatened with regard to (i) the Control or use of any Business Intellectual Property; (ii) any actual or potential infringement, misappropriation or unauthorized use of Business Intellectual Property; (iii) any actual or potential infringement, misappropriation or unauthorized use of any Third Party's Intellectual Property Rights with respect to any Business Intellectual Property or the Business; or (iv) the validity or enforceability of any Business Intellectual Property. Sellers have the right to bring actions for infringement, including all rights to recover damages for past infringement (to the extent permitted by applicable Law), of all Business Intellectual Property.

(d) Schedule 2.2(a)(iii) sets forth, as of the date hereof, a complete and accurate list of all patents and applications therefor, registered trademarks and applications therefor (if any), domain name registrations (if any), copyright registrations (if any) and all invention disclosures, that, in each case, are Controlled by any Seller and related to the Business, a Product or the Compound. The patent applications listed in Schedule 2.2(a)(iii) that are owned by any Seller are (and such applications that are otherwise Controlled by Sellers are, to Sellers' Knowledge) pending and have not been abandoned and have been and continue to be timely prosecuted. All patents, registered trademarks and applications therefor owned by Sellers that are related to the Business, a Product or the Compound have been (and all such patents, registered trademarks and applications otherwise Controlled by Sellers have been, to Sellers' Knowledge) duly registered or filed with or issued by each appropriate Governmental Authority in the jurisdiction indicated in Schedule 2.2(a)(iii), all related necessary affidavits of continuing use have been (or, with respect to licenses, to Sellers' Knowledge have been) timely filed, and all related necessary maintenance fees have been (or, with respect to licenses, to Sellers' Knowledge have been) timely paid to continue all such rights in effect. None of the patents listed in Schedule 2.2(a)(iii) that are owned by Sellers have (and no such patents that are otherwise Controlled by Sellers have, to Sellers' Knowledge) expired, been disclaimed, in whole or in part, been declared invalid, in whole or in part, or held to be unenforceable by any Governmental Authority. None of the trademarks or trademark applications listed in Schedule 2.2(a)(iii) that are owned by Sellers

are (and no such trademarks or trademark applications that are otherwise Controlled by Sellers are, to Sellers' Knowledge) involved in or the subject of any ongoing oppositions, cancellations or other proceedings. None of the patents or patent applications listed in Schedule 2.2(a)(iii) that are owned by Sellers are (and no such patents or patent applications that are otherwise Controlled by Sellers are, to Sellers' Knowledge) involved in or the subject of any material ongoing interferences, oppositions, reissues, reexaminations or other proceedings, including ex parte (other than ex parte proceedings in connection with such patent applications) and post-grant proceedings, in the United States Patent and Trademark Office or in any foreign patent office or similar administrative agency. Each of the patents and patent applications listed in Schedule 2.2(a)(iii) that are owned by Sellers properly identifies (and, to Sellers' Knowledge, such patents and applications otherwise Controlled by Sellers properly identify) each and every inventor of the claims thereof as determined in accordance with the Laws of the jurisdiction in which such patent is issued or such patent application is pending. Each inventor named on the patents and patent applications listed in Schedule 2.2(a)(iii) that are owned by Sellers has executed (and, to Sellers' Knowledge, such inventors named on such patents and applications that are otherwise Controlled by Sellers and material to the Business, a Product or the Compound have executed) an agreement assigning his, her or its entire right, title and interest in and to such patent or patent application, and the inventions embodied and claimed therein, to Sellers, or in the case of licensed Patents, to the appropriate owners. To Sellers' Knowledge, no such inventor has any contractual or other obligation that would preclude any such assignment or otherwise conflict with the obligations of such inventor to Sellers under such agreement with any Seller.

(e) No current or former director, officer, employee, contractor or consultant of any Seller owns any rights in or to any Business Intellectual Property. All current and former directors, officers, employees, contractors and consultants of any Seller who contributed to the discovery, creation or development of any Business Intellectual Property did so (i) within the scope of his or her employment such that it constituted a work made for hire and all Business Intellectual Property arising therefrom became the exclusive property of Sellers or (ii) pursuant to a written agreement assigning all of his or her rights in Business Intellectual Property to Sellers. No current or former directors, officers, employees, contractors or consultants of any Seller has made or, to Sellers' Knowledge, threatened to make any claim or challenge against any Seller or any Affiliates of any Seller in connection with their contribution to the discovery, creation or development of any Business Intellectual Property.

(f) Schedule 3.5(f) sets forth a complete and accurate list as of the date hereof of all options, rights, licenses or interests of any kind relating to any Business Intellectual Property (i) granted to any Seller by any other Person (other than software licenses for commercially available off the shelf software and except pursuant to employee proprietary inventions agreements (or similar employee agreements)), or (ii) granted by any Seller to any other Person (including any obligations of such other Person to make any fixed or contingent payments, including royalty payments). All material obligations for payment of monies currently



due and payable by any Seller and other material obligations in connection with such options, rights, licenses or interests have been satisfied in a timely manner.

(g) Sellers have used reasonable efforts to make all filings with Governmental Authorities and obtain all grants and registrations as may be reasonably necessary or appropriate to preserve and protect the Business Intellectual Property.

(h) Sellers have used reasonable efforts and taken commercially reasonable steps designed to maintain in confidence its Trade Secrets and other confidential information acquired, conceived, developed, collected, compiled, generated, reduced to practice or otherwise made or used in connection with the Business or related to a Product or the Compound, including through the development of a policy for the protection of intellectual property and periodic training for all employees of each Seller on the implementation of such policy; requiring all employees of each Seller to execute confidentiality agreements with respect to intellectual property developed for or obtained from Sellers; and entering into licenses and Contracts that generally require licensees, contractors and other Third Parties with access to the Trade Secrets or other confidential information to keep such Trade Secrets or other confidential information confidential.

(i) The execution and delivery of this Agreement and the Related Documents by Sellers do not, and the consummation of the Contemplated Transactions and compliance by Sellers with the provisions of this Agreement and any Related Document will not, conflict with, or result in any violation or breach of, or default (with or without notice or lapse of time, or both) under, or give rise to a right of, or result in, termination, cancellation or acceleration of any right or obligation or to the loss of a benefit under, or result in the creation of any Lien in or upon or the transfer of, any Business Intellectual Property that is material to the Compound, a Product or the Business.

Section 3.6. Assumed Contracts.

(a) There are no Contracts, other than the Assumed Contracts and Excluded Contracts, to which any Seller is a party or by which any Seller is bound, in either case, to which the Business or any of the Purchased Assets are subject.

(b) The Assumed Contracts are legal, valid and binding agreements of Sellers and are in full force and effect and are enforceable against the applicable Sellers and, to Sellers' Knowledge, each other party thereto, in accordance with their terms, subject to bankruptcy, insolvency, moratorium, reorganization or similar Laws affecting the rights of creditors generally and the availability of equitable remedies. Each Seller has performed all material obligations required to be performed by it to date under the Assumed Contracts, and no Seller is or will be (with or without notice or lapse of time, or both) in breach or default in any material respect thereunder and, to Sellers' Knowledge, no other party to any Assumed Contract is (with or without notice or lapse of time, or both) in breach or default in any material respect thereunder.

No Seller has received any written notice of intention to terminate any Assumed Contract or of any claim of breach with respect to the performance of any Seller's obligations under any Assumed Contract.

Section 3.7. Compliance with Law . The Purchased Assets and the Business (i) have been since the Measurement Date and are conducted in all respects in compliance with all applicable Laws, except where the failure to be in compliance would not have a Material Adverse Effect, and (ii) have had since the Measurement Date and have all material Regulatory Authorizations, except where the failure to obtain or hold such Permits would not have a Material Adverse Effect. Each such Regulatory Authorization is valid and in full force and effect. There has occurred no material default by Seller under, or material violation by any Seller of, any such Permit. No Seller has received any written notice from any Governmental Authority or other Person to the effect that any Seller is not, or may not be, in compliance with any material Law with respect to the Purchased Assets or the Business.

Section 3.8. Litigation. There is no Action pending or, to Sellers' Knowledge, threatened, that affects or, if successful, would reasonably be expected to be materially adverse to the Purchased Assets or that, if successful, would reasonably be expected to result in restraining, enjoining or otherwise preventing the completion by any Seller of the Contemplated Transactions. There is no outstanding Order of any Governmental Authority against any Seller arising out of or relating to the Purchased Assets or that would reasonably be expected to be materially adverse to the Purchased Assets or that would reasonably be expected to result in restraining, enjoining or otherwise preventing the completion by any Seller of the Contemplated Transactions.

Section 3.9. Taxes.

(a) Each Seller has filed all material Tax Returns that it was required to file. Each Seller has timely withheld, remitted, or paid all Taxes required to be paid by it, the non-payment of which would result in a Lien (other than Permitted Liens) on any Purchased Asset, would otherwise adversely affect the Purchased Assets or would result in Buyer becoming liable or responsible therefor.

(b) Each Seller has established, in accordance with GAAP as applied on a basis consistent with that of preceding periods, adequate reserves for the payment of all Taxes that arise from or with respect to the Purchased Assets and are incurred or attributable to the Pre-Closing Tax Period, the non-payment of which would result in a Lien on any Purchased Asset, would otherwise adversely affect the Purchased Assets, or would result in Buyer becoming liable therefor.

Section 3.10. Regulatory Matters.

(a) Schedule 3.10(a) sets forth a true and complete list of (i) all Regulatory Authorizations held by each Seller or under which any Seller conducts business, or that have been submitted by or on behalf of any Seller, in each case, relating to the Business or a Product, and (ii) all applications or notifications or submissions for Regulatory Authorizations pending in relation thereto. Sellers possess all material Regulatory Authorizations that are required for or relate to the Business. Sellers are the sole and exclusive owner(s) of the Regulatory Authorizations and none of the Regulatory Authorizations has been sold, conveyed, delivered, transferred or assigned to another party. Each such Regulatory Authorization (A) has, to Sellers' Knowledge, been validly issued or acknowledged by the appropriate Regulatory Authority and is in full force and effect and (B) is transferable to Buyer. To Sellers' Knowledge, there are no facts, circumstances or conditions that would prevent the transfer of any Regulatory Authorization to Buyer on or after the Closing Date.

(b) Except as set forth on Schedule 3.10(b), all pre-clinical and clinical studies, trials and investigations conducted or sponsored in relation to the Business are being, and at all times have been, conducted in compliance in all material respects with all applicable clinical protocols, informed consents and applicable Laws administered or issued by applicable Regulatory Authorities, including (to the extent applicable) (i) the U.S. Food and Drug Administration ("FDA") or other health authority standards for conducting non-clinical laboratory studies contained in Title 21 part 58 of the Code of Federal Regulations and associated regulatory guidance, (ii) investigational new drug requirements and associated regulatory guidance, (iii) FDA or other health authority standards for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials contained in Title 21 parts 50, 54, 56, 312, 314, and 320 of the Code of Federal Regulations and associated regulatory guidance, (iv) federal and state laws or other regulatory authority standards for restricting the use and disclosure of individually identifiable health information, (v) the International Council for Harmonisation Guideline on Good Clinical Practice (ICH Topic E6) and associated regulatory guidance and (vi) communications or notices from Regulatory Authorities regarding the conduct of such studies, trials and investigations. Except as set forth on Schedule 3.10(b), there have been no drug-related adverse event or events in patients in a clinical trial conducted or sponsored in relation to the Business, the effect of which would reasonably be expected to (x) prevent Buyer from obtaining approval from a Regulatory Authority to market a Product in the United States or (y) delay such approval to such an extent that the delay (taking into account the expected length of such delay and the basis or reasons therefor) would materially impair the aggregate financial value to be derived by Buyer from a Product. All clinical trial adverse events in patients in a clinical trial conducted or sponsored in relation to the Business within the knowledge of any Seller have been disclosed to Buyer and all associated correspondence, including actual or potential claims for recompense, have been made available to Buyer.

(c) No Regulatory Authority has commenced, or, to Sellers' Knowledge, threatened to initiate, any Action to place a clinical hold order on, or otherwise terminate, delay

or suspend any proposed or ongoing pre-clinical or clinical studies, trials, investigational new drug application or investigations conducted or proposed to be conducted in connection with the Business.

(d) No Seller has directly or indirectly received any written communication (including any warning letter, untitled letter, Form 483 or similar notice) from any Regulatory Authority, and to Sellers' Knowledge there are no material Actions related to the Business pending or threatened (including any prosecution, injunction, seizure, civil fine, suspension or recall), in each case (i) relating to, arising under or alleging that any Seller or any of its officers, employees or agents is not currently in compliance with, any Law administered or issued by any Regulatory Authority or (ii) regarding any debarment action or investigation in respect of any Seller or any of its officers, employees or agents undertaken pursuant to 21 U.S.C. Sections 335(a), (b) and (c), or any similar regulation of a Regulatory Authority. There are no pending voluntary or involuntary destruction orders, seizures or other regulatory enforcement actions related to the Business and, to Sellers' Knowledge, no Data relating to a Product or the Compound that has been made public is the subject of any regulatory or other Action, either pending or threatened, by any Regulatory Authority relating to the truthfulness or scientific adequacy of such Data.

(e) Since the Measurement Date, neither any Seller nor, to Sellers' Knowledge, any officer, employee, agent or distributor of any Seller, has made an untrue statement of a material fact or fraudulent statement to the FDA or any other Governmental Authority, failed to disclose a material fact required to be disclosed to the FDA or any other Governmental Authority, or committed an act, made a statement, or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) or for any other Governmental Authority to invoke any similar policy. Neither any Seller nor, to Sellers' Knowledge, any officer, employee or agent of any Seller has been convicted of any crime or engaged in any conduct for which debarment is mandated by or authorized by 21 U.S.C. Sections 335(a), (b) and (c) or any similar Laws. Neither Seller nor, to Sellers' Knowledge, any officer, employee or agent of any Seller has been convicted of any crime or engaged in any conduct for which such Person would be excluded from participating in the Federal health care programs under Section 1128 of the Social Security Act of 1935, as amended (the "Social Security Act"), or any similar Laws.

(f) Each Seller is, and, since the Measurement Date, has been, in compliance with: (i) laws, regulations and guidance pertaining to state and federal Anti-Kickback Statutes (42 U.S.C. §§ 1320a-7b(b), et seq. and their implementing regulations) and the related Safe Harbor Statutes; (ii) laws, regulations and guidance pertaining to submission of false claims to governmental or private health care payors (31 U.S.C. §§ 3729, et seq. and its implementing

regulations); and (iii) state laws and federal laws and regulations relating to providing and reporting of payments to health care professionals or health care entities.

(g) No Seller is a “covered entity” or a “business associate” pursuant to the Health Insurance Portability and Accountability Act of 1996 (as those terms are defined in 45 §160.103), and each Seller has complied in all material respects with all other applicable Laws relating to the privacy and security of individually identifiable information, including the Federal Trade Commission Act, the Children’s Online Privacy Protection Act (COPPA), and similar applicable Laws in any foreign jurisdiction in which the applicable Seller does business.

Section 3.11. Inventory. Schedule 2.2(a)(v) sets forth the Inventory as of the second Business Day prior to the date hereof. As of the date hereof, the Inventory is (a) free from any material defect or deficiency, (b) is in good and usable condition for its use in the Business and (c) meets in all material respects all of the applicable requirements and specifications.

Section 3.12. Relationships with Suppliers. Since the Measurement Date, no supplier of a Product or any Person materially involved in the Exploitation of a Product has canceled or otherwise terminated, or provided written notice to any Seller of its intent, or to Sellers’ Knowledge, threatened in writing, to terminate its relationship with any Seller with respect to a Product, or, since the Measurement Date, decreased or limited by more than five percent (5%), or provided written notice to any Seller of its intent, or, to Sellers’ Knowledge, threatened in writing, to so decrease or limit its sales to Seller.

Section 3.13. Brokers and Other Advisors. No broker, investment banker, financial advisor or other Person is entitled to any broker’s, finder’s, financial advisor’s or other similar fee or commission for which Buyer could become responsible in connection with the Contemplated Transactions based upon arrangements made by or on behalf of any Seller.

Section 3.14. Insurance. Each Seller maintains such policies of insurance relating to the Purchased Assets and the Business as are reasonably sufficient for compliance by such Seller with (i) all requirements of applicable Laws and (ii) all Assumed Contracts, and each Seller has complied in all material respects with the provisions of each such policy under which it is an insured party. No Seller has been refused any insurance with respect to any Purchased Asset or the Business, nor has any Seller’s coverage been limited by any insurance carrier to which it has applied for insurance or with which it has carried insurance. To Sellers’ Knowledge, there are no existing claims under any insurance policy relating to the Purchased Assets or the Business. No written notice of cancellation or termination has been received with respect to any insurance policy relating to the Purchased Assets or the Business.

Section 3.15. Adequate Consideration; Solvency. Each Seller is (a) able to pay its debts as they become due and (b) solvent and will be solvent immediately following the Closing. As of the date of this Agreement, no Seller is engaged or intends to be engaged in business or a transaction for which its remaining assets and capital are or will be insufficient. As

of the date of this Agreement, no Seller intends to incur Liabilities that would be beyond its ability to pay as such Liabilities matured. No Seller has entered into this Agreement for the purpose of hindering, delaying or defrauding its creditors.

Section 3.16. Related Party Transactions. Schedule 3.15 describes any transaction between any Seller, on the one hand, and any current or former partner, director, officer, employee, manager, member or stockholder (who holds at least five percent (5%) of any Seller's outstanding capital stock) of any Seller, on the other hand, in each case, related to the Purchased Assets or the Business. No current or former partner, director, officer, employee, manager, member or stockholder (who holds at least five percent (5%) of Seller's outstanding capital stock) of any Seller has any ownership interest in the Purchased Assets, or, to Sellers' Knowledge, any Person that is a supplier of a Product or the Compound (directly or indirectly) or actively engaged in the business of Exploiting a Competing Product (in each case, other than equity positions in companies that such Person does not Control).

Section 3.17. Anticorruption Matters.

(a) Neither any Seller, nor any of its Affiliates, any of their respective directors, officers, managers or employees or, to Sellers' Knowledge, any of their other respective Representatives, in any way relating to the Purchased Assets or the Business: (i) has taken any action in violation of any applicable anticorruption Law, including the U.S. Foreign Corrupt Practices Act ("FCPA") (15 U.S.C. § 78 dd-1 et seq.); or (ii) has corruptly, offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any "Public Official", as defined in this Section 3.17, for purposes of (A) influencing any act or decision of any Public Official in his official capacity; (B) inducing such Public Official to do or omit to do any act in violation of his lawful duty; (C) securing any improper advantage; or (D) inducing such Public Official to use his or her influence with a government, Governmental Authority, or commercial enterprise owned or controlled by any Governmental Authority (including state-owned or controlled veterinary or medical facilities), in order to assist any Seller or any Affiliates of any Seller, related in any way to the Purchased Assets or the Business, in obtaining or retaining business.

(b) No Seller's officers, directors, employees or agents acting on behalf of any Seller are themselves Public Officials.

(c) For purposes of this Section 3.17, "Public Official" means: (i) any officer, employee or representative of any regional, Federal, state, provincial, county or municipal government or government department, agency, or other division; (ii) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary or medical facility; (iii) any officer, employee or representative of any public international organization, such as the African Union, the International Monetary Fund, the United Nations or the World Bank; (iv) any person acting in an

official capacity for any government or Governmental Authority, enterprise, or organization identified above; and (v) any official of a political party or candidate for political office.

(d) There are no pending proceedings against any Seller, its Affiliates, any of their respective directors, officers, managers or employees or, to Sellers' Knowledge, any of their other respective Representatives, with respect to the violation of any applicable anticorruption Law, including the FCPA, relating to the Purchased Assets or the Business.

(e) Each Seller and its Affiliates have been subject to an anticorruption compliance policy with respect to the Purchased Assets and the Business reasonably appropriate to ensure compliance with applicable anticorruption Laws, including the FCPA.

Section 3.18. No Other Representations and Warranties. (A) EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE III (INCLUDING THE RELATED PORTIONS OF THE DISCLOSURE LETTER), NO SELLER OR ANY OTHER PERSON HAS MADE OR MAKES ANY REPRESENTATION OR WARRANTY, WRITTEN OR ORAL, STATUTORY, EXPRESS OR IMPLIED, AT COMMON LAW OR OTHERWISE, WITH RESPECT TO ANY SELLER, THE PURCHASED ASSETS, THE BUSINESS OR THE CONTEMPLATED TRANSACTIONS; AND (B) NO SELLER OR ANY OTHER PERSON HAS MADE OR MAKES ANY REPRESENTATION OR WARRANTY, WRITTEN OR ORAL, STATUTORY, EXPRESS OR IMPLIED, AT COMMON LAW OR OTHERWISE, AS TO THE ACCURACY, COMPLETENESS OR MATERIALITY OF ANY INFORMATION, DATA OR OTHER MATERIALS (WRITTEN OR ORAL) HERETOFORE FURNISHED TO BUYER AND ITS REPRESENTATIVES BY OR ON BEHALF OF SELLERS AND ANY INFORMATION, DOCUMENTS OR MATERIAL MADE AVAILABLE TO BUYER IN THE DATA ROOM, MANAGEMENT PRESENTATIONS OR IN ANY OTHER FORM IN EXPECTATION OF THE CONTEMPLATED TRANSACTIONS, OTHER THAN IN THE CASE OF CLAUSE (B), TO THE EXTENT ANY SUCH INFORMATION, DATA OR MATERIAL IS ITSELF THE SUBJECT OF A REPRESENTATION OR WARRANTY CONTAINED IN THIS ARTICLE III (INCLUDING THE RELATED PORTION OF THE DISCLOSURE LETTER). EACH SELLER ACKNOWLEDGES AND AGREES THAT NONE OF BUYER OR ANY OTHER PERSON HAS MADE OR MAKES ANY REPRESENTATION OR WARRANTY, WRITTEN OR ORAL, STATUTORY, EXPRESS OR IMPLIED, AT COMMON LAW OR OTHERWISE, WITH RESPECT TO BUYER EXCEPT AS SET FORTH IN ARTICLE IV.

#### **ARTICLE IV.**

#### **REPRESENTATIONS AND WARRANTIES OF BUYER**

Buyer represents and warrants to Seller as set forth in this Article IV.

Section 4.1. Organization, Standing and Power. Buyer is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated and has all requisite corporate power and authority to carry on its business as presently conducted, except where the failure to be in good standing or have such power or authority, individually or in the aggregate, has not been and would not reasonably be expected to be material and adverse to Buyer, taken as a whole. Buyer is duly qualified or licensed to do business and is in good standing (in jurisdictions that recognize the concept of good standing) in each jurisdiction in which the nature of its business or the ownership, leasing or operation of its properties makes such qualification or licensing necessary, other than in such jurisdictions where the failure to be so qualified or licensed or to be in good standing individually or in the aggregate has not been and would not reasonably be expected to be material and adverse to Buyer.

Section 4.2. Authority; Noncontravention.

(a) Buyer has all requisite corporate power and authority to execute and deliver this Agreement and the Related Documents and to consummate the Contemplated Transactions. The execution and delivery of this Agreement and the Related Documents by Buyer and the consummation by Buyer of the Contemplated Transactions have been duly authorized by all necessary corporate action on the part of Buyer and no other corporate proceedings on the part of Buyer are necessary to authorize this Agreement, the Related Documents or to consummate the Contemplated Transactions. Each of this Agreement and the Related Documents has been duly executed and delivered by Buyer and assuming the due authorization, execution and delivery by Sellers, constitutes a legal, valid and binding obligation of Buyer, enforceable against Buyer in accordance with its terms, subject to bankruptcy, insolvency, moratorium, reorganization or similar Laws affecting the rights of creditors generally and the availability of equitable remedies.

(b) The execution and delivery of this Agreement and the Related Documents by Buyer do not, and the consummation of the Contemplated Transactions and compliance by Buyer with the provisions of this Agreement and the Related Documents will not, conflict with, or result in any violation or breach of, or default under (with or without notice or lapse of time, or both), or give rise to a right of, or result in, termination, cancellation or acceleration of any obligation or to the loss of a benefit under, or result in the creation of any Lien in or upon any of the properties or other assets of Buyer under (i) the certificate of incorporation or bylaws of Buyer, (ii) any Contract to which Buyer is a party or any of its respective properties or other assets is subject or (iii) any (A) statute, ordinance, rule, regulation or other Law applicable to Buyer or its properties or other assets or (B) Order applicable to Buyer or its properties or other assets, except in the cases of clauses (ii) and (iii), where the conflict, violation, breach, default, termination, cancellation, acceleration or creation of a Lien, individually or in the aggregate, would not reasonably be expected to prevent, materially impede or materially delay the consummation by Buyer of the Contemplated Transactions (including the payments required to be made pursuant to Article II).



(c) No consent, approval, order or authorization of, action by or in respect of, or registration, declaration or filing with, any Governmental Authority is required by or with respect to Buyer in connection with the execution and delivery of this Agreement or any Related Document by Buyer or the consummation by Buyer of the Contemplated Transactions.

Section 4.3. Capital Resources; Solvency.

(a) Buyer has immediately available funds sufficient to consummate the Contemplated Transactions on the terms contemplated by this Agreement including the payment of all fees, expenses and obligations payable by Buyer in connection with the Contemplated Transactions.

(b) Immediately after giving effect to the Contemplated Transactions, Buyer shall be solvent and shall: (a) be able to pay its debts as they become due and (b) have adequate capital to carry on its business.

Section 4.4. Litigation. There is no Action pending or, to the actual knowledge of Buyer's officers, threatened before any Governmental Authority, and there is no claim, investigation or administrative action of any Governmental Authority pending or, to the actual knowledge of Buyer's officers, threatened, that if successful, would reasonably be expected to result in restraining, enjoining or otherwise preventing the completion by Buyer of the Contemplated Transactions. There is no outstanding Order of any Governmental Authority against Buyer that would reasonably be expected to result in restraining, enjoining or otherwise preventing the completion by Buyer of the Contemplated Transactions.

Section 4.5. Brokers and Other Advisors. No broker, investment banker, financial advisor or other Person is entitled to any broker's, finder's, financial advisor's or other similar fee or commission for which Seller could become responsible in connection with the Contemplated Transactions based upon arrangements made by or on behalf of Buyer.

Section 4.6. Independent Investigation. Buyer has conducted its own independent investigation, review and analysis of the Purchased Assets and the Business and acknowledges that it has been provided access to the personnel, properties, assets, premises, books and records, and other documents and data of Sellers for such purpose. Buyer acknowledges and represents that in making its decision to enter into this Agreement and consummate the Contemplated Transactions, Buyer has relied solely on its own investigation and the express representations and warranties of Sellers set forth in Article III (including the Schedules to the Disclosure Letter) and Buyer is not relying on any representation or warranty, written or oral, statutory, express or implied, at common law or otherwise, with respect to any Seller, the Purchased Assets, the Business or the Contemplated Transactions not expressly set forth in Article III (including any information, data or other materials (written or oral) heretofore furnished to Buyer and its Representatives by or on behalf of Sellers and any information, documents or material made available to Buyer in the Data Room, management presentations or

in any other form in expectation of the Contemplated Transactions, other than to the extent any such information, data or material is itself the subject of a representation or warranty contained in Article III).

## ARTICLE V.

### ADDITIONAL AGREEMENTS

#### Section 5.1. Confidentiality; Non-Competition.

##### (a) Confidentiality.

(i) Each of Buyer and each Seller acknowledges that the information provided to them in connection with this Agreement and the consummation of the Contemplated Transactions is subject to the terms of the Confidentiality Agreement. Effective upon, and only upon, the Closing, the Confidentiality Agreement shall terminate with respect to information included in or related to the Business or the Purchased Assets.

(ii) Each Seller recognizes that it possesses information of a confidential or secret nature in both written and unwritten form, which has unique commercial value as related to the Business or the Purchased Assets (hereinafter referred to as "Confidential Information"). For purposes of this Agreement, the foregoing "Confidential Information" (A) shall include each of the following, to the extent constituting a Purchased Asset: (1) any pre-clinical, clinical, pharmaceutical development, prescription, or sales and marketing data for a Product or the Compound; (2) Trade Secrets, processes, methods, data, know-how, prototypes, improvements, inventions, techniques, product plans, strategies and forecasts, including any development plans for the use of a Product or the Compound; (3) forms, contracts or promotional materials created for or used solely in relation to a Product or Compound; (4) any correspondence, memoranda or files related solely to a Product or Compound which contain Confidential Information; and (5) any information, knowledge and data solely related to the Business and (B) shall not include any information which (1) is or becomes generally available to and known by the general public (other than as a result of a disclosure through the actions of Seller or any of its Representatives in violation of this Section 5.1 or any other obligation of confidentiality owed to Buyer or any of its Affiliates), (2) is independently developed by any Seller after the Closing without reference to the Confidential Information or any Purchased Assets or (3) any information, forms, contracts or other items relating to the Excluded Assets. Information that is not novel or copyrighted may nonetheless be Confidential Information.

(iii) Each Seller agrees that, following the Closing, all Confidential Information shall be the sole property of Buyer and its assigns.

(iv) For a period of [\*\*\*] after the Closing, each Seller will, and will cause its Affiliates and Representatives to, keep in strict confidence all Confidential Information and will not use or disclose any Confidential Information or anything relating to it, in whole or in part, nor permit others to use or disclose it in any way, without the prior written consent of Buyer. Each Seller further agrees to inform Buyer as promptly as practicable in writing in the event of any breach of this obligation of confidentiality that becomes known to any such Seller.

(v) Notwithstanding anything contained in this Agreement to the contrary, each Seller is permitted to disclose the Confidential Information pursuant to a court order or other requirement of a judicial, administrative or governmental proceeding, or otherwise to the extent required for Seller to comply with applicable Law, provided that, in each instance, Seller (A) notifies Buyer of the court order or other requirement promptly after Seller becomes aware of the court order or other requirement (unless such notification would be unlawful); (B) cooperates with Buyer in seeking a protective order or similar relief to protect the confidentiality of the information to be disclosed (in each case at the expense of Buyer); and (C) limits the disclosure to what is requested by the court order or other requirement.

(b) Non-Competition. Each Seller agrees that for a period of:

(i) [\*\*\*] commencing upon the Closing Date (the “First Restricted Period”), no Seller or any direct or indirect subsidiary thereof (now existing or hereafter incorporated, formed or otherwise organized) shall, alone or in conjunction with any Third Party, directly or indirectly, conduct human clinical studies with respect to, or manufacture or commercialize, any product that is competitive with the Products, taking into account the suggested indication and target market of each Product in any geographic area (such product, a “Competing Product”), other than pursuant to the Development Agreement.

(ii) [\*\*\*] commencing upon the Closing Date (the “Second Restricted Period”), no Seller or any direct or indirect subsidiary thereof (now existing or hereafter incorporated, formed or otherwise organized) shall, alone or in conjunction with any Third Party, directly or indirectly, manufacture or commercialize, any Product or any other product containing a Compound in any geographic area (such product, a “Similar Product”), other than pursuant to the Development Agreement.

(iii) In the event that any Seller is acquired by or merges with a Third Party that is engaged in human clinical studies with respect to, or the manufacture or commercialization of, a Competing Product, then such Seller shall not be deemed to be in

breach of this Section 5.1(b) with respect to any such Competing Product or Similar Product, and the terms of this Section 5.1(b) will not apply in any way to limit or restrict such Third Party or its Affiliates (other than such Seller and its direct and indirect subsidiaries).

(c) Acknowledgments, Interpretation and Validity.

(i) Each Seller agrees and acknowledges that the covenants in this Section 5.1 are reasonable and valid in all respects (including with respect to the subject matter, the First Restricted Period, the Second Restricted Period, and geographical area) and are necessary to protect the interests of Buyer in the Products, the Compound, the other Purchased Assets and the Confidential Information, and such covenants represent only a limited restraint. Further, each Seller acknowledges that, without the restrictions contained in this Section 5.1, the benefits of the Contemplated Transactions could be devalued, lost or circumvented, particularly in light of the nature and ongoing development of the Products and the Compound, and that Buyer would not have entered into this Agreement without the restrictions contained in this Section 5.1.

(ii) Each Seller acknowledges and agrees that the provisions of this Section 5.1 are necessary and reasonable to protect Buyer in the conduct of its business and are a material inducement to Buyer's execution and delivery of this Agreement and its willingness to enter into the Contemplated Transactions.

(iii) It is the desire and intent of the Parties that this Section 5.1 will be enforced to the fullest extent permissible under the Laws applied in each jurisdiction in which enforcement is sought. If any restriction set forth in this Section 5.1 is found by any court of competent jurisdiction to be unenforceable for any reason (*e.g.*, because it extends for too long a period of time, over too great a range of activities or in too broad a geographic area), this Section 5.1 shall be interpreted to extend over the maximum period of time, range of activities or geographic area as to which it may be enforceable. The agreements contained in this Section 5.1 shall each constitute a separate agreement independently supported by good and adequate consideration. For the avoidance of doubt, the Parties hereby acknowledge that each Seller will benefit substantially from the consummation of the Contemplated Transactions and that the consideration that Sellers will receive upon such consummation is adequate to support each Seller's agreement to be bound by the covenants set forth herein.

(d) Remedies. In accordance with Section 7.8(c), Buyer will be entitled to injunctive or other equitable relief to enforce the provisions hereof, in addition to such other remedies to which Buyer may be entitled, including the recovery of money damages.

(e) Extensions of Limitations. If any Seller or any of its subsidiaries violate any term or provision of this Section 5.1, the duration set forth in this Section 5.1 shall

automatically be extended as against each Seller and its subsidiaries for a period equal to the periods during which any Seller or such subsidiary shall have been in violation of this Section 5.1.

Section 5.2. Certain Tax Matters.

(a) Transfer Taxes. All recordation, transfer, documentary, excise, sales, value added, use, stamp, conveyance or other similar Taxes, duties or governmental charges, and all recording or filing fees or similar costs, imposed or levied by reason of, in connection with or attributable to this Agreement, the Related Documents or the Contemplated Transactions (collectively, "Transfer Taxes") shall be the borne equally between Sellers, on the one hand, and Buyer, on the other.

(b) Allocation of Taxes.

(i) All ad valorem obligations levied with respect to the Purchased Assets for any Straddle Period (collectively, the "Apportioned Obligations") shall be apportioned between Sellers, on the one hand, and Buyer, on the other, on a per diem basis. Sellers shall be jointly and severally liable for the proportionate amount of such Apportioned Obligations that is attributable to the Pre-Closing Tax Period, and Buyer shall be liable for the proportionate amount of such Apportioned Obligations that is attributable to the Post-Closing Tax Period.

(ii) All Taxes levied with respect to the Purchased Assets (other than the Apportioned Obligations) for any Straddle Period ("Other Taxes") shall be allocated between the Pre-Closing Tax Period and the Post-Closing Tax Period as follows: (i) in the case of Taxes other than income Taxes (however denominated), sales and use Taxes, value added Taxes and withholding Taxes, such Taxes shall be allocated on a per diem basis, and (ii) in the case of income Taxes (however denominated), sales and use Taxes, value added Taxes and withholding Taxes, such Taxes shall be allocated based on the assumption that the taxable period ended on the Closing Date. The Sellers shall be liable for all Other Taxes allocated to the Purchased Assets for the Pre-Closing Tax Period, and the Buyer shall be liable for all Other Taxes allocable to the Post-Closing Tax Period.

(c) Reimbursement. Apportioned Obligations, Other Taxes and Transfer Taxes shall be timely paid, and all applicable filings, reports and returns shall be filed, as provided by applicable Law. The paying Party (if not specified as the responsible Party therefor) shall be entitled to reimbursement from the non-paying Party in accordance with Section 5.2(a) or Section 5.2(b), as the case may be. Upon payment of any such Apportioned Obligation or Transfer Tax, the paying Party shall present a statement to the non-paying Party setting forth the amount of reimbursement to which the paying Party is entitled under Section 5.2(a) or Section 5.2(b), as the case may be, together with such supporting evidence as is reasonably necessary to

calculate the amount to be reimbursed. The non-paying Party shall make such reimbursement promptly but in no event later than 10 days after the presentation of such statement. For the avoidance of doubt, reimbursement for Transfer Taxes, Other Taxes or Apportioned Obligations shall be governed first by this Section 5.2(c) and, if unsatisfied, then pursuant to Article VI.

(d) Tax Withholding. The Parties agree that all payments under this Agreement will be made without any deduction or withholding for or on account of any Taxes or other amounts unless required by applicable Law. In the event Buyer determines that it is required under applicable Law to withhold and pay any Tax to any Taxing Authority in respect of any payments made to any Seller, the amount of such Tax shall be deducted by Buyer and paid to the relevant Taxing Authority, and Buyer shall notify the applicable Seller thereof and shall promptly furnish to such Seller all copies of any Tax certificate or other documentation evidencing such withholding. Buyer shall not be required to pay any additional amounts to any Seller in respect of any amounts paid to any Taxing Authority pursuant to the immediately preceding sentence. The Parties agree to reasonably cooperate with each other, including by completing or filing documents required under the provisions of any applicable income tax treaty or applicable Law, to claim any applicable exemption from, or reduction of, any such applicable Taxes. To the extent that any amounts are so deducted or withheld by Buyer from any payment hereunder to any Seller, such deducted or withheld amounts shall be treated for all purposes of this Agreement as having been paid to such Seller. In the event any such amounts are not or can not be so deducted or withheld, Sellers will indemnify and promptly reimburse Buyer therefor, without regard to the limitations of Section 6.3 hereof.

(e) Cooperation and Exchange of Information. Each of the Sellers, on the one hand, and Buyer, on the other, shall (i) provide the other with such assistance as may reasonably be requested by the other Party in connection with the preparation of any Tax Return, audit or other examination by any Taxing Authority or Action relating to liability for Taxes in connection with the Purchased Assets or the Business, (ii) retain and provide the other with any records or other information that may be relevant to such Tax Return, audit or examination, Action or determination and (iii) provide the other with any final determination of any such audit or examination, Action or determination that affects any amount required to be shown on any Tax Return of the other for any period.

(f) Tax Treatment of Payments. Unless otherwise required by a change in Law after the date hereof, or a final “determination” as defined in Section 1313(a) of the Code, Sellers and Buyer shall treat any payment under Article VI as an adjustment to the Purchase Price for Tax purposes.

Section 5.3. Public Announcements. Neither Buyer nor any Seller, nor any Affiliate of any Party, shall issue any press release or otherwise make any public statement with respect to the provisions of this Agreement or the Contemplated Transactions without the prior written consent of the other Party. Notwithstanding anything to the contrary in this Agreement or

any Related Document, any Party may issue a press release or make a public statement with respect to the Contemplated Transactions without the consent of the other Party as may be required by Law or the rules and regulations of any applicable securities exchange or market (it being understood that Buyer may make a public announcement and file the appropriate filings with the Securities and Exchange Commission (including filing this Agreement), and conduct investor calls, with respect to this Agreement and the Contemplated Transactions). If any Party proposes to issue a press release or make a public statement with respect to the Contemplated Transactions pursuant to this Section 5.3, it will provide copies of such press release or public statement to the other Party before such press release or public statement is made to allow the other Party to comment upon and agree on such press release or public statement, unless the provision of such press release or public statement to the other Party before such press release or public statement is made (or any delay in reaching agreement with respect thereto) would be in breach of any Law or the rules and regulations of any applicable securities exchange or market, in which case a copy of such press release or public statement will be provided to the other Party as soon as reasonably practicable or in accordance with such Law, rules or regulations.

Section 5.4. Regulatory Matters.

(a) Transfer of Regulatory Authorizations. At the Closing, each Seller shall transfer the exclusive benefit of the Regulatory Authorizations to Buyer free of all Liens, other than Permitted Liens, on the terms and conditions set forth in this Section 5.4. As soon as practicable following the Closing Date but in any event no later than 30 days after the Closing Date, each Seller shall make such notifications or filings with applicable Regulatory Authorities as may be necessary to effect the transfer of each of the Regulatory Authorizations to Buyer.

(b) Buyer Responsibilities. Subject to the provisions of Section 5.4(a), after the Closing Date, Buyer (on behalf of Sellers to the extent required under Applicable Law), at its cost, shall be solely responsible (subject to each Seller's obligations set forth in clause (c) below) and liable for (i) taking all actions, paying all fees and conducting all communication with the appropriate Regulatory Authority required by Law in respect of the Regulatory Authorizations, including preparing and filing all reports (including adverse drug experience reports) with the appropriate Regulatory Authority; (ii) investigating all complaints and reports of adverse drug experiences with respect to any Product or the Compound pursuant to such Regulatory Authorizations (whether Exploited before or after transfer of such Regulatory Authorizations); and (iii) fulfilling all other applicable legal and regulatory obligations of a holder of each Regulatory Authorization.

(c) Complaints. After the Closing Date, Sellers shall notify Buyer within 48 hours (or such shorter period required by Law) if any Seller receives a complaint or a report of an adverse drug experience with respect to any Product or the Compound. In addition, each Seller shall use commercially reasonable efforts to assist Buyer (and Buyer shall reimburse the applicable Seller its reasonable expenses incurred in connection therewith) in connection with

the investigation of and response to any complaint or adverse drug experience report related to any Product or the Compound, to the extent attributable to the period prior to the Closing. All notifications pursuant to this Section 5.4(c) shall be by facsimile or electronic mail at such numbers or addresses agreed upon by the Parties' respective safety divisions.

(d) Cooperation. Each Seller shall cooperate with Buyer in supplying information or assistance in Buyer's fulfillment of its obligations under this Section 5.4.

Section 5.5. Access.

(a) From and after the Closing Date for a period of 12 months, each Seller shall provide Buyer with reasonable access (which shall not unreasonably interfere with the business of the applicable Seller), upon reasonable written notice and during normal business hours, to the management and other personnel of each Seller for the purpose of (i) discussing all reasonable inquiries regarding the Purchased Assets or the Business and (ii) providing such other assistance as Buyer may reasonably request related to the sale, conveyance, delivery, transfer and assignment of the Purchased Assets.

(b) From and after the Closing Date, Buyer shall provide each Seller and its Representatives with reasonable access (which shall not unreasonably interfere with the business of Buyer), upon reasonable written notice and during normal business hours, to the Books and Records and the right to make copies and extracts therefrom (subject to Sellers' obligations under Section 5.1), to the extent that such access may be reasonably required by such Seller or any of its Representatives (i) to facilitate the investigation, litigation and final disposition of any Third Party Claim the defense or opposition of which Seller has assumed pursuant to Section 6.4 (unless such Third Party Claim is the subject of a dispute between Buyer and any Seller or any of their respective Affiliates), or (ii) in connection with the preparation of any Seller's Tax Returns or financial statements.

Section 5.6. Expenses. Except as expressly set forth herein, each Seller and Buyer shall bear its own costs and expenses incurred in connection with this Agreement and the Contemplated Transactions.

Section 5.7. Wrong Pockets. Subject to Section 2.5, for a period of up to 12 months after the Closing Date, if Buyer, on the one hand, or any Seller, on the other, becomes aware that any of the Purchased Assets have not been transferred to Buyer or that any of the Excluded Assets have been transferred to Buyer, it shall promptly notify the other Parties, and the Parties hereto shall, as soon as reasonably practicable, ensure that such assets are transferred, at Sellers' expense (except that Buyer shall be responsible for the shipping cost of any Inventory) and with any necessary prior Third Party consent or approval, to:

(a) Buyer, in the case of any Purchased Asset which was not transferred at the Closing; or



(b) Sellers, in the case of any Excluded Asset which was transferred at the Closing.

Section 5.8. Further Assurances. Each Party shall, at any time and from time to time after the Closing Date, upon the request of the other Party(ies), do, execute, acknowledge, deliver and file, or cause to be done, executed, acknowledged, delivered or filed, all such further acts, deeds, transfers, conveyances, assignments or assurances as may be reasonably required for the transferring, conveying, assigning and assuring to Buyer, or for the aiding and assisting in the reducing to possession by Buyer of, any of the Purchased Assets, or for otherwise carrying out the purposes of this Agreement and the Related Documents and the consummation of the Contemplated Transactions.

Section 5.9. TRIS Make-Whole Payments.

(a) By each of January 30, 2019 and January 30, 2020, Buyer will furnish to US Holdings a written report setting forth for the prior calendar year the Net Sales of Karbinal (including the number of units shipped times the invoiced price per unit and the details of all deductions from gross sales to arrive at Net Sales) (the "Written Report"). US Holdings shall inform Buyer in writing within fifteen (15) calendar days of the receipt of the Written Report of US Holdings acceptance or of any objection. If US Holdings does not so inform Buyer, Sellers shall be deemed to have accepted the Written Report. To the extent that any such objection is timely received, Buyer and US Holdings shall attempt in good faith to resolve any dispute. If Buyer and US Holdings are unable to reach such agreement within fifteen (15) days after receipt by Buyer of such notice, the disputed items shall be resolved by the Independent Accountant, and any determination by the Independent Accountant shall be final. The Independent Accountant shall resolve any disputed items within fifteen (15) days of having the item referred to it pursuant to such procedures as it may require. The costs, fees and expenses of the Independent Accountant shall be borne equally by Buyer and Sellers.

(b) Upon resolution of the Written Report as described in Section 5.9(a) above, US Holdings shall pay Buyer an amount equal to [\*\*\*]% of the Net Sales of Karbinal set forth in such report; provided, however, that if the royalty rate pursuant to the Net Sales of Karbinal for the 2018 and 2019 calendar years is reduced, then US Holdings' obligation under this Section 5.9(b) shall be reduced in proportion to such royalty reduction.

(c) In no event shall the foregoing payments from US Holdings to Buyer under this Section 5.9 exceed \$[\*\*\*] per year.

(d) All capitalized terms used in this Section 5.9 have the meanings set forth for them in the Supply and Distribution Agreement dated as of August 9, 2013 by and between TRIS Pharma, Inc., a New Jersey corporation, and US Holdings, as amended from time to time.

Section 5.10. Name. Buyer acknowledges and agrees that it shall (i) not obtain or retain any right, title or interest in or to the “Avadel” name or any, whether registered or unregistered, associated names, service marks, trademarks, trade names, identifying symbols, logos, emblems, signs or insignia related thereto or containing or comprising the foregoing, including any name or mark confusingly similar thereto and (ii) immediately after the Closing, cease to hold itself out as having any affiliation with Sellers or any of their Affiliates other than under this Agreement and the Development Agreement.

Section 5.11. Employment.

(a) Buyer shall, or shall cause its Affiliates to, offer employment to those employees of Seller who provide services exclusively or primarily with respect to the Business and who are listed on Schedule 5.11(a) (each, a “Business Employee”), as determined in the sole discretion of Buyer no later than five (5) days prior to the Closing Date. Buyer retains the sole discretion to determine the compensation and benefits offered to each Business Employee.

(b) Nothing herein shall provide or be construed to provide the rights of a third-party beneficiary on any Person, including any Business Employee or dependent or beneficiary thereof. Except as set forth herein, the provisions of this Section 5.11 shall not amend or other modify the terms of any compensation or employee benefit plan or arrangement of Sellers or Buyer or their respective Affiliates

Section 5.12. Conduct of Business Prior to the Closing. From the date hereof until the Closing, except as otherwise provided in this Agreement or consented to in writing by Buyer (which consent shall not be unreasonably withheld or delayed), Sellers shall (x) conduct the Business in the Ordinary Course of Business and (y) use commercially reasonable efforts to maintain and preserve intact the Business’ current organization and operations and to preserve the rights, goodwill and relationships of the Sellers with the Business Employees (it being understood and agreed Sellers shall not have any obligations or liabilities hereunder with respect to the other employees of Sellers or if a Business Employee refuses to accept employment with Buyer), customers, licensors, suppliers, distributors and others having relationships with the Business. Without limiting the foregoing, from the date hereof until the Closing Date, Sellers shall not:

(a) waive or release any material right or material claim of the Business other than in the Ordinary Course of Business;

(b) sell, transfer, lease, license (other than in the Ordinary Course of Business), or otherwise dispose of any of the Purchased Assets;

(c) incur, assume, guarantee, issue, assume or otherwise become responsible for, any new indebtedness or create any new encumbrance or Lien on the Business or Purchased Assets (other than Permitted Liens);

- (d) amend, waive, modify or consent to the termination of any Assumed Contracts, or amend, waive, modify or consent to the termination of any Seller's rights thereunder;
- (e) initiate, settle, agree to settle, waive or compromise any Action;
- (f) adopt a plan or agreement for or carry out any complete or partial liquidation, dissolution, restructuring, recapitalization, merger, consolidation or other reorganization;
- (g) permit the lapse of any existing policy of insurance relating to the Business or its assets;
- (h) permit the lapse of any material right relating to Intellectual Property Rights or any other intangible asset used in or related to the Business;
- (i) increase or decrease the wages, salary, bonus or other compensation or benefits payable to any Business Employee (other than in the Ordinary Course of Business);
- (j) hire any new director, officer or employee (other than in the Ordinary Course of Business) of the Business;
- (k) sell any Product, it being understood and agreed that Sellers will, promptly after execution and delivery of this Agreement, transfer all Inventory under Sellers' control to Buyer pursuant to its written instructions so that Buyer can begin relabeling it, and that in the event this Agreement is terminated for any reason Buyer will at its expense return such Inventory to Sellers pursuant to their written instructions;
- (l) increase or decrease marketing efforts of the Business from the levels conducted by the Sellers in the six (6) months prior to the date hereof; or
- (m) agree or commit to do any of the foregoing.

## ARTICLE VI.

### INDEMNIFICATION

Section 6.1. Indemnification of Buyer. (a) From and after the Closing, Sellers shall jointly and severally indemnify Buyer and its Affiliates and each of their respective officers, directors, employees, equity holders, agents and Representatives (each, a "Buyer Indemnified Party") against and hold each Buyer Indemnified Party harmless from any and all losses, damages, Liabilities, costs or expenses (collectively, "Losses"), suffered or incurred by such Buyer Indemnified Party, arising from, relating to or otherwise in connection with:

(i) any breach of or inaccuracy in any representation or warranty of any Seller contained in this Agreement (without giving effect to any materiality threshold or qualifier contained therein, including any Material Adverse Effect qualifier, except that this parenthetical shall not apply to Section 3.3(a));

(ii) any breach of or failure to perform any covenant or agreement of any Seller contained in this Agreement;

(iii) any Excluded Liability or Excluded Asset; or

(iv) any Taxes with respect to the Business or Purchased Assets for any Pre-Closing Tax Period, including, with respect to any Straddle Period, any Other Taxes, or any Apportioned Obligations allocated to any Seller pursuant to Section 5.2(b), as well as any Transfer Taxes allocated to the Sellers pursuant to Section 5.2(a).

(b) No consent of any Seller will be required in order for Buyer to be indemnified under this Article VI.

(c) In the case of a Buyer Indemnified Party's rights to indemnification pursuant to this Section 6.1, any and all Losses payable by any Seller to the Buyer Indemnified Parties with respect to indemnifiable Losses will be paid directly by Sellers to the applicable Buyer Indemnified Parties (subject to the applicable limitations set forth in this Article VI).

Section 6.2. Indemnification of Seller Indemnified Parties. (a) From and after the Closing, Buyer shall indemnify Sellers and their Affiliates and each of their respective officers, directors, employees, equity holders, agents and Representatives (each a "Seller Indemnified Party") against and hold each Seller Indemnified Party harmless from any and all Losses suffered or incurred by any such Seller Indemnified Party arising from, relating to or otherwise in connection with:

(i) any breach of or inaccuracy in any representation or warranty of Buyer contained in this Agreement (without giving effect to any materiality threshold or qualifier contained therein);

(ii) any breach of or failure to perform any covenant or agreement of Buyer contained in this Agreement;

(iii) any Assumed Liability;

(iv) any Transfer Taxes or Apportioned Obligations allocated to Buyer pursuant to Section 5.2; or

(v) any Liabilities arising out of Buyer's or its Affiliates' operation of the Purchased Assets after the Closing, excluding, for the avoidance of doubt, any Excluded Liabilities.

(b) The consent of Buyer shall not be required in order for Seller to be indemnified under this Article VI.

Section 6.3. Limitations.

(a) Notwithstanding anything to the contrary contained herein, no Buyer Indemnified Party or Seller Indemnified Party, as applicable, shall be entitled to be indemnified pursuant to Section 6.1(a)(i) and Section 6.2(a)(i):

(i) unless and until the aggregate of all Losses for which the Buyer Indemnified Parties or the Seller Indemnified Parties, as applicable, would, but for this paragraph (i), be entitled to indemnification hereunder exceeds on a cumulative basis \$[\*\*\*] (the "Indemnity Threshold"), at which point each Buyer Indemnified Party or Seller Indemnified Party, as applicable, shall be entitled to be indemnified for the aggregate of all Losses in excess of the Indemnity Threshold; and

(ii) unless the amount of an individual claim for Losses under Section 6.1(a)(i) or Section 6.2(a)(i) (aggregating all claims and Losses arising from substantially the same or similar facts as applicable to each of Section 6.1(a)(i) or Section 6.2(a)(i), as applicable) exceeds \$[\*\*\*], and no such claim shall be applied toward the Indemnity Threshold;

(b) provided, however, that the foregoing provisions of Section 6.3(a) shall not apply with respect to any act of fraud or any breach of or inaccuracy in the representations and warranties set forth in Sections 3.1, 3.2(a), or 3.13 (the "Specified Representations").

(c) Other than in the case of any act of fraud (in which case the Buyer Indemnified Parties' and the Seller Indemnified Parties' rights shall not be limited by anything set forth in this Article VI to the contrary), in no event shall the aggregate amount for which Buyer Indemnified Parties or Seller Indemnified Parties shall be indemnified and held harmless under Article VI exceed \$[\*\*\*] (the "Cap").

(d) The amount of any Losses payable pursuant to this Article VI shall be reduced to reflect any amount actually recovered by the Indemnified Party from a Third Party, including any insurance provider (less the cost to collect or recover such amount). If the Indemnified Party realizes any such amount after the date on which a payment pursuant to this Article VI has been made to the Indemnified Party, the Indemnified Party shall promptly make payment to the Indemnifying Party equal to such amount; provided that such payment shall not exceed the amount of the payment made to the Indemnified Party pursuant to this Article VI. For

the avoidance of doubt, this Section 6.3(b) shall not be construed to apply to any amounts recovered from any self insurance, captive insurance vehicle, or other similar arrangement.

(e) To the extent that a Tax Benefit due to any Loss actually is realized by an Indemnified Party due to Losses in the same taxable year in which such Indemnified Party received a payment pursuant to Section 6.1 or Section 6.2, as applicable, for such Loss, the Indemnified Party shall reimburse the Indemnifying Party the amount of such Tax Benefit within a reasonable time after the Tax Return reflecting such Tax Benefit is filed with the applicable taxing authority; provided that such calculation shall be a one-time determination by the Indemnified Party in connection with such Tax filing and shall not be subject to re-calculation or further claim for reimbursement by the Indemnifying Party thereafter. For purposes of this Section 6.3(e), a “Tax Benefit” means an amount by which the Tax liability of the Indemnified Party actually is reduced by a deduction, reduction of income, or a refund or credit, in other words the difference between (A) the aggregate amount of Taxes that the Indemnified Party would have been required to pay for the relevant Tax year if such Loss had not been incurred and (B) the aggregate amount of Taxes that the Indemnified Party is actually required to pay for the relevant Tax year taking such Loss into account.

(f) Notwithstanding anything in this Agreement to the contrary, neither Buyer nor any Seller shall be liable for any special, indirect, punitive, exemplary or consequential damages, any lost profits, lost business opportunity, diminution in value or similar theory, except to the extent actually awarded in a Third Party Claim.

Section 6.4. Indemnification Claims. (a) In order for a Buyer Indemnified Party or a Seller Indemnified Party (an “Indemnified Party”) to be entitled to any indemnification provided for under Section 6.1 or 6.2 in respect of, arising out of or involving an Action initiated or commenced by or on behalf of a Third Party (a “Third Party Claim”), such Indemnified Party must notify, with respect to a claim for indemnification pursuant to Section 6.1, US Holdings, or, with respect to a claim for indemnification pursuant to Section 6.2, Buyer (each, an “Indemnifying Party”) in writing of the Third Party Claim (including in such notice a brief description of the applicable claim(s), including damages sought or estimated, to the extent actually known by such Indemnified Party) within 20 Business Days after receipt by such Indemnified Party of actual notice of the Third Party Claim (or such earlier deadline as may be required to timely respond to the Third Party Claim); provided, however, that failure to give such notification shall not affect the indemnification provided under Section 6.1 or 6.2 except to the extent the Indemnifying Party has been actually prejudiced as a result of such failure. The Indemnifying Party shall have the right to undertake the defense or opposition to such Third Party Claim (at the Indemnifying Party’s expense) with counsel selected by it and reasonably satisfactory to the Indemnified Party so long as (i) the Indemnifying Party gives written notice to the Indemnified Party within 20 Business Days after it has been notified of the Third Party Claim that it will defend the Indemnified Party against such Third Party Claim, (ii) the Third Party Claim does not seek an injunction or other equitable relief against the Indemnified Party and

does not relate to or arise in connection with any criminal proceeding, action, indictment, allegation or investigation, (iii) the amount claimed in such Third Party Claim, taken together with the reasonably estimated costs of defense thereof and the claimed amount with respect to any unresolved claims for indemnification under this Article VI then pending, is (A) if applicable, greater than the remaining portion, if any, of the Indemnity Threshold and (B) if applicable, less than the Cap, (iv) the Indemnified Party has not been advised in writing by outside counsel that a substantive legal conflict exists between the Indemnified Party and the Indemnifying Party in connection with conducting the defense of the Third Party Claim, and (v) the Third Party Claim does not allege the infringement of the Intellectual Property Rights of any Person by the Indemnified Party. Neither the Indemnified Party nor the Indemnifying Party shall settle any Third Party Claim without the prior written consent of the other party (which consent shall not be unreasonably withheld, conditioned or delayed); provided, that the Indemnifying Party may settle such Third Party Claim without the prior written consent of the Indemnified Party if (1) the claimant in such Third Party Claim provides to the Indemnified Party an unqualified release of such Indemnified Party from all liability in respect of such Third Party Claim, (2) such settlement does not involve any injunctive relief binding upon the Indemnified Party, (3) such settlement does not encumber any of the material assets of the Indemnified Party or impose any restriction or condition that would apply to or materially affect such Indemnified Party or the conduct of such Indemnified Party's businesses, (4) such settlement does not give rise to any material adverse Tax consequences of the Indemnified Party and (5) such settlement does not involve any admission of liability or wrongdoing by the Indemnified Party.

(b) In order for an Indemnified Party to be entitled to any indemnification provided for under this Agreement other than in respect of, arising out of or involving a Third Party Claim, such Indemnified Party shall deliver written notice of such claim with reasonable promptness to the Indemnifying Party (including in such notice a brief description of the applicable claim(s), including damages in good faith sought or estimated, to the extent actually known by such Indemnified Party); provided, however, that failure to give such notification shall not affect the indemnification provided under Section 6.1 or 6.2 except to the extent the Indemnifying Party has been actually prejudiced as a result of such failure. If the Indemnifying Party does not notify the Indemnified Party within 20 Business Days following its receipt of such notice that the Indemnifying Party disputes the indemnity claimed by the Indemnified Party under Section 6.1 or 6.2 such indemnity claim specified by the Indemnified Party in such notice shall be conclusively deemed a liability to be indemnified under Section 6.1 or 6.2 and the Indemnified Party shall be indemnified for the amount of the Losses stated in such notice to the Indemnified Party on demand or, in the case of any notice in which the Losses (or any portion thereof) are estimated, on such later date when the amount of such Losses (or such portion thereof) becomes finally determined, but in all cases subject to the Indemnity Threshold and the Cap, to the extent applicable, and the other limitations set forth herein.

Section 6.5. Termination of Indemnification. The obligations to indemnify and hold harmless an Indemnified Party hereto pursuant to Article VI with respect to the Specified

Representations will survive for the applicable statute of limitations, and all other representations, warranties, covenants and obligations contained in this Agreement shall terminate on February 5, 2020. It is the express intent of the parties that each termination or expiration date contemplated by this Section 6.5 may be shorter than the statute of limitations that may otherwise apply, and by contract, the applicable statute of limitations is hereby reduced.

Section 6.6. Exclusive Remedies. Buyer and each Seller acknowledge and agree that after the Closing, the indemnification provisions of this Article VI shall be the sole and exclusive remedies of Buyer and each Seller for any breach of the representations or warranties or nonperformance of or default under any covenants or agreements of Buyer or any Seller contained in this Agreement or any Related Document, or otherwise in connection with the Contemplated Transactions (other than claims for equitable relief under Section 7.8 and fraud).

## ARTICLE VII.

### GENERAL PROVISIONS

Section 7.1. Rules of Construction. The Parties agree that they have been represented by counsel during the negotiation and execution of this Agreement and have together drafted this Agreement and, therefore, waive the application of any Law, regulation, holding or rule of construction providing that ambiguities in an agreement or other document will be construed against the Party drafting such agreement or document.

Section 7.2. Notices. All notices, requests, claims, demands and other communications hereunder shall be given (and shall be deemed to have been duly given upon receipt) by hand delivery, by prepaid overnight courier (providing written proof of delivery), by transmission-mail (with confirmation of transmission other than by means of an automatically-generated reply) or by certified or registered mail (return receipt requested and first class postage prepaid), addressed as follows (or at such other address for a Party as shall be specified by like notice):

if to Buyer, to:

Cerecor Inc.  
400 East Pratt Street, Suite 606  
Baltimore, MD 21202  
E-mail:  
Attention: Mariam Morris, Chief Financial Officer

with a copy (which shall not constitute notice) to:

Wyrick Robbins Yates & Ponton LLP  
4101 Lake Boone Trail



Suite 300  
Raleigh, North Carolina 27607  
Fax: (919) 781-4865  
E-mail:  
Attention: Don Reynolds

and if to Sellers, to:

Avadel US Holdings, Inc.  
Attn: General Counsel  
16640 Chesterfield Grove Rd.  
Suite 200  
Chesterfield, MO 63005

with a copy (which shall not constitute notice) to:

Orrick, Herrington & Sutcliffe LLP  
51 W. 52nd St.  
New York, NY 10019  
Attn: R. King Milling, Jr.; Tal Hacothen  
e-mail:

provided that any notice received at the addressee's location on any Business Day after 5:00 p.m. (addressee's local time) shall be deemed to have been received at 9:00 a.m. (addressee's local time) on the next Business Day.

Section 7.3. Consents and Approvals. For any matter under this Agreement requiring the consent or approval of a Party to be valid and binding on the Party, such consent or approval must be in writing.

Section 7.4. Counterparts. This Agreement may be executed in one or more counterparts (including by transmission-mail), all of which shall be considered one and the same agreement and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to the other Party.

Section 7.5. Entire Agreement; No Third Party Beneficiaries. This Agreement, the Confidentiality Agreement and the other Related Documents constitute the entire agreement, and supersede all prior agreements and understandings, both written and oral, among the Parties with respect to the subject matter of this Agreement, the Confidentiality Agreement and the other Related Documents. Except as provided in Article VI, this Agreement is for the sole benefit of the Parties hereto and is not intended to and does not confer upon any Person other than the Parties any legal or equitable rights or remedies.

Section 7.6. Assignment. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned, in whole or in part, by operation of law or otherwise by any of the Parties without the prior written consent of the other Parties, and any assignment without such consent shall be null and void, except that Buyer may assign any or all of its rights and obligations under this Agreement to any of its Affiliates without the consent of any Seller. No assignment pursuant to this Section 7.6 will relieve the assigning Party of its responsibility for the performance of any of its obligations hereunder to the extent not performed by the assignee. This Agreement will be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

Section 7.7. Governing Law. THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, REGARDLESS OF THE LAWS THAT MIGHT OTHERWISE GOVERN UNDER APPLICABLE PRINCIPLES OF CONFLICTS OF LAWS THEREOF.

Section 7.8. Enforcement.

(a) Each Party irrevocably submits to the exclusive jurisdiction of (i) the state courts of New York located in New York County, and (ii) the United States District Court for the Southern District of New York, for the purposes of any suit, action or other proceeding arising out of this Agreement or the Contemplated Transactions. Each Party agrees to commence any such action, suit or proceeding either in the United States District Court for the Southern District of New York or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the state courts of New York located in New York County. Each Party further agrees that service of any process, summons, notice or document by the U.S. registered mail to such Party's respective address set forth above shall be effective service of process for any action, suit or proceeding in New York with respect to any matters to which it has submitted to jurisdiction in this Section 7.8. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the Contemplated Transactions in (x) the state courts of New York located in New York County, and (y) the United States District Court for the Southern District of New York, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

(b) EACH PARTY WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY. Each Party (i) certifies that no representative, agent or attorney of the other Party has represented, expressly or otherwise, that such Party would not, in the event of any action, suit or proceeding, seek to enforce the foregoing waiver and (ii) acknowledges that it and the other Party has been induced to enter into this Agreement, by, among other things, the mutual waiver and certifications in this Section 7.8(b).

(c) The Parties agree that irreparable damage would occur and that the Parties would not have any adequate remedy at law in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in the state courts of New York located in New York County, and the United States District Court for the Southern District of New York, this being in addition to any other remedy to which they are entitled at law (subject to Section 6.6) or in equity and as further set forth in this Section 7.8.

Section 7.9. Severability. If any term or other provision of this Agreement or any Related Document is invalid, illegal or incapable of being enforced by any rule of law or public policy, all other conditions and provisions of this Agreement or such Related Document shall nevertheless remain in full force and effect. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Parties shall negotiate in good faith to modify this Agreement or such Related Document so as to effect the original intent of the Parties as closely as possible to the fullest extent permitted by applicable Law in an acceptable manner to the end that the transactions contemplated hereby are fulfilled to the extent possible.

Section 7.10. Amendment; Waiver. No modification, amendment or waiver of any provision of this Agreement shall be effective unless it is in writing and signed by the Party against whom enforcement of any such modification, amendment or waiver is sought. No action taken pursuant to this Agreement, including any investigation by or on behalf of any Party, shall be deemed to constitute a waiver by the Party taking such action of compliance by the other Parties with any representation, warranty, covenant, agreement or obligation contained herein. The waiver by any Party of a breach of any provision of this Agreement shall not operate or be construed as a further or continuing waiver of such breach or as a waiver of any other or subsequent breach. Neither the failure of any Party to enforce, nor the delay of any Party in enforcing, any condition or part of this Agreement at any time shall be construed as a waiver of that condition or part or forfeit any rights to future enforcement thereof.

## ARTICLE VIII.

### CONDITIONS TO CLOSING

Section 8.1. Conditions to Obligations of Buyer. The obligations of Buyer to consummate the transactions contemplated by this Agreement shall be subject to the fulfillment or Buyer's waiver, at or prior to the Closing, of each of the following conditions:

(a) The representations and warranties of Sellers contained in Article III, disregarding in each case any reference to "materiality", "Material Adverse Effect" or similar qualifications therein, shall be true and correct in all respects as of the Closing Date with the same effect as though made at and as of such date (except those representations and warranties

that address matters only as of a specified date, which shall be true and correct as of that specified date), except where the failure of such representations and warranties to be true and correct would not, in the aggregate, have a Material Adverse Effect.

(b) Sellers shall have duly performed and complied in all material respects with all agreements, covenants and conditions required by this Agreement to be performed or complied with by them prior to or on the Closing Date.

(c) Sellers shall have delivered to Buyer the items set forth in Section 2.4(b).

Section 8.2. Conditions to Obligations of Sellers. The obligations of Sellers to consummate the transactions contemplated by this Agreement shall be subject to the fulfillment or Sellers' waiver, at or prior to the Closing, of each of the following conditions:

(a) The representations and warranties of Buyer contained in Article IV shall be true and correct in all respects as of the Closing Date with the same effect as though made at and as of such date (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all respects as of that specified date), except where the failure of such representations and warranties to be true and correct would not, in the aggregate, have a material adverse effect on Buyer's ability to consummate the transactions contemplated hereby.

(b) Buyer shall have duly performed and complied in all material respects with all agreements, covenants and conditions required by this Agreement to be performed or complied with by it prior to or on the Closing Date.

(c) Buyer shall have delivered to Sellers the items set forth in Section 2.4(c).

## **ARTICLE IX.**

### **TERMINATION.**

Section 9.1. Termination. This Agreement may be terminated at any time prior to the Closing:

(a) by the mutual written consent of Sellers and Buyer;

(b) by Buyer or Sellers by written notice to the other Party if such is not then in material breach of any provision of this Agreement and there has been a material breach, inaccuracy in or failure to perform any representation, warranty, covenant or agreement made by the other Party pursuant to this Agreement that would give rise to the failure of any of the conditions specified in Article VIII and such breach, inaccuracy or failure cannot be cured by the 10<sup>th</sup> Business Day after the date of this Agreement (the "Drop Dead Date");

(c) by Buyer or Sellers if the Closing has not occurred on or before the Drop Dead Date; or

(d) by Buyer or Sellers in the event that:

(i) there shall be any Law that makes consummation of the transactions contemplated by this Agreement illegal or otherwise prohibited; or

(ii) any Governmental Authority shall have issued an Order restraining or enjoining the transactions contemplated by this Agreement, and such Order shall have become final and non-appealable.

Section 9.2. Effect of Termination. In the event of the termination of this Agreement in accordance with this Article, this Agreement shall forthwith become void and there shall be no liability on the part of any party hereto except:

(a) as set forth in this Article IX, Section 5.1 and Article VII hereof; and

(b) that nothing herein shall relieve any party hereto from liability for any intentional breach of any provision hereof.

*[Remainder of page intentionally left blank]*

IN WITNESS WHEREOF, the Parties have caused this Agreement to be signed by their respective officers hereunto duly authorized, all as of the date first written above.

**BUYER:**

CERECOR, INC.

By: /s/ Robert Moscato \_\_\_\_\_  
Name: Robert Moscato  
Title: President, COO and Director

**SELLERS:**

AVADEL PHARMACEUTICALS (USA),  
INC.

By: /s/ Phillandas T. Thompson  
Name: Phillandas T. Thompson  
Title: Secretary

FSC THERAPEUTICS, LLC

By: /s/ Phillandas T. Thompson  
Name: Phillandas T. Thompson  
Title: Secretary

AVADEL PHARMACEUTICALS PLC

By: /s/ Michael S. Anderson  
Name: Michael S. Anderson  
Title: Chief Executive Officer

AVADEL PEDIATRICS, INC.

By: /s/ Phillandas T. Thompson  
Name: Phillandas T. Thompson  
Title: Secretary

AVADEL US HOLDINGS, INC.

By: /s/ Michael F. Kanan  
Name: Michael F. Kanan  
Title: Treasurer

[Signature Page to Asset Purchase Agreement]

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

**DISCLOSURE SCHEDULE**

to the Asset Purchase Agreement

by and between

CERECOR, INC.

and

AVADEL PHARMACEUTICALS (USA), INC.,

AVADEL PEDIATRICS, INC.,

AVADEL THERAPEUTICS, LLC,

AVADEL US HOLDINGS, INC.

AND

AVADEL PHARMACEUTICALS PLC

dated as of February 12, 2018

This disclosure schedule (this "Disclosure Schedule") is being delivered on the date hereof in connection with that certain Asset Purchase Agreement (the "Agreement"), dated of even date herewith, by and between Cerecor, Inc., a Delaware corporation ("Buyer"), Avadel Pharmaceuticals (USA), Inc., a Delaware corporation ("Pharma"), Avadel Pediatrics, Inc., a Delaware corporation ("Pediatrics"), Avadel Therapeutics, LLC, a Delaware limited liability company ("Therapeutics"), Avadel US Holdings, Inc., a Delaware corporation ("US Holdings"), and Avadel Pharmaceuticals plc, an Irish corporation ("Parent"). Each of Pharma, Pediatrics, Therapeutics, US Holdings and Parent are individually referred to herein as a "Seller" and are collectively referred to as "Sellers". Terms not otherwise defined herein shall have the meaning ascribed to them in the Agreement.

The specific disclosures set forth in the Disclosure Schedule attached hereto have been organized to correspond to certain Sections in the Agreement to which each such disclosure may relate, but each such disclosure will apply to and will be deemed to be an exception to or modification or qualification of all representations and/or warranties contained in the Agreement to which it is reasonably apparent on the face of such disclosure that such disclosure applies. The inclusion of any information in the Disclosure Schedule attached hereto shall not be deemed an admission or acknowledgement that such information is material, has resulted or would result in a Material Adverse Effect, is outside the ordinary course of business or is otherwise required to be disclosed.

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

**Schedule 1.1(a)**

**Items Not Included in Business Intellectual Property**

Tradenames

1. Avadel Pharmaceuticals PLC
2. Avadel USA Holdings, Inc.
3. Avadel Pharmaceuticals (USA), Inc.
4. Avadel Pediatrics, Inc.
5. FSC Laboratories, Inc.
6. FSC Holdings, LLC
7. FSC Therapeutics, LLC
8. FSC Pediatrics, Inc.

Trademarks

**FSC PEDIATRICS**



**FSC LABORATORIES**



**AVADEL**



Software

1. Salesforce.com – SFA
2. Cornerstone - Performance Management
3. Microsoft Outlook - Email
4. Sage – ERP Management
5. IQVIA – Sales Data
6. Concur – Expense Reporting
7. DocuSign – Electronic Signature



**Schedule 1.1(b)**

**Compounds**

- 1.Cefaclor USP
- 2.rabeprazole sodium
- 3.carbinoxamine maleate

**Schedule 1.1(c)**

**Product**

1. Karbinal ER oral suspension 4mg/5mL
2. Cefaclor for oral suspension USP 125mg/5mL; 250mg/5mL; 375mg/5mL
3. Achiphex Sprinkle Delayed-Release Capsules
4. Flexichamber Anti-static Valved Collapsible Holding Chamber

**Schedule 2.1(b)(i)**

**Seller Wire Information**

Bank Name:  
Bank Address:  
Account Name:  
ABA/Routing Number:  
SWIFT Code:  
Account Number:

**Schedule 2.2(a)(i)**

**Assumed Contracts\***

1. The following provisions of the Membership Interest Purchase Agreement dated February 5, 2016 between FSC Holding Company, LLC; FSC Therapeutics, LLC; FSC Laboratories, Inc, Peter Steelman, James Flynn, Deerfield CSF, LLC; and Flamel US Holdings, Inc. and Flamel Technologies SA (the "Deerfield Agreement"):

Section 1.2(a), beginning with the payment to be made July 30, 2018
Section 1.2(b)
Section 1.6(a) through (j), provided, Buyer is not bound by the first sentence of Section 1.6(i)
Section 1.7(a) through (e), provided, the FSC Assets Collateral (as defined in the Deerfield Agreement) is limited to the Purchased Assets
Section 1.8
Section 5.2
Section 5.3
Section 6.1
Section 6.2
Section 6.3(b), but only to the extent related to a breach or non-fulfillment by Buyer of a covenant, agreement or obligation that is included in a provision of the Deerfield Agreement listed on this Appendix A; otherwise the obligations in Section 6.3(b) are not assigned hereunder and remain obligations of the Company.
Section 6.4
Section 6.5
Section 6.6
Section 6.7
Section 6.8
Section 6.9
Section 7.1 through 7.5
Section 7.6, provided written notice to Buyer shall be given to:  <p style="margin-left: 40px;">Cerecor Inc.  400 East Pratt Street, Suite 606  Baltimore, MD 21202  E-mail:  Attention: Mariam Morris, Chief Financial Officer</p> <p style="margin-left: 40px;">with a copy (which shall not constitute notice) to:</p> <p style="margin-left: 40px;">Wyrick Robbins Yates &amp; Ponton LLP  4101 Lake Boone Trail, Suite 300  Raleigh, North Carolina 27607  E-mail:  Attention: Don Reynolds</p>
Section 7.7 through 7.9

2. Supply Agreement between Eisai, Inc. and FSC Labs, dated June 12, 2014. (related to Achiphex Sprinkle)
3. License and Assignment Agreement between Eisai, Inc. and FSC Therapeutics, LLC, dated June 12, 2014.
4. Supply and Distribution Agreement between Tris Pharmaceuticals, Inc. and FSC Labs dated August 9, 2013. (related to Karbinal ER)
5. Manufacturing Agreement between FSC Labs and Brevet, Incorporated, dated January 22, 2016. (related to Flexichamber)
6. License, Supply & Distribution Agreement between Yung Shin Pharm. Ind. Co., Ltd., FSC Therapeutics, FSC Labs and Rising Pharmaceuticals, Inc., dated March 17, 2015. (related to Cefaclor Oral Suspension)
7. Quality Agreement between Eisai Inc. and FSC Labs, dated January 20, 2016.
8. Safety Data Exchange Agreement between FSC Therapeutics and Eisai Inc., dated August 28, 2016
9. Quality Agreement between FSC Labs and Yung Shin Pharm. Ind. Co., LTD, dated August 12, 2015.
10. Quality Agreement between Avadel Pharmaceuticals (USA), Inc. and Brevet Inc., dated August 11, 2017.
11. Supply Agreement between Independence Pharmaceuticals, LLC and Avadel Pharmaceuticals (USA), Inc., dated April 17, 2017.
12. Safety Data Exchange Agreement for Karbinal ER between FSC Laboratories, Inc. and Tris Pharma Inc. dated April 2016.

**Schedule 2.2(a)(ii)**

**Regulatory Authorizations**

1. ACIPHEX® Sprinkle (rabeprazole sodium) Delayed-Release Capsules, for oral use NDA 204736
2. FLEXICHAMBER Anti-Static Valved Collapsible Holding Chamber  
510K 140062  
Device classification: Holding Chamber, Direct Patient Interface
3. EZ-SPACER  
510K 933090  
Device classification: Nebulizer, Direct Patient Interface

NOTE: The Regulatory applications for the 2 other products marketed by Avadel are not owned by Avadel. Avadel is a distributor. These information about these products is as follows:

<b>Product</b>	<b>Owner of application</b>	<b>Application Number</b>
Cefaclor for oral suspension, USP 125 mg/5mL, 250 mg/5mL, 375 mg/5mL	Yung Shin Pharmaceutical	ANDA 065412
Karbinal™ ER (carbinoxamine maleate) Extended-Release Oral Suspension 4mg/5mL	Tris Pharma Inc.	NDA 022556

**Schedule 2.2(a)(iii)****Business Intellectual Property**Owned Patents

COUNTRY	TITLE	APP. NO.	PUB. NO.	PUB. DATE	PATENT NO.	GRANT DATE
USA	Inhalation devices and Systems and Methods including the same	13/862,533	US 2013276781	10/24/2013	US 9364622	6/14/2016
USA	Inhalation devices and Systems and Methods including the same	15/153,482	US 2017021118	1/26/2017		
PCT	Inhalation devices and Systems and Methods including the same	PCT/US13/36936	WO 2013/158738	10/24/2013		N/A
Australia	Inhalation devices and Systems and Methods including the same	2013249336	AU 2013249336	11/27/2014		
Brazil	Inhalation devices and Systems and Methods including the same	112014026010 9				
Canada	Inhalation devices and Systems and Methods including the same	2870857	CA 2870857	10/24/2013		
Chile	Inhalation devices and Systems and Methods including the same	20142808	CL 2014002808	10/2/2015		
China	Inhalation devices and Systems and Methods including the same	201380032320.9	CN 104640589	5/20/2015	CN104640589	1/12/2018
Europe	Inhalation devices and Systems and Methods including the same	13720185	EP 2838595	2/25/2015		
Hong Kong	Inhalation devices and Systems and Methods including the same	15106904.5	HK 1206289	1/8/2016	HK 1206289	1/8/2016
India	Inhalation devices and Systems and Methods including the same	8327CHENP2014	IN 8327/CHENP/2014	7/1/2016		
Japan	Inhalation devices and Systems and Methods including the same	2015 507142	JP 2015-514511	5/21/2015	JP 6216367	29/09/2017
South Africa	Inhalation devices and Systems and Methods including the same	2014/08263	ZA 201408263	12/23/2015	ZA 201408263	12/23/2015
USA	Inhalation spacer	29/418,799	N/A		US D717424	11/11/2014



Licensed Patents

Title	Country or Jurisdiction	Patent No.	App/Publication No.	Filing Date	Issue Date	Status	Owner of Record	Expires
Karbinal ER (2) Modified release formulations containing drug-ion exchange resin complexes	United States	8,062,667	11/724,966	03/15/07	11/22/11	Issued	Tris Pharma	03/29/2029
AcipHex Sprinkle (3) Stabilized Composition	United States	9,040,564	11/937,393	11/08/07	5/26/15	Issued	Eisai R&D Management Co, Ltd.	03/14/2031

Licenses to Intellectual Property Received by Avadel Pharmaceuticals (USA), Inc.

1. Pursuant to the Supply and Distribution Agreement between Tris Pharmaceuticals, Inc. and FSC Labs dated August 9, 2013, FSC Labs received an exclusive license to distribute and sell carbinoxamine maleate (US Patent 8,062,667) under the trademark KARBINAL, U.S. Serial No. 85/344587 (expired but refiled now U.S. Serial No. 86/568,380), as such license is more fully described in that agreement.
2. Pursuant to the License and Assignment Agreement between Eisai, Inc. and FSC Therapeutics, dated June 12, 2014, FSC Therapeutics received an exclusive license for manufacturing, marketing, and sale of sprinkle (US Pending Patent 11/937393) under the trademark ACIPHEX Sprinkle, U.S. Registration No. 2,338,915 for ACIPHEX, as such license is more fully described in that agreement. Please note that because of the descriptive nature of the term SPRINKLE, registration of ACIPHEX SPRINKLE would not provide any additional protection.

Owned Trademarks

Registered:

Trademark	Country or Jurisdiction	App. No.	Reg. No.	Reg. Date	Goods	Status
E-Z SPACER	United States	74/558,755	2,004,852	10/01/96	IC 010: Medicament inhalation devices	Renewed
E-Z SPACER	Canada	1450552	TMA814697	12/29/11	Medicament inhalation device	Renewal due 12/29/2026
FLEXICHAMBER	United States	86/239,483	4,827,962	10/06/15	IC 010: Medical delivery apparatus, namely, a valved holding chamber sold empty for use with metered dose inhalers	Section 8 due 10/06/2021

Licensed Trademarks

Trademark	Country or Jurisdiction	App. No.	Reg. No.	Reg. Date	Goods	Status	Owner of Record
KARBINAL (2)	United States	85/344,587				Dead as of 06/22/15 (Used all extensions)	Tris Pharma, Inc.
KARBINAL (2)	United States	86/568,380			IC 005: Oral modified release, extended release, and/or sustained release pharmaceutical preparations for the drug carbinoxamine, a pharmaceutically acceptable salt thereof and/or carbinoxamine polistirex, intended for the treatment of seasonal and perennial allergic rhinitis, and other approved uses	New Intent to Use App filed 3/18/2015 – Notice of Allowance issued 10/13/2015	Tris Pharma, Inc.
ACIPHEX® SprinkleTM (3)	United States	75/037,680	2,338,914 (for ACIPHEX)	04/04/00	IC 005: Pharmaceutical preparations for the treatment of gastro- intestinal diseases.	Active	Eisai R&D Management Co. Ltd.

Domain Name Registrations

aciphexsprinkle.co  
 aciphexsprinkle.com  
 aciphexsprinkle.info  
 aciphexsprinkle.net  
 aciphexsprinkle.org  
 aciphexsprinkle.us

aciphexsprinkles.co  
aciphexsprinkles.com  
aciphexsprinkles.info  
aciphexsprinkles.net  
aciphexsprinkles.org  
aciphexsprinkles.us  
cefaclororal.com  
cefaclororal.net  
cefaclorsuspension.com  
cefaclorsuspension.net  
e-zspacer.com  
fairviewpharma.com  
flexichamber.co  
flexichamber.com  
flexichamber.net  
flexichamber.org  
flexichamberforkids.com  
fsclaboratories.com  
fsclabs.com  
fscpediatrics.com  
karbinal.co  
karbinal.com  
karbinal.net  
karbinal.org  
karbinalcr.com  
karbinaler.co  
karbinaler.com  
karbinaler.net  
karbinaler.org  
karbinalxr.com

**Schedule 2.2(a)(v)**

**Inventory**

See Exhibit 2.2(a)(v) attached hereto.

NONE

**Schedule 2.3**

**Assumed Liabilities**

See Exhibit 2.3 attached hereto.

**Schedule 3.2(c)**

**Consents**

NDA Transfer Letter between Seller and Buyer NDA Acceptance Letter





**Schedule 3.2(c)**

**NDA Transfer Letter Between Seller and Buyer**

X February 2018  
Donna Griebel, M.D., Division Director  
Division of Gastroenterology and Inborn Error Products  
Food and Drug Administration - Office of Drug Evaluation III  
Central Document Room  
5901 B Ammendale Road  
Beltsville, MD 20705-1266

**RE: NDA 204736 – AcipHex® Sprinkle™ (rabeprazole sodium) 5 and 10 mg Capsules for the treatment of Gastroesophageal Reflux Disease (GERD) in pediatric patients 1 to 11 years of age  
Sequence No. 006X: Transfer of NDA Ownership/Sponsor**

Dear Dr. Griebel:

Avadel Pharmaceuticals (USA), Inc. (Avadel) is making reference to the New Drug Application (NDA) 204736 for AcipHex® Sprinkle™. With this submission, in accordance with 21CFR 314.72, Avadel is transferring all rights and responsibilities related to NDA 204736 to Cerecor, Inc. effective <DAY> XX February 2018. Cerecor, Inc. will have a complete copy of the approved application on <DAY> XX February 2018.

The address of record for Cerecor, Inc. is:

Cerecor, Inc.  
400 East Pratt Street  
Suite 606  
Baltimore, MD 21202  
(410) 522-8707

The Official Correspondent at Cerecor, Inc. is:

Michael Bouchon  
Associate Director of Regulatory  
Cerecor, Inc.  
400 East Pratt Street  
Suite 606  
Baltimore, MD 21202  
Ph: (XXX) XXX-XXXX  
Fax: (XXX) XXX-XXXX

All future correspondence from the Agency should be directed to Cerecor, Inc.  
Should you have any questions or require additional information, please contact me by phone at +1 202.730.4129 or email at .

Sincerely,

Marla E. Scarola, MS  
Senior Consultant  
The Weinberg Group

**Schedule 3.2(c)**

**NDA Acceptance Letter**

X February 2018  
Donna Griebel, M.D., Division Director  
Division of Gastroenterology and Inborn Error Products  
Food and Drug Administration - Office of Drug Evaluation III  
Central Document Room  
5901 B Ammendale Road  
Beltsville, MD 20705-1266

**RE: NDA 204736 – AcipHex® Sprinkle™ (rabeprazole sodium) 5 and 10 mg Capsules for the treatment of Gastroesophageal Reflux Disease (GERD) in pediatric patients 1 to 11 years of age  
Sequence No. 006X: Acceptance of NDA Ownership/Sponsor**

Dear Dr. Griebel:

Reference is made to the New Drug Application (NDA) 204736 for AcipHex® Sprinkle™. With this submission, in accordance with 21CFR 314.72, Cerecor, Inc is accepting all rights and responsibilities related to NDA 204736 effective <DAY> XX February 2018. Cerecor, Inc. has received a complete copy of the approved NDA.

The address of record for Cerecor, Inc. is:

Cerecor, Inc.  
400 East Pratt Street  
Suite 606  
Baltimore, MD 21202  
(410) 522-8707

The Official Correspondent at Cerecor, Inc. is:

Michael Bouchon  
Associate Director of Regulatory  
Cerecor, Inc.  
400 East Pratt Street  
Suite 606  
Baltimore, MD 21202  
Ph: (XXX) XXX-XXXX  
Fax: (XXX) XXX-XXXX

All future correspondence from the Agency should be directed to Cerecor, Inc.  
Should you have any questions or require additional information, please contact me by phone at XXX-XXX-XXXX or email at XXXXXXXX.

Sincerely,

**Schedule 3.4**

**Liens**

Security Interests in the Purchased Assets granted to James Flynn, Peter Steelman and Deerfield CSF, LLC pursuant to Section 1.7 of the Deerfield Agreement.

**Schedule 3.5(f)**

**Interests Relating to Business Intellectual Property**

Pursuant to the Supply and Distribution Agreement between Tris Pharmaceuticals, Inc. and FSC Labs dated August 9, 2013, FSC Labs received an exclusive license to distribute and sell carbinoxamine maleate (US Patent 8,062,667) under the trademark KARBINAL, U.S. Serial No. 85/344587 (expired but refiled now U.S. Serial No. 86/568,380), as such license is more fully described in that agreement.

Pursuant to the License and Assignment Agreement between Eisai, Inc. and FSC Therapeutics, dated June 12, 2014, FSC Therapeutics received an exclusive license for manufacturing, marketing, and sale of sprinkle (US Pending Patent 11/937393) under the trademark ACIPHEX Sprinkle, U.S. Registration No. 2,338,915 for ACIPHEX, as such license is more fully described in that agreement. Please note that because of the descriptive nature of the term SPRINKLE, registration of ACIPHEX SPRINKLE would not provide any additional protection.

**Schedule 3.10(a)**  
**Regulatory Matters**

1. ACIPHEX® Sprinkle (rabeprazole sodium) Delayed-Release Capsules, for oral use NDA 204736
2. FLEXICHAMBER Anti-Static Valved Collapsible Holding Chamber  
510K 140062  
Device classification: Holding Chamber, Direct Patient Interface
3. EZ-SPACER  
510K 933090  
Device classification: Nebulizer, Direct Patient Interface

Schedule 3.10(b)

Clinical Studies

NONE

**Schedule 3.16**

**Related Party Transactions**

Deerfield Agreement



**Schedule 5.11(a)**  
**Business Employees**

wh_id	prtnum	client_id	lngdsc	total_inventory	available	unshp_qty	avg_dly_demand	DaysonHand	LocCount	Std Cost	LocCount
MEM	1355110105	FC	KARBINAL ER 480ML/4MG/5ML	[***]	[***]	[***]	[***]	[***]	[***]	[***]	\$[***]
MEM	1355112501	FC	CEFACTOR USP 125MG/5ML BOTTLE	[***]	[***]	[***]	[***]	[***]	[***]	[***]	\$[***]
MEM	1355120501	FC	ACIPHEX SPRINKLE DELAYED RELEASE CAPSULE 5MG 30CT	[***]	[***]	[***]	[***]	[***]	[***]	[***]	\$[***]
MEM	1355121001	FC	ACIPHEX SPRINKLE DELAYED RELEASE CAPSULE 10MG 30CT	[***]	[***]	[***]	[***]	[***]	[***]	[***]	\$[***]
MEM	1355125001	FC	CEFACTOR USP 250MG/5ML BOTTLE	[***]	[***]	[***]	[***]	[***]	[***]	[***]	\$[***]
MEM	1355137501	FC	CEFACTOR USP 375MG/5ML BOTTLE	[***]	[***]	[***]	[***]	[***]	[***]	[***]	\$[***]
MEM	1355190101	FC	FLEXICHAMBER	[***]	[***]	[***]	[***]	[***]	[***]	[***]	\$[***]
MEM	1355190301	FC	FLEXICHAMBER SMALL CHILD MASK 1 UNIT	[***]	[***]	[***]	[***]	[***]	[***]	[***]	\$[***]
MEM	1355190302	FC	FLEXICHAMBER LARGE CHILD MASK 1 UNIT	[***]	[***]	[***]	[***]	[***]	[***]	[***]	\$[***]
MEM	1355190303	FC	FLEXICHAMBER SMALL ADULT MASK 1 UNIT	[***]	[***]	[***]	[***]	[***]	[***]	[***]	\$[***]
<b>Total:</b>				[***]	[***]	[***]	[***]	[***]	[***]	[***]	\$[***]

**Inventory Stock Status Report** Report Date: 1/31/2018  
 Company: 1194 - AVADEL PHARMACEUTICALS  
 Product Division: ALL  
 Product Class: ALL  
 Product Code: ALL

Item Number	Item Description	Product Class	Unit Pack	Unit Cost	Max Qty	Item Owner	Square Footage	Lot Flag	Lot Number	Ship Expiration Date	Product Expiration Date	Manufacturing Date	Lot Status	Lot Qty on Hand	x2 pack	STD Cost	
13551-101-01	Karbinal ER Oral Suspension 4 mg/5 mL	Karbinal	[**]	0.00	[**]	UNKNOWN	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
13551-902-01	FLEXICHAMBER DEMOS	FLEXICHAMBER	[**]	0.00	[**]	UNKNOWN	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
13551-902-01	FLEXICHAMBER DEMOS	FLEXICHAMBER	[**]	0.00	[**]	UNKNOWN	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
13551-903-01	Flexichamber Small Child	FLEXICHAMBER	[**]	0.00	[**]	UNKNOWN	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
13551-903-02	Flexichamber Large Child	FLEXICHAMBER	[**]	0.00	[**]	UNKNOWN	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
13551-903-03	Flexichamber Small Adult	FLEXICHAMBER	[**]	0.00	[**]	UNKNOWN	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
19229-15	FLEXICHAMBER FACE MASK RX ANTISTATIC VALVED FLEXICHAMBER COLLAP		[**][**]		[**]	UNKNOWN	[**]										
Total Sample Inventory Value																[**]	

**Schedule of Assumed Liabilities**

**Liabilities associated with the Membership Interest Purchase Agreement: Section 1.2 Fixed payments due dates:**

Jul-18 \$		262,500	1
	Oct-18 \$	262,500	2
Jan-19 \$		262,500	3
	Apr-19 \$	262,500	4
Jul-19 \$		262,500	5
	Oct-19 \$	262,500	6
Jan-20 \$		262,500	7
	Apr-20 \$	262,500	8
Jul-20 \$		262,500	9
	Oct-20 \$	262,500	10
	Feb-21 \$	15,262,500	11

15% of net sales of the Products up to \$[\*\*\*] or Feb 5 2026, whichever comes

**Section 1.6 Deferred consideration**

Cumulative payments to date through September 30, 2017

sooner

\$ [\*\*\*]

Expected payment to be made relating to net sales in 4Q 2017\*:

[\*\*\*]

Expected payment to be made associated with 2018 revenues through the Closing Date\*:

[\*\*\*]

Total applied to the \$[\*\*\*] max

[\*\*\*]

Maximum amount contingently due

[\*\*\*]

**Amount contingently due**

\$ [\*\*\*]

\*Avadel is responsible for making payments under Section 1.6 of the Deerfield Agreement through the Closing Date.

**CONFIDENTIAL TREATMENT REQUESTED**

**THE PORTIONS OF THIS AGREEMENT MARKED WITH ASTERISKS WITHIN BRACKETS (“[\*\*\*]”) HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER 17 C.F.R. SECTIONS 200.80(B)(4), 200.83 AND 230.406. A COMPLETE COPY OF THIS AGREEMENT HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.**

**LICENSE AND DEVELOPMENT AGREEMENT**

This **LICENSE AND DEVELOPMENT AGREEMENT** (the “Agreement”) is entered into as of February 16, 2018 (the “Effective Date”) by and between **Cerecor, Inc.**, a Delaware corporation having an address at 400 East Pratt Street, Suite 606, Baltimore, MD 21202 (“Cerecor”), and Flamel Ireland Limited, operating under the trade name of **Avadel Ireland**, an Irish limited company having an address at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15 Ireland (“Avadel”). Avadel and Cerecor may be referred to herein individually as a “Party” or collectively, as the “Parties.”

**RECITALS**

**WHEREAS**, Cerecor, Inc. (“Cerecor Buyer”), Avadel Pharmaceuticals plc (“Avadel Seller”) and certain Affiliates of Avadel Seller have, as of the Effective Date, entered into that certain Asset Purchase Agreement pursuant to which Cerecor Buyer is purchasing Avadel Seller’s and such Affiliates’ pediatric pharmaceuticals business (such agreement, the “APA”);

**WHEREAS**, Avadel has developed and owns or controls certain technology and intellectual property rights with respect to the LiquiTime Technology (as defined below), and owns or controls certain know-how, technology, documentation, data, and other materials relating thereto;

**WHEREAS** in conjunction with, and as part of, the transaction contemplated by the APA, Avadel has agreed to develop three pharmaceutical products utilizing the LiquiTime Technology and a fourth pharmaceutical product consisting of an orally disintegrating tablet formulation and grant Cerecor rights to develop, manufacture, and commercialize such products, all as further set forth herein.

**NOW, THEREFORE**, in consideration of the foregoing and the covenants and promises contained in this Agreement, the Parties agree as follows:

- 1. DEFINITIONS.** Any capitalized terms not defined below or elsewhere in this Agreement shall have the meanings established therefor in the APA.

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

1.1 “API” means active pharmaceutical ingredient.

1.2 “Applicable Law” means all applicable laws, rules, regulations and guidelines that may apply to the development, marketing, manufacturing or sale of Products or the performance of either Party’s obligations, or the exercise of either Party’s rights, under this Agreement, including but not limited to all laws, regulations and guidelines governing the import, export, development, marketing, distribution and sale of a Product in the Territory and, to the extent relevant, all GCP, GLP or GMP standards or guidelines promulgated by any Regulatory Authorities or the ICH.

1.3 “Avadel Know-How” means all Know-How owned, licensed, or controlled by Avadel or its Affiliates as of the Effective Date, or becoming owned, controlled, or licensed by Avadel or any Affiliate thereof following the Effective Date, that is necessary for the discovery, research, Development, manufacture, or Commercialization of any Product.

1.4 “Avadel Patents” means (a) those Patents set forth on Exhibit A attached hereto (the “Initial Avadel Patents”); (b) any other Patents owned, controlled, or licensed by Avadel or any Affiliate thereof, or subject to an obligation of assignment to Avadel or any Affiliate thereof, as of the Effective Date, or becoming owned, controlled, or licensed by Avadel or any Affiliate thereof following the Effective Date, that (x) Cover any of the subject matter described in or Covered by the Initial Avadel Patents or any portion of the LiquiTime Technology or Tablet Technology or (y) is otherwise necessary to Develop, make, have made, use, offer for sale, sell, import, or otherwise Commercialize any Product; (c) any additions, divisionals, continuations, continuations-in-part, conversion, supplemental examinations, extensions, term restorations, registrations, reinstatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of the Initial Avadel Patents or the Patents described in (b) above, and any other Patents owned, controlled, or licensed by Avadel or any Affiliate thereof claiming priority to any of the foregoing or any of the Patents referenced in clause (a) or (b) above; and (d) all patents issuing from any of the Patents mentioned in clause (a), (b), or (c) above and any foreign counterparts of any such Patents, and which shall include, in any case, patents surviving post grant review and inter partes review.

1.5 “Avadel Technology” means the Avadel Know-How and the Avadel Patents.

1.6 “Calendar Day” means each of those seven (7) days in the week.

1.7 “Calendar Quarter” means each of those three (3) calendar month periods of each Calendar Year ending March 31, June 30, September 30 and December 31, provided, that (i) the initial Calendar Quarter shall begin on the Effective Date and end March 31, 2018 and (ii) the Calendar Quarter in which this Agreement expires or is terminated shall extend from the first Calendar Day of such Calendar Quarter until the effective date of such expiration or termination.

1.8 “Calendar Year” means (a) for the first Calendar Year, the period commencing on the Effective Date and ending on December 31 of the same year, (b) for the Calendar Year in which this Agreement expires or is terminated, the period beginning on January 1 of such

Calendar Year and ending on the effective date of such expiration or termination, and (c) for all other years, each successive twelve (12) consecutive month period beginning on January 1 and ending December 31.

**1.9** “Commercialization” means all activities that are undertaken after Regulatory Approval of a Product in a particular jurisdiction and that relate to the commercial marketing, sale, and/or distribution of such Product, including but not limited advertising and/or promotional activities. “Commercialize” shall have a corresponding meaning.

**1.10** “Commercially Reasonable Efforts” means the carrying out of obligations or tasks in a manner consistent with the efforts a Party devotes to research, development or marketing of a pharmaceutical product or products of similar market potential, profit potential or strategic value resulting from its own research efforts or for its own benefit, taking into account technical, regulatory and intellectual property factors, target product profiles, product labeling, past performance, costs, economic return, the regulatory environment and competitive market conditions in the therapeutic or market niche, all based on conditions then prevailing.

**1.11** “Confidential Information” means all information and know-how and any tangible embodiments thereof provided by or on behalf of one Party to the other Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing under this Agreement, which may include data, knowledge, practices, processes, ideas, research plans, formulation or manufacturing processes and techniques, scientific, manufacturing, marketing and business plans, and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business; provided, that (1) Development Documentation, Development Results, and information related thereto shall be the Confidential Information of Cerecor (and Cerecor shall be considered the disclosing party, and Avadel the receiving party, with respect thereto) and (2) information or know-how of a Party will not be deemed Confidential Information of such Party for purposes of this Agreement if such information or know-how: (a) was already known to the receiving Party, other than under an obligation of confidentiality or non-use, at the time of disclosure to such receiving Party, as can be shown by written records; (b) was generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or was otherwise part of the public domain, at the time of its disclosure to such receiving Party; (c) became generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or otherwise became part of the public domain, after its disclosure to such receiving Party through no fault of the receiving Party; (d) was disclosed to such receiving Party, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the disclosing Party not to disclose such information or know-how to others, as can be shown by written records; or (e) was independently discovered or developed by such receiving Party, as can be shown by its written records, without the use or benefit of, or reliance on, Confidential Information belonging to the disclosing Party.

**1.12** “Cover” means that the use, manufacture, sale, offer for sale, development, commercialization or importation of the subject matter in question by an unlicensed entity would infringe a Valid Claim of a Patent.

**1.13** “Develop” or “Development” means, with respect to a Product, engaging in preclinical, clinical, and other research or development activities, which may include but is not limited to research, pre-clinical, clinical and regulatory activities directed towards obtaining the initial Regulatory Approval of a Product in a particular jurisdiction.

**1.14** “Direct Cost” means, to the extent incurred with respect to the performance of the Avadel Development program following the Effective Date, Avadel’s cost that are documented, specifically identifiable and directly related to the Products. Such costs shall include but not be limited to direct labor costs, including salary and benefits (which shall be the only labor costs included in Direct Costs) and API, other materials and third party contractor or supplier costs.

**1.15** “DMF” means a drug master file, as provided for in 21 CFR § 314.420 or similar submission to or file maintained with the FDA or other Governmental Authority or Regulatory Authority that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

**1.16** “Field” means any use, application, or purpose, including, without limitation, the treatment, palliation, diagnosis, or prevention of any human or animal disease, disorder or condition, provided that, with respect to the portion of the Territory constituting the United States, including its territories and possessions, the Field shall, for so long as Elan Pharma International Limited (“Elan”), any of its affiliates, or any sublicensees of any of the foregoing enjoy rights in over-the-counter, non-prescription pharmaceutical markets to certain LiquiTime-based products under that certain Exclusive License Agreement, dated September 30, 2015, exclude the over-the-counter, non-prescription pharmaceutical markets.

**1.17** “GCP” means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (a) CFR Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application), as may be amended from time to time, (b) as set forth in European Commission Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, and brought into law by European Commission Directive 2005/28/EC laying down the principles and detailed guidelines for good clinical practice for investigational medicinal products, (c) as set forth in the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, and (d) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

**1.18** “Generic Entry” shall be deemed to exist in a particular country of the Territory for a particular Product as of the earlier of the first date upon which a Generic Product with respect to such Product has been sold in such country.



**1.19** “Generic Product” means, with respect to a Product sold pursuant to the rights granted under this Agreement in any country of the Territory, any product, other than such Product, that is (A) with respect to products sold in the U.S., (i) approved through an ANDA, or an application under Section 505(b)(2) of the FD&C Act, that references any NDA for such Product (or future functional equivalent) listed in the FDA Publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as the Orange Book), submitted by a Third Party and (ii) rated as a therapeutic equivalent to the corresponding Product sold in and designated as substitutable for such Product at the pharmacy level under any applicable administrative or formulary designation or by decision of the prescriber or the pharmacist, or (B) with respect to products sold in any jurisdiction in the Territory other than the U.S., a product that (X) (1) has obtained a regulatory Approval granted in reliance, in whole or in substantial part (e.g. on safety or efficacy data with respect to the Compound) on a prior Regulatory Approval granted for such Product and (2) is substitutable by a pharmacist or at the pharmacy level under Applicable Law in the country of sale, or (Y) has otherwise been approved and sold under any foreign equivalent of the processes and criteria described in clause (A).

**1.20** “GLP” means all applicable Good Laboratory Practice standards, including, as applicable, (a) as set forth in the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in Title 21, Part 58 of the CFR, (b) as set forth in European Commission Directive 2004/10/EC relating to the application of the principles of good laboratory practices, as may be amended from time to time as well as any Rules Governing Medicinal Products in the European Community Vol. III, ISBN 92.825 9619-2 (ex—OECD principles of GLP), and (c) the Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

**1.21** “GMP” means all applicable Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, Title 21, Parts 210, 211, 601 and 610 of the CFR, (b) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principals and guidelines of good manufacturing practice, (c) the principles detailed in the ICH Q7A guidelines, (d) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

**1.22** “Governmental Authority” means any court, agency, department or other instrumentality of any foreign, federal, state, county, city or other political subdivision (including any supra-national agency such as in the European Union).

**1.23** “ICH” means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

**1.24** “IND” means an Investigational New Drug Application filed with the FDA or the equivalent application or filing filed with any Regulatory Authority outside of the United States (including any supra-national agency such as in the European Union) necessary to commence

human clinical trials in such jurisdiction, and including all regulations at 21 CFR § 312 et. seq., and equivalent foreign regulations.

**1.25** “Initial LiquiTime Product” means:

- a. the LiquiTime Product incorporating [\*\*\*] as its API described on Exhibit B;
- b. the LiquiTime Product incorporating [\*\*\*] as its API described on Exhibit B; or
- c. the LiquiTime Product incorporating the Selected Compound as its API described on Exhibit B, provided that such description shall be updated as reasonably necessary and agreed to by the Parties upon determination of the Selected Compound pursuant to Section 4.1.

**1.26** “Initial Product” means an Initial LiquiTime Product or the Initial Tablet Product.

**1.27** “Initial Tablet Product” means the Tablet Product described on Exhibit B.

**1.28** “Know-How” means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, inventions, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, and other drug discovery and development technology, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and all improvements, whether to the foregoing or otherwise, and other discoveries, developments inventions and other intellectual property (whether or not confidential, proprietary, patented or patentable), provided that Know-How shall not include Patents.

**1.29** “LiquiTime Product” means a product incorporating the LiquiTime Technology and any Product Compound(s), including but not limited to the Initial LiquiTime Products.

**1.30** “LiquiTime Technology” means Avadel’s and its Affiliates’ modified/controlled release liquid suspension formulation technologies for pharmaceuticals, including as further described in the Initial Avadel Patents set forth under the heading “LiquiTime Technology” on Exhibit A.

**1.31** “NDA” means a new drug application (as defined in Title 21 of the United States Code of Federal Regulations, as amended from time to time) submitted to the FDA seeking regulatory approval to market and sell a Product for human therapeutic use in the United States (including a new drug application submitted under Section 505(b)(2) of the Act).

**1.32** “Net Sales” means gross amounts invoiced or otherwise received for Cerecor’s, its Affiliates’, and Sublicensees’ sales of Products, less the sum of the following, to the extent related to the sale of such Products: (1) discounts in amounts reasonable or customary in the trade, including but not limited to trade, cash, consumer, and quantity discounts, and credits, price adjustments or allowances for damaged Products, returns, defects, recalls or rejections of Products or retroactive price reductions; (2) reasonable rebates, credits, and chargeback payments granted to federal, state/provincial, local and other governments, managed health care organizations, or private payors, including their agencies, purchasers, and/or reimbursers, under programs available under or required by Applicable Law, or reasonably entered into to sustain and/or increase market share for Products; (3) sales, value added, use, excise, and similar taxes, provided that value added taxes shall only be deducted to the extent not recovered by Cerecor from the applicable tax authority; (4) amounts allowed or credited on returns for defective, damaged, returned, expired, or otherwise unuseable or unsaleable Products; (5) freight, shipping, handling, and insurance charges; (6) import or export duties, tariffs, or similar charges; and (7) distribution commissions/fees (including fees related to services provided pursuant to distribution service agreements with wholesalers) payable to any Third Party providing distribution services with respect to Products. Such amounts shall be determined from the books and records of Cerecor, its Affiliates, and Sublicensees maintained in accordance with such reasonable accounting principles as may be consistently applied by Cerecor, its Affiliates, and Sublicensees.

Products are considered “sold” at the earlier of: (a) when such Product is shipped to the Third Party purchaser thereof or (b) when billed out or invoiced. Notwithstanding the foregoing, Net Sales shall not include, and shall be deemed zero with respect to, (i) Products used by Cerecor, its Affiliates, or Sublicensees for their internal use, (ii) the distribution of reasonable quantities of promotional samples of Products, (iii) Products provided for clinical trials or research, development, or evaluation purposes, or (iv) Products provided by or on behalf of Cerecor, an Affiliate thereof, or a Sublicensee to Cerecor, an Affiliate thereof, or a Sublicensee for purposes of resale, provided such resale is subject to or triggers payments due Avadel under Section 3.1 of this Agreement.

In the event Cerecor, an Affiliate thereof, or a Sublicensee sell the Product together with other products to Third Parties in a particular country in the Territory and the price attributable to the Product is less than the average price of “arm’s length” sales of the Product alone in the particular country for the reporting period in which such sales occur (such sales to be excluded from the calculation of the average price of “arm’s length” sales of the Product alone), Net Sales for any such sales shall be calculated based on the average price of “arm’s length” sales by Licensee, Affiliate or Sublicensee, as applicable, of the Product alone and in the country during the reporting period in which such sales occur. If the average price of “arm’s length” sale of the Product cannot be determined in any given country, the Net Sales for any applicable sales under this paragraph will be calculated based on the value of the Product sold to similar customers in countries with similar pricing and reimbursement structures and for similar quantities.

**1.33** “Paragraph IV Certification” means a certification pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), as amended, which

shall include but not be limited to any such certification pursuant to 21 U.S.C. §355(b)(2)(A)(iv) or 21 U.S.C. §355(j)(2)(A)(vii)(IV), or any reasonably similar or equivalent certification or notice in the United States or any jurisdiction outside the United States, included in (or made with respect to or in connection with) a regulatory filing concerning a Product and challenging the validity, infringement, or enforceability of any Avadel Patent(s).

**1.34** “Patent(s)” means any granted or issued patents and pending patent applications, together with all additions, divisionals, continuations, continuations-in-part, substitutions, reissues, re-examinations, supplemental examinations, patents reviewed under post grant review or inter partes review, extensions, registrations, patent term extensions, revalidations, supplementary protection certificates, and renewals of any of the foregoing, and all foreign applications and patents corresponding to or claiming priority from any of the foregoing.

**1.35** “Pilot BE Studies” means the studies described on Exhibit C. The exact number of healthy volunteers and number of formulation arms to be studied in the Pilot PK study for each product will be agreed by the Parties prior to the initiation of each study.

**1.36** “Product” means a Tablet Product or LiquiTime Product.

**1.37** “Product Compound” means [\*\*\*], [\*\*\*], and the Selected Compound.

**1.38** “Regulatory Approval” means any and all approvals (including supplements, amendments, and pre- and post-approvals, but excluding pricing or reimbursement approvals), licenses, registrations, clearances, or authorizations of any national, supra-national (e.g., the European Commission or the Council of the European Union), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or, in Cerecor’s reasonable judgment, sale of a Product for use as a human pharmaceutical or biologic in a particular jurisdiction.

**1.39** “Regulatory Authority” means any Governmental Authority with responsibility for granting any licenses or approvals necessary for the marketing and sale of pharmaceutical or biological products in a particular jurisdiction, including the FDA with respect to the United States, and where applicable any ethics committee or any equivalent review board.

**1.40** “Regulatory Filing” means, with respect to the United States, an NDA, BLA, or IND, any foreign counterparts or equivalents of any of the foregoing, any DMFs, and any other filings or submissions required by or provided to Regulatory Authorities relating to the manufacture, Development or Commercialization of any Product, including any supporting documentation, data, correspondence, meeting minutes, amendments, supplements, registrations, licenses, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files, and manufacturing, shipping, or storage records with respect to any of the foregoing.

**1.41** “Selected Compound” means the API selected for development in a LiquiTime Technology-based Product in accordance with Section 4.1.

1.42 “Sublicensee” means a Third Party granted a sublicense to any of the rights granted to Cerecor and, if and as applicable, its Affiliates under this Agreement.

1.43 “Tablet Product” means a product incorporating the Tablet Technology and [\*\*\*]

1.44 as an API, including but not limited to the Initial Tablet Product.

1.45 “Tablet Technology” means the composition and process for producing Orally Disintegrating Tablets (ODTs) containing the appropriate microparticles to produce the target dissolution profiles and PK profiles. Such ODT approaches are well known and widely available and at present Avadel does not have any proprietary technology in this field.

1.46 “Term” has the meaning assigned to it in Section 8.1.

1.47 “Territory” means the world.

1.48 “Third Party Fees” means any and all licensing fees and payments received by Cerecor from a Sublicensee as consideration for the grant of any rights thereto under any Avadel Know-How or Avadel Patents with respect to any Product, including, but not limited to, up-front, milestone and similar payments, but which shall exclude (i) royalties or similar payments calculated on the basis of Product sales, (ii) amounts received (in advance or as reimbursement) to cover costs incurred or to be incurred by Cerecor or its Affiliates with respect to the performance of research, development, manufacturing, regulatory, or Commercialization activities under the applicable sublicense agreement, (iii) amounts received as advances or reimbursement for costs incurred or to be incurred by Cerecor or its Affiliates with respect to the filing, prosecution, maintenance, defense, or enforcement of patent or other intellectual property rights or any regulatory activities or matters, and (iv) purchases of debt or equity securities by a Sublicensee to the extent the price paid therefor does not exceed the fair market value thereof, as reasonably determined in good faith by Cerecor’s, board of directors. For the avoidance of doubt, payments in consideration of a sale of all or substantially all of the assets or business of Cerecor (or that portion thereof related to the subject matter of this Agreement) in a transaction, including but not limited to those which include an assignment of this Agreement, shall not be deemed Third Party Fees.

1.49 “United States” or “U.S.” shall mean the United States of America and its territories and protectorates.

1.50 “Valid Claim” means a claim of any pending patent application or any issued, unexpired United States or granted foreign patent that has not been dedicated to the public, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction from which no further appeal can be taken, and that has not been explicitly disclaimed, or admitted in writing to be invalid or unenforceable or of a scope not Covering a particular product or service through reissue, disclaimer or otherwise, provided that if a particular claim has not issued within five (5) years of its initial filing, it shall not be considered a Valid Claim for purposes of this Agreement unless and until such claim is included in an issued Patent, notwithstanding the foregoing definition.

## 2. LICENSES; SUBLICENSING.

**2.1 License to Cerecor.** Avadel hereby grants to Cerecor and its Affiliates a royalty-bearing exclusive license, with the right to sublicense as set forth in Section 2.2 and transferable with this Agreement pursuant to Section 11.1, under the Avadel Technology to make, have made, use, sell, offer for sale, import, export, Develop, and Commercialize the Products in the Field in the Territory.

**2.2 Sublicensing.** Cerecor and its Affiliates shall have the right to sublicense their rights under this Agreement (including but not limited to such rights granted under Section 2.1) to one or more Third Parties (and such Third Parties' rights may include the right to further sublicense the rights granted hereunder). Each such sublicense shall (i) be consistent with this Agreement and (ii) contain terms and conditions reasonably sufficient to enable Cerecor to comply with the terms of this Agreement.

**2.3 Section 365(n).** All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined in Section 101 of such Code. The Parties agree that Cerecor may fully exercise all of its rights and elections under the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets. The Parties further agree that, in the event Cerecor elects to retain its rights as a licensee under such Code, Cerecor shall be entitled to complete access to any technology or intellectual property licensed to it hereunder and all embodiments of such technology and intellectual property. Such embodiments of the technology and intellectual property shall be delivered to Cerecor not later than:

a. the commencement of bankruptcy proceedings against Avadel, upon written request, unless Avadel elects to perform its obligations under this Agreement, or

b. if not delivered above under this Section 2.3, upon the rejection of this Agreement by or on behalf of Avadel, upon Cerecor's written request.

## 3. FINANCIAL TERMS

**3.1 Royalty Payments.** Except as otherwise set forth in this Agreement, Cerecor shall pay to Avadel [\*\*\*] percent ([\*\*\*]%) of (i) Net Sales of all Products sold by Cerecor, its Affiliates, and Sublicensees and (ii) any Third Party Fees received by Cerecor and its Affiliates in respect to the Products.

**3.2 Loss of Patent Coverage.** Beginning with the first Calendar Quarter during which, at any time therein, there are no Valid Claims Covering a particular Product in a particular country, the royalty rate applicable under Section 3.1 for Net Sales of such Product in such country shall, if not already reduced pursuant to Section 3.4 below, be reduced by [\*\*\*] percent ([\*\*\*]%) for such Calendar Quarter and each Calendar Quarter thereafter.

**3.3 Compulsory Licenses.** Should a compulsory license be granted, or be the subject of a possible grant, to a Third Party under the Applicable Laws of any country in the Territory under the Avadel Patents, the Party receiving notice thereof or otherwise becoming aware thereof shall promptly notify the other Party thereof, including any material information concerning such compulsory license, and the total amount payable under this Section 3 with respect to sales of Products in such country will be adjusted to match any lower amount such Third Party may be allowed to pay with respect to the sales of such Products in such country, with such lower amount subject to further adjustments pursuant to Sections 3.2 and 3.4.

**3.4 Royalty Term.** Subject to any earlier termination of this Agreement, amounts due under Section 3.1 (as such royalties may be adjusted under this Agreement) shall only be payable, on a Product-by-Product and country-by-country basis, with respect to Net Sales of a particular Product in a particular country until the [\*\*\*] anniversary of the Effective Date (the period from the Effective Date until such anniversary, the "Royalty Term"). Notwithstanding anything to the contrary, on a Product-by-Product and country-by-country basis, upon the Generic Entry with respect to a Product in a country in the Territory, the royalty rate applicable under Section 3.1 for Net Sales of such Product in such country during the Royalty Term shall be reduced to [\*\*\*] percent ([\*\*\*]%) of the royalty rate set forth in Section 3.1 for such Calendar Quarter and each Calendar Quarter thereafter. For clarity, Cerecor shall not have any payment obligations under this Section 3 with respect to any Products sold following the Royalty Term.

**3.5 Payments and Payment Reports.** Except as otherwise provided in this Section 3, all royalties and payments due under this Section 3 shall be paid within ninety (90) Calendar Days of the end of the Calendar Quarter during which the applicable Net Sales occur. Each royalty payment shall be accompanied by a statement stating (as applicable) the number, description, and aggregate Net Sales, by country, of each Product sold during the relevant Calendar Quarter by Cerecor, its Affiliates, and Sublicensees and detailing the calculation of royalties and amounts due for such Calendar Quarter.

**3.6 Payment Method.** All payments due under this Agreement to Avadel shall be made by bank wire transfer in immediately available funds to an account designated by Avadel in writing. All payments hereunder shall be made in the legal currency of the United States.

**3.7 Taxes.** In the event any tax or similar amount is paid or required to be withheld by Cerecor or any Affiliate thereof for the benefit of Avadel on account of any royalties or other payments payable to Avadel under this Agreement, the corresponding amounts payable to Avadel shall be reduced by the amount of taxes or similar amounts deducted and withheld, and Cerecor shall pay the amounts of such taxes or similar amounts to the proper Governmental Authority in a timely manner and promptly transmit to Avadel an official tax certificate or other evidence of such tax or other obligations together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable Avadel to claim such payment of taxes or similar amounts. Any such withholding taxes or similar amounts required under applicable law to be paid or withheld shall be an expense of, and borne solely by, Avadel. Cerecor will provide Avadel with, at Avadel's expense, reasonable assistance to enable Avadel to recover such taxes or amounts otherwise withheld as permitted by law.

**3.8 Sublicenses.** For avoidance of doubt, the Parties agree that in the event that Cerecor grants licenses or sublicenses to Third Parties any right under Avadel Technology to sell Products, Cerecor shall include in such licenses or sublicenses an obligation for such Sublicensee to account for and report its sales of Products on a basis reasonably sufficient to enable Cerecor to pay Avadel the royalties due under this Agreement and satisfy Cerecor's reporting obligations hereunder.

**3.9 Foreign Exchange.** With respect to Net Sales invoiced in a currency other than United States dollars, such Net Sales will be converted into the United States dollar equivalent using the average conversion rate existing in the United States (as reported in The Wall Street Journal, New York edition) during the applicable Calendar Quarter. If The Wall Street Journal ceases to be published, then the rate of exchange to be used shall be that reported in such other business publication of national circulation in the United States on which the Parties reasonably agree.

**3.10 Interest.** If Cerecor fails to make any payment when due to Avadel under this Agreement, then interest shall accrue on the balance due on a daily basis at a rate equal to LIBOR (as published in The Wall Street Journal, New York edition) plus one percent (1%), or at the maximum rate permitted by applicable law, whichever is the lower, until Cerecor meets the full financial obligation due.

**3.11 Records; Audits.** Cerecor shall keep or cause its Affiliates to keep such records as are reasonably required to determine, in a manner, with respect to any financial records, consistent with generally accepted accounting principles in the United States, the amounts due under this Agreement; such records must be kept for a minimum of three (3) years following the Calendar Year to which such records pertain. At the request (and expense) of Avadel, Cerecor shall permit Avadel to engage an independent certified public accounting firm reasonably acceptable to Cerecor, at reasonable times not more than once a year and upon reasonable notice, to examine only those records as may be necessary to determine, with respect to any Calendar Year ending not more than three (3) years prior to Avadel's request, the correctness or completeness of any royalty report or payment made under this Agreement. Avadel shall promptly provide a copy of the results of any such audit or examination to Cerecor. Avadel shall bear the full cost of the performance of any such audit or examination, unless such audit or examination discloses an underpayment exceeding [\*\*\*] percent ([\*\*\*]%) of the amount actually due hereunder with respect to any particular Calendar Year, in which case Cerecor shall bear the reasonable, documented cost of the performance of such audit or examination. Cerecor shall promptly pay to Avadel the amount of any underpayment of royalties revealed by such an examination and review. Any overpayment by Cerecor of royalties or any other amount paid to Avadel revealed by an examination and review shall, in Cerecor's sole discretion, (i) be fully-creditable against future payments under this Agreement or (ii) refunded to Cerecor within thirty (30) Calendar Days of its request.



#### 4. COMPOUND SELECTION; PRODUCT DEVELOPMENT; TECHNOLOGY TRANSFER

**4.1 Compound Selection.** The Parties shall use reasonable good faith efforts to, within ninety (90) Calendar Days of the Effective Date (such period, the “Selection Period”), agree in writing on the API to be incorporated into the third Initial LiquiTime Product (other than those incorporating [\*\*\*] and [\*\*\*]) to be developed pursuant to Section 4.2 and with respect to which API and corresponding Products rights are granted under Section 2.1, provided that, in the event the Parties do not agree on such API within the Selection Period, Cerecor shall be entitled, upon written notice to Avadel given at any time within fifteen (15) Calendar Days of the end of the Selection Period, to select stiripentol or any other API as the “Selected Compound” for purposes of this Agreement.

#### **4.2 Product Development.**

a. **Performance of Avadel Development Program.** Avadel shall use reasonable diligent efforts to research and develop the Initial Products in order to develop a stable formulation of each Initial Product satisfying the applicable criteria set forth therefor on Exhibit C and otherwise reasonably suitable for Development and Commercialization as a pediatric pharmaceutical, which obligations shall include (i) the prompt performance of the research, development, manufacturing, and related obligations and responsibilities specified in the development program set forth on Exhibit B with respect to each Initial Product (the “Avadel Development Program”) according to the timelines set forth therein and (ii) the completion of Pilot BE Studies for each Initial Product satisfying the criteria for success therefor set forth on Exhibit C (such completion, “Successful Completion” for an Initial Product). Avadel shall provide Cerecor a written quarterly update, within fifteen (15) days of the end of each month, summarizing the progress and results of Avadel’s efforts to perform its obligations and responsibilities under this Section 4.2.a., and any ongoing plans with respect thereto. Avadel shall use reasonable diligent efforts to complete the Avadel Development Program for the Initial Products within eighteen (18) months from the Effective Date.

b. **Changes to Development Program.** The Parties shall reasonably cooperate in good faith to develop a more detailed and complete version of the Avadel Development Program and budget for the various components thereof as soon as reasonably possible, but in any event within thirty (30) days, following the Effective Date. Upon the Parties’ written agreement with respect to such more detailed and complete version of the Avadel Development Program and budget therefore, such more detailed and complete version of the Avadel Development Program shall, subject to any further changes made thereto in accordance with this subsection b., be the Avadel Development Program for purposes of this Agreement. The Parties shall reasonably cooperate in good faith to adjust the Avadel Development Program in a manner useful or necessary to achieve its goal of developing the Initial LiquiTime Products and Initial Tablet Product for Development and Commercialization by Cerecor for pediatric human

health applications, provided that any changes to the Avadel Development Program shall only be effective as agreed to in writing by the Parties.

**c. Development Documentation, Results, Reporting, and Inspection.**

1. Cerecor will own all documentation, including all notes, summaries, reports, and analyses related thereto, developed or generated by or on behalf of either Party or any Affiliate thereof solely in connection with the Avadel Development Program or performance of Avadel's obligations under Section 4 (collectively, all of the foregoing, the "Development Documentation"), and all data, results, information, and know-how resulting solely from the conduct of the Avadel Development Program or performance of Avadel's obligations under Section 4 (the "Development Results"). Avadel hereby assigns, and shall cause its Affiliates to assign, to Cerecor all right, title, and interest in all Development Documentation, Development Results, and any intellectual property rights solely associated with such Development Documentation or Development Results. Avadel shall take all actions, and shall cause its Affiliates and its and their contractors to take all actions, including but not limited to the execution of patent assignments or other documents, reasonably required, and reasonably requested by Cerecor, to effect the purposes of the foregoing. Notwithstanding the foregoing, Avadel shall have a royalty-free license and right to use any Development Documentation or Development Results as necessary for the filing, maintaining or prosecution of any Avadel Patent.

2. Avadel shall maintain, and shall cause its Affiliates to maintain, accurate and adequate books and records in connection with the performance of its obligations and responsibilities under the Avadel Development Program, Section 4, and this Agreement in accordance with Applicable Laws and in reasonably sufficient detail and a scientific and professional manner appropriate for regulatory and commercial purposes, including to support Regulatory Filings and support and obtain Regulatory Approvals. Avadel shall retain, and shall cause its Avadel to retain, all such books and records for not less than three (3) years following the expiration or termination of this Agreement or for such longer period as required by Applicable Law. Thereafter, Avadel shall not destroy such records without giving Cerecor prior written notice of such proposed destruction and the reasonable opportunity to store such records or to have such records shipped to Cerecor, at Cerecor's reasonable, documented expense. During the term of this Agreement, Avadel shall (i) promptly provide Cerecor all Development Results as they are generated, (ii) furnish detailed written reports regarding the progress and results of Avadel's obligations under the Avadel Development Program on a quarterly basis, and (iii) provide to Cerecor or any designee thereof any Development Documentation upon request.

3. At the request (and expense) of Cerecor, at reasonable times and upon reasonable notice, to examine only those records as may be necessary to

determine, with respect to any Calendar Year ending not more than three (3) years prior to such request, the correctness or completeness of any report or invoice by Avadel under this Agreement or whether or not Avadel has complied with the terms of this Agreement. Cerecor shall bear the full cost of the performance of any such audit or examination, unless such audit or examination discloses a breach of this Agreement or error in invoicing by Avadel, in which case Avadel shall bear the reasonable, documented cost of the performance of such audit or examination and, if an overpayment was made by Cerecor, promptly refund to Cerecor the amount of such overpayment.

d. **Development Costs.** Except as otherwise set forth in this Section 4.2.d., Avadel shall bear the entire cost and expense of performing the Avadel Development Program and its other obligations under this Section 4. Avadel shall maintain reasonably complete and accurate records of all costs and expenses incurred with respect to the performance of the Avadel Development Program and Avadel's obligations under this Section 4. Avadel will use Commercially Reasonable Efforts to perform the Avadel Development Program and perform its obligations under Section 4.2.a. without incurring any Direct Costs in excess of \$1,000,000. To the extent the reasonable, documented, Direct Cost of Avadel's performance of its obligations under Section 4.2.a. will exceed \$1,000,000, Avadel will provide reasonable written advance notice thereof to Cerecor, including in such notice a written itemized detailed description of the reasonably expected costs, on an Initial Product-by-Initial Product and activity-by-activity basis, to complete the performance of such obligations. To the extent Cerecor elects in writing to support any such Direct Costs in excess of \$1,000,000 for any such activity(ies) for any Initial Product(s), (i) Avadel shall promptly perform such activity(ies) for such Initial Product(s) and (ii) Cerecor shall reimburse Avadel for such Direct Costs within thirty (30) days of its receipt of a written invoice with respect thereto. In the event Cerecor elects to not support any such Direct Costs in excess of \$1,000,000 with respect to any particular activity(ies), Avadel shall not be obligated to perform such activity(ies) to the extent doing so would cause Direct Costs for the Avadel Development Program to exceed \$1,000,000. Cerecor shall not be responsible for any costs under this Section 4.2.d. except to the extent it has made such a written election with respect thereto as set forth above.

**4.3 Technology Transfer.** Upon the Effective Date and, as applicable, (i) Successful Completion for an Initial Product or (ii) Cerecor's written election prior to Successful Completion, Avadel shall transfer to Cerecor, at no additional cost, all Avadel Know-How, which shall include but not be limited to all formulation, development, manufacturing, analytical testing, device testing, stability, pre-clinical, and clinical data, trade secrets, and other regulatory data related to any Product, including the formulation therefor. Avadel shall, at Avadel's cost, take any and all actions requested by Cerecor to effect the foregoing transfer as promptly as practicable following the Effective Date and, as applicable, (i) Successful Completion for an Initial Product or (ii) Cerecor's written election prior to Successful Completion, which shall include but not be limited to taking all reasonable actions necessary to enable Cerecor to

undertake the manufacture, Development and Commercialization of Products under this Agreement. Such actions shall include providing Cerecor with:

- i. DMFs and any study, drug, device, or other master files relating to any Product;
- ii. copies of all data files, analyses, listings and tables of results, and copies of all case report forms from all research, development, or formulation work relating to any Product;
- iii. access to all contractors relating to any Product and any contracts therewith;
- iv. the data, files and results of any chemistry, manufacturing, or control-related activities regarding any Product; and
- v. all other information generated as part of the Avadel Development Program or constituting Development Results, Development Documentation, or Avadel Know-How that Cerecor may reasonably request that may be necessary to Cerecor for the manufacturing of Products or conducting preclinical studies and clinical trials and other Development activities with respect to any Products, or manufacture or Commercialization of any Products.

**4.4 Additional Assistance.** In the event Cerecor desires assistance from Avadel in connection with any activities related to preclinical development of a Product, including further lead optimization, assay development and validation, production of toxicology/GMP material or performance of toxicology studies, Cerecor shall provide written notice thereof to Avadel and the parties shall enter into good faith discussions concerning the financial and other terms upon which such assistance may be provided by Avadel, provided that Avadel shall not have any obligation to provide such assistance unless and until the Parties have executed a mutually agreeable definitive written agreement governing the provision of such assistance.

**4.5 Regulatory Filings.** Cerecor (or its Affiliates or Sublicensees) will own and be responsible for all Regulatory Filings and Regulatory Approvals in the Territory. Cerecor shall use Commercially Reasonable Efforts to maintain (or cause its Affiliates and Sublicensees to maintain) reasonably complete and accurate records of all material work performed by Cerecor in furtherance of the Development and Commercialization of Products and all material results, data and developments generated by Cerecor in conducting such activities. Such records shall be maintained in reasonably sufficient detail and in a manner reasonably appropriate for patent and regulatory purposes.

**4.6 Compliance.** Cerecor shall comply, and shall use Commercially Reasonable Efforts to ensure that its Affiliates and any Sublicensees comply, with all Applicable Laws in the exercise of the rights granted under this Agreement.

## 5. PATENT PROSECUTION, MAINTENANCE, AND DEFENSE.

**5.1 Prosecution and Maintenance.** Avadel shall have primary responsibility for, and use Commercially Reasonable Efforts to pursue, the filing, prosecution, maintenance, and, subject to Section 6.4, defense of the Avadel Patents and be responsible for all reasonable costs and expenses it incurs with respect thereto. Avadel will, to the extent reasonably practicable, provide Cerecor a reasonable opportunity to review and comment on any material patent filings or correspondence with patent authorities pertaining to the Avadel Patents, provided that all decisions with respect to the filing, prosecution, maintenance, and, subject to Section 6.4, defense of the Avadel Patents under this Section 5.1 shall be made by Avadel in its reasonable discretion. Exhibit A shall be updated periodically to reflect the further prosecution of Avadel Patents and the addition of any Avadel Patents coming under the ownership or control of Avadel or any Affiliate thereof after the Effective Date. Avadel shall not abandon prosecution, maintenance, or defense of any Avadel Patent without first notifying Cerecor in writing in a reasonably timely manner of Avadel's intention and reason therefor, and providing Cerecor with reasonable opportunity to assume the prosecution, maintenance, and defense of such Avadel Patent as set forth in Section 5.2.

**5.2 Abandonment.** Avadel shall not abandon the prosecution, maintenance, or defense of any Avadel Patent unless it first gives Cerecor prior written notice of such abandonment, which notice shall specify the specific Avadel Patent(s) subject to such abandonment and be given at least [\*\*\*] ([\*\*\*)] Calendar Days prior to any deadlines relating to such Avadel Patent(s). Cerecor shall have the right, upon written notice to Avadel given during such [\*\*\*] ([\*\*\*)] Calendar Day period, to assume control of prosecution, maintenance, and defense of such Avadel Patent(s) by having Avadel assign such Patent(s) to Cerecor. In the event of such a notice from Cerecor with respect to a particular Patent, (i) Avadel shall assign, and hereby assigns, all right, title, and interest therein to Cerecor, free and clear of all liens, claims, and encumbrances, and agrees to take any and all actions reasonably requested by Cerecor to effect and further the foregoing and (ii) such Patent(s) assigned to Cerecor shall no longer be considered an Avadel Patent for purposes of this Agreement.

**5.3 Patent Term Extensions.** Cerecor shall promptly notify Avadel of the issuance of each Regulatory Approval and, where reasonably and legally possible and reasonably useful or materially valuable in the Commercialization of Products, Avadel shall, if and as requested by Cerecor, (i) use Commercially Reasonable Efforts to, assist Cerecor, its Affiliates, and Sublicensees in obtaining all available Patent Term Extensions and (ii) take all actions necessary to obtain all Patent Term Extensions. The Parties shall cooperate with each other in obtaining Patent Term Extensions wherever and whenever applicable.

## 6. PATENT INFRINGEMENT.

**6.1 Notice.** If either Party becomes aware of any actual, potential, or alleged infringement of any of the rights to Avadel Patents granted to Cerecor under this Agreement with respect to Products, such Party shall give to the other Party prompt and reasonably detailed written notice of such actual, potential, or alleged infringement. Notwithstanding the foregoing,

each Party shall notify the other Party within two (2) Business Days of its receipt of, or receipt of notice of, any Paragraph IV Certification.

**6.2 Infringement of Avadel Patents.** With respect to any actual, potential, or alleged infringement of the rights to Avadel Patents granted hereunder, which shall include, to the extent permitted under Applicable Law, any infringement or other claims resulting from, or legal actions or proceedings enabled or permitted by, any Paragraph IV Certification, Cerecor shall have the first and primary right, but not the obligation, to, at its expense, initiate, prosecute, and control any action or legal proceedings, and/or enter into a settlement, including any declaratory judgment action, with respect thereto. In any such litigation brought by Cerecor, Cerecor shall have the right to use and sue in Avadel's name and join Avadel as a party to such litigation, and Avadel shall cooperate reasonably with respect thereto, as requested by Cerecor, at Cerecor's expense. If, within one hundred eighty (180) Calendar Days of the notice in Section 6.1 (or, in the case of a Paragraph IV Certification, thirty-five (35) Calendar Days from the date of Cerecor's receipt of the Paragraph IV Certification or notice thereof from Avadel), Cerecor shall, (i) have been unsuccessful in persuading the actual, potential, or alleged infringer to desist, (ii) shall not have brought and shall not be diligently prosecuting an infringement or other action with respect to such actual, potential, or alleged infringement or Paragraph IV Certification, or (iii) has not entered into settlement discussions with respect to such actual, potential, or alleged infringement or Paragraph IV Certification, or if Cerecor notifies Avadel that it has decided not to undertake any of the foregoing against any such alleged, potential, or actual infringer or Third Party making such Paragraph IV Certification, then Avadel shall have the right, at its expense, to bring suit to enforce such Avadel Patents against such actual, alleged, or potential infringer, or take action with respect to such Paragraph IV Certification, at its own expense, unless Cerecor has provided Avadel with a reasonable strategic rationale for not taking action to terminate such actual, potential, or alleged infringement or with respect to such Paragraph IV Certification. Notwithstanding the foregoing, neither Cerecor nor Avadel shall, and neither Cerecor nor Avadel shall permit any Affiliate thereof or Third Party to, proceed against an alleged infringer of the Avadel Patents in the Territory without first consulting with the other Party regarding the strategy for such proceeding and considering in good faith the other Party's comments regarding such proceeding.

**6.3 Infringement of Third Party Rights.** In the event that a claim of infringement of a Third Party's Patents is made or brought against either Party with respect to the manufacture, use, sale, or importation of a Product, the Party receiving such claim shall promptly inform the other Party in writing, and the Parties shall consult with each other in order to develop a strategy for addressing the alleged infringement. Each Party shall reasonably cooperate with the other Party, as reasonable requested thereby, in any investigations undertaken to determine any potential infringement. As between the Parties, Cerecor (and/or its Affiliates and Sublicensees) shall have the first and primary right, but not the obligation, at its own expense (subject to Section 6.6) to defend, control the defense of, and/or settle any such claim against Cerecor, its Affiliates, or Sublicensees, using counsel of its own choice.

#### 6.4 Defense of Avadel Patents Against Third Party Challenge.

(a) **Notice.** If either Party becomes aware of any declaratory judgment or similar legal actions brought by any Third Party seeking to invalidate or hold any Avadel Patents unenforceable (such an action, a “**Challenge**”), such Party shall give to the other Party prompt and reasonably detailed written notice of such Challenge. This Section 6.4 sets forth the rights of the Parties to commence and/or undertake a defense of any Challenge (such defense, a “**Defensive Action**”).

(b) **Right to Defend.** Cerecor shall have the first right but not the obligation to commence and undertake a Defensive Action or, subject to Section 6.5, negotiate or enter into any settlement or voluntary disposition thereof. If Cerecor has not exercised its first right to commence and/or undertake a Defensive Action within thirty (30) days of receipt of notice of the applicable Challenge, it shall promptly notify Avadel in writing and Avadel may, by written notice to Cerecor, commence and/or undertake such defense (either such Party who commences and/or undertakes such defense, the “**Defending Party**”). At the Defending Party’s request, the non-Defending Party shall provide the Defending Party with all relevant documentation (as may be requested by the Defending Party) evidencing that the Defending Party is validly empowered by the non-Defending Party to initiate and undertake such Defensive Action, as applicable. The non-Defending Party shall join the Defending Party in its Defensive Action if the Defending Party reasonably determines that this is necessary to demonstrate “standing to defend.” The Defending Party shall have the sole and exclusive right to select counsel for any defense initiated by it pursuant to this Section 6.4(b) (but not the non-Defending Party’s counsel). Cerecor’s or Avadel’s rights under this Section 6.4(b) may be exercised by their respective Affiliates or in Cerecor’s case, Sublicensees.

(c) **Reasonable Assistance.** Each Party (if it is not the Defending Party) shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence and making its employees and consultants available, subject to the other Party’s reimbursement, pursuant to Sections 6.4(d) and 6.6, of any reasonable out-of-pocket expenses incurred on an on-going basis by the non-Defending Party in providing such assistance.

(d) **Costs and Expenses of a Defensive Action.** In the event Cerecor is the Defending Party, Cerecor shall bear one hundred percent (100%) of its reasonable, documented out of pocket expenses incurred in such Defensive Action, including, for such purposes, Avadel’s reasonable, documented out of pocket cost of rendering any assistance provided at Cerecor’s request pursuant to Section 6.4(c). In the event Avadel is the Defending Party, Avadel shall bear one hundred percent (100%) of the reasonable, documented out of pocket expenses incurred in such Defensive Action, including, for such purposes, Cerecor’s reasonable, documented cost and expense of rendering any assistance provided at Avadel’s request pursuant to Section 6.4(c),

**6.5 Litigation Control.** The Party pursuing or controlling any action or defense under Section 6.2, 6.3, or 6.4 (the “Controlling Party”) shall be free to enter into a settlement,

consent judgment, or other voluntary disposition of any such action or defense, provided, however, that (i) the Controlling Party shall consult with the other Party (the “Secondary Party”) prior to entering into any settlement or voluntary disposition thereof, (ii) any settlement, consent judgment or other voluntary disposition of such actions which (1) subjects the Secondary Party to any non-indemnified liability or non-indemnified obligation or (2) admits fault or wrongdoing on the part of Secondary Party must, in each case, be approved in advance and in writing by the Secondary Party, (iii) any settlement, consent judgment or other voluntary disposition of such actions which limits the scope, validity, or enforceability of, or otherwise may adversely affect, any Avadel Patents shall not be entered into, consented to, approved, or agreed upon without the other Party’s prior written approval, (iv) any settlement, consent judgment or other voluntary disposition of such actions which would reasonably be anticipated to materially, adversely, and directly affect Avadel’s ability to make, use, or sell any products, other than the Products, incorporating the LiquiTime Technology shall not be entered into, consented to, approved, or agreed upon without Avadel’s prior written consent, and (v) any settlement, consent judgment or other voluntary disposition of such actions that would reasonably be expected to materially adversely affect the ability of Cerecor, its Affiliates, or any Sublicensees to manufacture, Develop or Commercialize Products shall not be entered into, consented to, approved, or agreed upon without Cerecor’s prior written consent. With respect to clause (ii) or (iii) above in this Section 6.5, the Secondary Party shall provide the Controlling Party notice of its approval or denial of such approval within fifteen (15) Business Days of any request for such approval by the Controlling Party, provided that (X) in the event Secondary Party wishes to deny such approval, such notice shall include a written description summarizing the Secondary Party’s reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition and (Y) Secondary Party shall be deemed to have approved such proposed settlement, consent judgment, or other voluntary disposition in the event it fails to provide such notice within such fifteen (15) Business Day period. Any recovery or damages received by the Controlling Party with respect to the infringement of the rights to Avadel Patents granted under this Agreement, or in settlement of any matter subject to Section 6.2, 6.3, or 6.4, shall be used first to reimburse the Parties for unreimbursed reasonable, documented expenses (excluding, with respect to any costs or expenses incurred by Avadel, compensation of any employees or consultants of Avadel or any Affiliate thereof) incurred in connection with such action or settlement, and the remainder shall be split [\*\*\*] percent ([\*\*\*]%) to Controlling Party and [\*\*\*] percent ([\*\*\*]%) to Secondary Party. Notwithstanding the foregoing, the Secondary Party, at its expense, shall have the right to be represented by counsel of its choice in any proceeding governed by this Section 6.5.

**6.6 Reimbursement.** Each Party shall invoice the other Party for any reasonable, documented costs incurred that are to be borne by the other Party pursuant to this Section 6 (which reimburseable costs shall exclude any costs or expenses incurred by Avadel with respect to its compensation of any employees or consultants of Avadel or any Affiliate thereof). Each Party shall pay the other Party such amounts within thirty (30) Calendar Days of its receipt of any such invoice, except to the extent such amounts are the subject of a good faith dispute, in which the amounts subject to such dispute shall be due within thirty (30) Calendar Days of the resolution of such dispute.



**6.7 Litigation Credit.** To the extent there is no recovery of damages, or amounts received in settlement, by Cerecor or its Affiliates with respect to any matter contemplated by Section 6.2, 6.3, or 6.4 above, or all such amounts received with respect to a particular matter are insufficient to fully reimburse Cerecor or its Affiliates for any amounts incurred thereby with respect to such matter (including but not limited to attorneys' fees, out-of-pocket costs, and all amounts paid as judgments, damages, or in settlement) (such amounts, "Infringement Costs"), Cerecor shall be entitled to credit [\*\*\*] percent ([\*\*\*]%) of Infringement Costs (such [\*\*\*] percent ([\*\*\*]%), the "Infringement Cost Credit") against royalties or other fees thereafter payable to Avadel under this Agreement. If the total Infringement Cost Credit applicable for any particular Calendar Quarter exceeds more than [\*\*\*] percent ([\*\*\*]%) of amounts payable to Avadel under this Agreement with respect to such Calendar Quarter, then the amount of such Infringement Cost Credit in excess of [\*\*\*] percent ([\*\*\*]%) of the amounts payable to Avadel under this Agreement with respect to such Calendar Quarter shall be carried over and credited against payments due in future Calendar Quarters, subject to such [\*\*\*] percent ([\*\*\*]%) limitation (and continued rollover) in each case.

**6.8 Covenant Not To Challenge.** Cerecor and its Affiliates covenant not to directly or indirectly challenge the validity or enforceability of any of the Avadel Patents from the Effective Date of this Agreement through the last-to-expire Term of this Agreement, and Cerecor shall obtain from, and use Commercially Reasonable Efforts to enforce against, each of its Sublicensees a corresponding covenant with respect to any Avadel Patents sublicensed to such Sublicensee. This covenant is personal to Avadel and its Affiliates and its successors and assigns.

**6.9 Trademarks.** Cerecor, its Affiliates, and Sublicensees may, in their sole discretion, select trademarks for the Products ("Product Marks") and shall own all such trademarks. To the extent Cerecor, its Affiliates, and Sublicensees pursue trademarks for Products, as between the parties, Cerecor, its Affiliates, and Sublicensees shall have the sole responsibility for the filing, prosecution and maintenance of registrations of trademarks for Products, at their sole expense.

## 7. CONFIDENTIALITY

**7.1 Confidentiality Obligations.** The Parties agree that, for the Royalty Term and for five (5) years thereafter, each Party will keep completely confidential and will not publish, submit for publication or otherwise disclose, and will not use for any purpose except for the purposes contemplated by this Agreement, any Confidential Information of the other Party.

**7.2 Authorized Disclosure.** Each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

(a) made in response to a valid order of a court of competent jurisdiction; provided, however, that in each case such disclosing Party will, to the extent reasonably practicable, (i) first have given written notice to the other Party and given such other Party a reasonable opportunity to take appropriate action and (ii) cooperate with such other Party as necessary to obtain an appropriate protective order or other protective remedy or treatment; provided, further, that in each case, the Confidential Information

disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order, as determined in good faith by counsel to the Party that is obligated to disclose Confidential Information pursuant to such order;

(b) otherwise required to be disclosed by any applicable law, rule, or regulation (including, without limitation, the U.S. federal securities laws and the rules and regulations promulgated thereunder) or the requirements of any stock exchange to which a Party is subject; provided, however, that the Party that is so required will provide such other Party with written notice of such disclosure reasonably in advance thereof to the extent reasonably practicable and reasonable measures will be taken to assure confidential treatment of such information, including such measures as may be reasonably requested by the disclosing Party with respect to such Confidential Information;

(c) made by such Party, in connection with the performance of this Agreement, to such Party's Affiliates, licensees or sublicensees, directors, officers, employees, consultants, representatives or agents, or to other Third Parties, in each case on a need to know basis and solely to use such information for business purposes relevant to and permitted by this Agreement, and provided that (i) each individual and entity to whom such Confidential Information is disclosed is bound in writing to non-use and non-disclosure obligations no less than substantially as restrictive as those set forth in this Agreement and (ii) the Party making such disclosure shall be liable for such Third Parties' compliance with such obligations; or

(d) made by such Party to existing or potential acquirers, collaborators, licensees, licensors, sublicensees, investment bankers, accountants, attorneys, investors, merger or acquisition candidates, partners, venture capital firms or other financial institutions or investors for use of such information for business purposes relevant to this Agreement or for due diligence in connection with the financing, licensing or acquisition of such Party (or such Party's acquisition of, or merger with, a Third Party), and provided that (i) each individual and entity to whom such Confidential Information is disclosed is bound in writing to non-use and non-disclosure obligations (or in the case of attorneys or accountants, an equivalent professional duty of confidentiality) at least as restrictive as those set forth in this Agreement and (ii) the Party making such disclosure shall be liable for such Third Parties' compliance with such obligations.

**7.3 Publicity.** Press releases or other similar public communication by either Party not required by any applicable law, rule, or regulation or the requirements of any stock exchange to which a Party is subject and disclosing the existence or terms of this Agreement, or concerning either Party's performance or exercise of its rights under this Agreement, will require the advance written approval of the other Party, provided that, notwithstanding the foregoing, any such release or communication by Cerecor, any Affiliate thereof, or any Sublicensee related to the Development or Commercialization of any Product shall not require Avadel's prior written consent. The foregoing notwithstanding, communications required by any applicable law, rule,

or regulation or the requirements of any stock exchange to which a Party is subject, and disclosures of information for which consent has previously been obtained, will not require advance approval, but will be provided to the other Party as soon as practicable after the release or communication thereof, provided that, with respect to any such communications required by any applicable law, rule, or regulation or the requirements of any stock exchange to which a Party is subject, the Party required to make such disclosure shall, to the extent reasonable practicable and such disclosure does not include information for which consent has previously been obtained, provide the other Party a reasonable opportunity to review and comment on such communications.

**7.4 Publications.** Subject to Sections 7.1, 7.2, and 7.3 and this Section 7.4, each Party shall have the right to publish, present or otherwise disclose, including in scientific journals or promotional literature, information pertaining to Avadel Technology or any Product; provided, however, that:

a. if Cerecor or any Affiliate thereof desires to publish or present any such information, then the following procedure shall apply: (i) Cerecor shall first provide a copy of the proposed publication or presentation to Avadel for review and comment thirty (30) Calendar Days in advance of any submission for publication or presentation (or, in the case of any presentation, fifteen (15) Calendar Days in advance of such submission) (such thirty (30) or fifteen (15) Calendar Day period, the "Review Period"); (ii) if during the Review Period Cerecor receives written notice from Avadel identifying specific Confidential Information of Avadel in such a proposed publication or presentation, then, at the reasonable request of Avadel in such notice and at Avadel's option, Cerecor shall, and Cerecor shall use Commercially Reasonable Efforts to ensure that its Affiliates and Sublicensees, delete such Confidential Information from the proposed publication and/or delay such publication or presentation for up to an additional thirty (30) Calendar Days in order to permit Avadel to file a patent application covering such Confidential Information; and

b. if Avadel or any Affiliate thereof desires to publish or present any such information pertaining to any Product, then Avadel shall first provide a copy of the proposed publication or presentation to Cerecor for review and approval for a period not to exceed thirty (30) Calendar Days in advance of any submission for publication or presentation (or, in the case of any presentation, fifteen (15) Calendar Days in advance of such submission), and Avadel shall not submit, publish, or present such proposed publication or presentation without Cerecor's prior written consent.

## **8. Term and Termination**

**8.1 Term.** This Agreement shall become effective on the Effective Date and shall continue, on a country-by-country and Product-by-Product basis, until the earlier of (i) the expiration of the Royalty Term for a particular Product in a particular country or (ii) the effective date of termination pursuant to Section 8.2, 8.3, 8.4, or 8.5 (the period from the Effective Date until such expiration or termination, the "Term"). Upon expiration of this Agreement pursuant to clause (i) above with respect to a particular Product and country, Cerecor and its Affiliates shall

have the perpetual, unrestricted, irrevocable, fully-paid, royalty-free exclusive right, with rights of sublicense, under Avadel Technology to make, have made, use, sell, offer for sale, and import such Product in such country.

**8.2 Termination for Material Breach.** If either Party (the “non-breaching Party”) believes the other Party (the “alleged breaching party”) is in material breach of any of such alleged breaching Party’s obligations under this Agreement, the non-breaching Party may give notice of such breach to the alleged breaching Party, and the alleged breaching Party shall have sixty (60) days in which to remedy such material breach or establish that it is not in material breach hereunder. If such alleged material breach is not remedied in the time period set forth above, the non-breaching Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement upon written notice to the alleged breaching Party.

**8.3 Termination upon Insolvency.** To the extent permitted under Applicable Laws, either Party may terminate this Agreement with respect to the other Party if, at any time, such other Party shall file, in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, or if such other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if such other Party shall propose or be a party to any dissolution or liquidation, or if such other Party shall make an assignment for the benefit of its creditors.

**8.4 Termination upon Force Majeure.** Either Party may terminate this agreement due to a Force Majeure event pursuant to Section 11.10.

**8.5 Termination by Cerecor.** This Agreement may be terminated by Cerecor, in its sole discretion, in its entirety, with respect to one or more Products, with respect to one or more countries, or with respect to one or more Products in one or more countries, upon sixty (60) Calendar Days’ written notice to Avadel.

**8.6 Effects of Termination.** Upon any termination of this Agreement (in whole or in part), other than the expiration of this Agreement or termination by Avadel pursuant to Section 8.2, Cerecor, its Affiliates, and Sublicensees shall have the privilege, subject to Cerecor’s payment of royalties as required under Section 3.1, of selling, within twelve (12) months of such termination (the “Termination Date”), any finished Products, or Products in inventory or the process of manufacture as of the Termination Date, that are subject to such termination. Cerecor shall also be responsible for any payments owed to Avadel pursuant to Section 4.2.d that have not yet been paid for the performance of the Avadel Development Program in accordance with this Agreement prior to the date of such termination. Upon termination of the Agreement by Avadel pursuant to Section 8.2 or by Cerecor pursuant to Section 8.5, the license granted pursuant to Section 2 herein shall be terminated and Avadel shall have all rights under the Avadel Know-How and Avadel Patents to make, have made, use, sell, offer for sale, import, export, Develop, and Commercialize the Products.

**8.7 Survival of Sublicenses.** Notwithstanding any provision herein to the contrary, any sublicense granted in accordance with this Agreement under any Avadel Know-How or Avadel Patents shall remain in effect following termination of this Agreement by Avadel (except, with respect to any particular sublicense, if Avadel terminates this Agreement pursuant to Section 8.2 and the applicable Sublicensee's uncured material breach of such sublicense is the direct cause of the uncured material breach of this Agreement enabling such termination by Avadel) and will, to the extent directly concerning the rights to Avadel Know-How and Avadel Patents granted hereunder and not imposing any obligations on Avadel in excess of those set forth herein, immediately and automatically be assigned to Avadel and deemed to be a direct license from Avadel to the applicable Sublicensee with respect to the rights originally granted under this Agreement that are the subject of such sublicense, in order to provide for the applicable Sublicensee's continued enjoyment of its rights thereunder, with all payments thereunder due by such Sublicensee thereafter, to the extent solely and directly corresponding to, and due with respect to, the rights to Avadel Know-How and Avadel Patents granted under this Agreement, to be made directly to Avadel.

**8.8 Survival.** Termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of any Party prior to such termination or expiration, and any termination or expiration of this Agreement shall not relieve either Party of any obligation which has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect. The following provisions shall survive any expiration or termination of this Agreement: Sections 1, 2.2, 2.3, 3.7, 3.9, 3.10, 3.11 (to the extent set forth therein), 7, 6 (other than Sections 6.8 and 6.9 thereof and only with respect to infringements occurring prior to termination or expiration) 8.1, 8.6, 8.7, 8.8, 9.3, 10.1, 10.2, 10.3, 10.4, 10.5 (to the extent set forth therein), and 11, together with any Sections referenced in such surviving provisions or necessary to give them effect.

## **9. REPRESENTATIONS AND WARRANTIES**

**9.1 Representations and Warranties of Avadel.** Avadel represents and warrants to Cerecor as follows:

- a. Avadel is a corporation, duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation, with full corporate power and authority to operate its properties and to carry on its business as presently conducted.
- b. Avadel has full power and authority to execute, deliver and perform this Agreement. There are no liens or other encumbrances on the Avadel Technology or any part of thereof which would interfere with the rights granted to Cerecor hereunder. This Agreement constitutes the legally binding and valid obligation of Avadel, enforceable in accordance with its terms, except as such enforcement may be limited by applicable bankruptcy, moratorium and other laws affecting creditors' rights generally.
- c. The execution, delivery and performance by Avadel of this Agreement and the consummation of the transactions contemplated hereby will not result in any

violation of, conflict with, result in a breach of or constitute a default under any contract or agreement to which Avadel or any Affiliate thereof is a party.

d. There is no action, suit, proceeding or investigation pending or, to Avadel's and its Affiliates' knowledge, currently threatened orally or in writing against or affecting Avadel or any Affiliate thereof that questions the validity of this Agreement, the validity, enforceability, scope, or ownership of any Avadel Patent(s), or the right of Avadel to enter into this Agreement or consummate the transactions contemplated hereby and, to Avadel's and its Affiliates' knowledge, there is no basis for the foregoing.

e. To the best of Avadel's and its Affiliates' knowledge, no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any Governmental Authority, or any Third Party, on the part of Avadel or any Affiliate thereof is required in connection with the execution, delivery and performance of this Agreement.

f. Avadel has disclosed in writing to Cerecor all Patents owned, controlled, or licensed by Avadel or its Affiliates as of the Effective Date which Cover the Initial LiquiTime Products containing [\*\*\*] and [\*\*\*], the Initial Tablet Product, the LiquiTime Technology, or the Tablet Technology, or which are necessary or appropriate to Develop, manufacture and Commercialize Products, the LiquiTime Technology, or the Tablet Technology, and all such Patents are set forth on Exhibit A attached hereto.

g. There are no inventors of Avadel Patents other than those listed as inventors on the Initial Avadel Patents as they exist as of the Effective Date, and no Avadel Patents are subject to any assignment of obligation of assignment, in whole or in part, to any Third Party.

h. No research or Development of the Avadel Technology, manufacture of Products, or research leading to the inventions Covered by the Avadel Patents was supported in whole or part by funding or grants by any governmental agency or philanthropic or charitable organization.

i. The Avadel Technology is wholly-owned by Avadel, free and clear of all mortgages, pledges, charges, liens, equities, security interests, shop rights, or other encumbrances or similar agreements, or any other obligation.

j. No Third Party or Affiliate of Avadel has any rights or ownership interest in any Avadel Technology, and neither Avadel nor any Affiliate thereof obtained rights to any of the Avadel Technology by license or any similar contract or agreement with any Third Party or Affiliate of Avadel.

k. Neither Avadel nor any Affiliate thereof is aware of any Third Party intellectual property rights (including any Patent(s)) that were (prior to the Effective Date) or would be (following the Effective Date) infringed, misappropriated, or otherwise

violated by the, or that are reasonably required for the anticipated, use, manufacture, sale, import, export, Development, or Commercialization of any Products.

l. No written or oral communication has been received by Avadel or any Affiliate thereof, and no investigation, regulatory enforcement action (including seizure, injunction, civil penalty or criminal action) or any related Governmental Authority or Regulatory Authority review is or, to the knowledge of the Avadel or any Affiliate thereof, was at any time pending or is threatened by any Governmental Authority or Regulatory Authority with respect to (i) any alleged or actual violation by the Avadel, any Affiliate thereof, or any contractor of either of the foregoing of any permit, Applicable Law or other requirement of any Governmental Authority or Regulatory Authority relating to the operations conducted by or on behalf of Avadel or any Affiliate thereof with respect to any Product, the LiquiTime Technology, the Tablet Technology, or any products incorporating, utilizing, or based on either of the foregoing or (ii) any alleged or actual failure to have or maintain in effect all permits required in connection with the operations conducted by or on behalf of Avadel or any Affiliate thereof with respect to any Product, the LiquiTime Technology, the Tablet Technology, or any products incorporating, utilizing, or based on either of the foregoing. Neither Avadel or any Affiliate thereof has received from the FDA, the U.S. Drug Enforcement Administration (“DEA”), or any similar state, local, federal, or foreign Governmental Authority or Regulatory Authority any written notice regarding the approvability or approval of any Products. With respect to any Products, the LiquiTime Technology, the Tablet Technology, or any products incorporating, utilizing, or based on either of the foregoing, no officer, employee or, to the knowledge of Avadel or any Affiliate thereof, agent of the Avadel has made any untrue statement of a material fact or a fraudulent statement to the FDA, DEA or any similar state, local, federal, or foreign Governmental Authority or Regulatory Authority, failed to disclose any material fact required to be disclosed to the FDA, the DEA or any similar state, local, federal, or foreign Governmental Authority or Regulatory Authority, or committed an act, made a statement or failed to make a statement that, at the time such act, statement or omission was made, could reasonably be expected to provide a basis for the FDA, the DEA or any similar state, local, federal or foreign Governmental Authority or Regulatory Authority to invoke the FDA’s policy respecting “Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities” set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy, nor has any director, officer, employee or, to the knowledge of Avadel or any Affiliate thereof, agent of Avadel or any Affiliate thereof been convicted of any crime or engaged in any conduct for which debarment is mandated by 21 U.S.C. Article 335a(a) (or any similar law, rule, or regulation) or authorized by 21 U.S.C. Article 335a(b) (or any similar law, rule, or regulation inside the United States or in any jurisdiction outside the United States).

m. To the knowledge of Avadel and its Affiliates, Avadel and its Affiliates have taken all reasonable actions necessary or appropriate to preserve the confidentiality of all trade secrets, proprietary and other confidential information material to Products and Avadel Technology.

n. Neither Avadel nor any Affiliate thereof is aware of any Third Party activities which would constitute misappropriation or infringement of any Avadel Technology.

o. To the actual knowledge of Avadel and its Affiliates, based on reasonable inquiry and investigation, all information provided to Cerecor, its Affiliates, and their employees, officers, directors, agents, and other representatives by or on behalf of Avadel or any Affiliate thereof with respect to Products, the Avadel Technology, the LiquiTime Technology, the Tablet Technology, or any products incorporating, utilizing, or based on either of the foregoing, has been accurate in all material respects.

p. All Development of Product performed by or on behalf of Avadel or any Affiliate thereof prior to the Effective Date was performed in all material respects in accordance with all Applicable Laws and, if reasonably applicable based on the type of work performed, GLP.

q. As of the Effective Date, there are no Patents owned, controlled, or licensed by Avadel or any Affiliate thereof Covering any portion of the Tablet Technology or the Initial Tablet Product.

**9.2 Representations and Warranties of Cerecor.** Cerecor represents and warrants to Avadel as follows as of the Effective Date:

a. Cerecor is a corporation, duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation, with full corporate power and authority to operate its properties and to carry on its business as presently conducted.

b. Cerecor has full power and authority to execute, deliver and perform this Agreement. This Agreement constitutes the legally binding and valid obligations of Cerecor, enforceable in accordance with their terms, except as such enforcement may be limited by applicable bankruptcy, moratorium and other laws affecting creditors' rights generally.

c. The execution, delivery and performance by Cerecor of this Agreement and the consummation of the transactions contemplated thereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any contract or agreement material to Cerecor, its business or its assets.

d. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any Governmental Authority on the part of Cerecor is required in connection with the execution, delivery and performance of this Agreement.

e. There is no action, suit, proceeding or investigation pending or, to Cerecor's knowledge, currently threatened against or affecting Cerecor or that questions the validity of this Agreement, or the right of Cerecor to enter into this Agreement or consummate



the transactions contemplated hereby and, to Cerecor's knowledge, there is no reasonable basis for the foregoing.

**9.3 Disclaimer.** EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT OR THE APA, INCLUDING SECTIONS 9.1 AND 9.2 HEREOF, AS APPLICABLE, THE PARTIES MAKE NO REPRESENTATIONS AND GRANT NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND THE PARTIES EACH SPECIFICALLY DISCLAIM ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OR AS TO THE SUCCESS OR LIKELIHOOD OF SUCCESS OF THE RESEARCH, DEVELOPMENT OR COMMERCIALIZATION OF ANY PRODUCT UNDER THIS AGREEMENT.

## **10. INDEMNITIES; LIMITS ON LIABILITY**

**10.1 Indemnification by Avadel.** Subject to Section 10.3, Avadel hereby agrees to defend, indemnify and hold harmless Cerecor, its Affiliates, Sublicensees, any contractors of any of the foregoing, and each of their directors, officers, employees, agents, and other representatives ("Cerecor Indemnitees") from and against all suits, claims, proceedings or causes of action brought by Third Parties ("Claims"), and all associated damages, liabilities, expenses and/or loss, including reasonable legal expenses and reasonable attorneys' fees ("Losses"), to the extent arising out of Avadel's, its Affiliates', or Avadel's or its Affiliates' officers', directors', employees', contractors', agents', or other representatives' (i) gross negligence or willful misconduct, (ii) breach of this Agreement, (iii) failure to comply with any Applicable Law, or (iv) manufacture, use, Development, Commercialization, import, or export of any Product(s) other than, for purposes of this clause (iv), the performance of the Avadel Development Program in accordance with this Agreement, except to the extent, in each case, resulting from the gross negligence or willful misconduct, breach of this Agreement, or failure to comply with Applicable Laws on the part of, in each case, any Cerecor Indemnitee.

**10.2 Indemnification by Cerecor.** Subject to Section 10.3, Cerecor hereby agrees to indemnify, defend and hold Avadel, its Affiliates, and Avadel's and its Affiliates' officers, directors, employees, agents, and other representatives (collectively, "Avadel Indemnitees") harmless from and against any Losses resulting from Claims brought against any Avadel Indemnitee(s) resulting from Cerecor's, its Affiliates', or any Sublicensees' (i) gross negligence or willful misconduct with respect to the subject matter of this Agreement, (ii) breach of this Agreement, (iii) failure to comply with Applicable Laws with respect to the subject matter of this Agreement, or (iv) manufacture, use, Development, Commercialization, import or export of any Product, except to the extent, in each case, resulting from the gross negligence or willful misconduct, breach of this Agreement, or failure to comply with Applicable Laws on the part of, in each case, any Avadel Indemnitee.

**10.3 Indemnification Procedures.** Each Party's agreement to indemnify, defend, and hold harmless under Section 10.1 or 10.2, as applicable, is conditioned upon the indemnified party (a) providing written notice to the indemnifying Party of any claim, demand or action

arising out of the indemnified matter as soon as reasonably possible, and in any event no later than within thirty (30) Calendar Days after the indemnified Party has actual knowledge of such claim, demand or action, (b) permitting the indemnifying Party to assume control over the investigation of, preparation and defense against, and settlement or voluntary disposition of any such claim, demand or action, (c) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation, preparation, defense, and settlement or voluntary disposition of any such claim, demand or action, and (d) not compromising, settling, or entering into any voluntary disposition of any such claim, demand or action without the indemnifying Party's prior written consent, which consent shall not be unreasonably withheld; provided, however, that, if the party entitled to indemnification fails to promptly notify the indemnifying Party pursuant to the foregoing clause (a), the indemnifying Party will only be relieved of its indemnification obligation to the extent materially prejudiced by such failure. In no event may the indemnifying Party compromise, settle, or enter into any voluntary disposition of any claim, demand or action in any manner that admits material fault or wrongdoing on the part of the indemnified party or incurs non-indemnified liability on the part of the indemnified party without the prior written consent of the indemnified party, and in no event may the indemnifying Party settle, compromise, or agree to any voluntary disposition of any matter subject to indemnification hereunder in any manner which may adversely affect any portion of the Avadel Technology, or Cerecor's ability to exploit Avadel Technology or Develop, manufacture, or Commercialize Products without Cerecor's prior written consent.

**10.4 Limitation of Liability.** IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT, PROVIDED THAT, NOTWITHSTANDING ANYTHING TO THE CONTRARY, THE FOREGOING SHALL NOT BE CONSTRUED TO LIMIT THE INDEMNITY OBLIGATIONS SET FORTH IN SECTIONS 10.1 AND 10.2 ABOVE OR EITHER PARTY'S LIABILITY FOR PATENT INFRINGEMENT OR BREACH OF SECTION 7.

**10.5 Insurance.** Each Party shall carry and maintain insurance of the types and in amounts which are reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size and activities. Such insurance will insure against all liability, including but not limited to, bodily injury or property damage arising out of the manufacture, sale, distribution, marketing, Development or Commercialization of Products. Such insurance shall include commercial general liability insurance, including product liability insurance, which coverage shall have limits of liability which are commercially reasonable for the U.S. pharmaceutical industry. Such coverage shall be maintained by each party for not less than three (3) Calendar Years following expiration or termination of this Agreement or, if such coverage is of the "claims made" type, for five (5) Calendar Years following expiration or termination of this Agreement. Upon written request from a Party, the other Party shall promptly provide written evidence (e.g., certificates) of such insurance that is reasonably satisfactory to the requesting Party.

## 11. MISCELLANEOUS

**11.1 Assignment.** Neither Party may assign this Agreement, or any of its rights or obligations hereunder without the other Party's prior written consent, provided that (X) neither Party will unreasonably withhold, condition, or delay any such consent sought by the other Party and (Y) either Party shall, notwithstanding anything to the contrary, be entitled, without the other Party's prior written consent, to assign or transfer this Agreement: (i) in connection with the transfer or sale of all or substantially all of such Party's assets or business (or that portion thereof related to the subject matter of this Agreement), (ii) in the event of such Party's merger, consolidation, reorganization, change of control or similar transaction, or (iii) to an Affiliate of such Party. Any permitted assignee of either Party shall, as a condition to such assignment, assume all obligations of its assignor arising under this Agreement following such assignment and any assignment to an Affiliate of any Party pursuant to Section 11.1(iii) shall not relieve the assigning Party of its obligations under this Agreement for so long as the applicable assignee remains an Affiliate of such assigning Party. Any purported assignment by a Party of this Agreement, or any of such Party's rights or obligations hereunder, in violation of this Section 11.1 shall be void.

**11.2 Severability.** If one or more provisions of this Agreement is held to be invalid, illegal or unenforceable, the Parties shall substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions which valid provisions are, in their economic effect, sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such provisions. In the event that such provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one or more provisions of this Agreement shall not affect the validity of this Agreement as a whole.

**11.3 Notices.** Any notice, consent or report required or permitted to be given or made under this Agreement by one Party to the other Party shall be in English and in writing, delivered personally or by U.S. first class mail or express courier providing evidence of receipt, postage prepaid (where applicable), at the following address for a Party (or such other address for a Party as may be specified by like notice):

To Cerecor:

Cerecor Inc.  
400 East Pratt Street, Suite 606  
Baltimore, MD 21202  
E-mail:  
Attention: Mariam Morris, Chief Financial Officer

To Avadel:

Avadel Ireland  
Block 10-1, Blanchardstown Corporate Park  
Ballycoolin, Dublin 15 Ireland  
Attention: General Counsel

With a copy (which shall not constitute notice) to:

Wyrick Robbins Yates & Ponton LLP  
4101 Lake Boone Trail, Suite 300  
Raleigh, NC 27607  
Attn: Donald R. Reynolds

With a copy (which shall not constitute notice) to:

Avadel Pharmaceuticals plc  
16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005  
Attention: Chief Executive Officer

All such notices, consents or reports shall be effective upon receipt.

**11.4 Applicable Law; Jurisdiction; Waiver of Jury Trial.**

a. THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, REGARDLESS OF THE LAWS THAT MIGHT OTHERWISE GOVERN UNDER APPLICABLE PRINCIPLES OF CONFLICTS OF LAWS THEREOF.

b. Each Party irrevocably submits to the exclusive jurisdiction of (i) the state courts of New York located in New York County, and (ii) the United States District Court for the Southern District of New York, for the purposes of any suit, action or other proceeding arising out of this Agreement. Each Party agrees to commence any such action, suit or proceeding either in the United States District Court for the Southern District of New York or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the state courts of New York located in New York County. Each Party further agrees that service of any process, summons, notice or document by the U.S. registered mail to such Party's respective address set forth above shall be effective service of process for any action, suit or proceeding in New York with respect to any matters to which it has submitted to jurisdiction in this Section 11.4.b. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the Contemplated Transactions in (x) the state courts of New York located in New York County, and (y) the United States District Court for the Southern District of New York, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

c. EACH PARTY WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY. Each Party (i) certifies that no representative, agent or attorney of the other Party has

represented, expressly or otherwise, that such Party would not, in the event of any action, suit or proceeding, seek to enforce the foregoing waiver and (ii) acknowledges that it and the other Party has been induced to enter into this Agreement, by, among other things, the mutual waiver and certifications in this Section 11.4.c.

**11.5 Entire Agreement.** This Agreement (including the Schedules or Exhibits attached hereto) contains the entire agreement by the Parties with respect to the subject matter hereof and supersedes any prior or contemporaneous express or implied agreements, understandings and representations, either oral or written, which may have related to the subject matter hereof in any way.

**11.6 Interpretation.** The captions to the several Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word “including” shall be deemed to be followed by the phrase “without limitation”, “including but not limited to”, or like expression; (b) the singular shall include the plural and *vice versa*; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable. The Parties expressly agree that any ambiguity in this Agreement shall not be construed against the Party who drafted this Agreement or the relevant provision hereof.

**11.7 Independent Contractors.** It is expressly agreed that Cerecor and Avadel shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency or other fiduciary relationship. Neither Cerecor nor Avadel shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party to do so.

**11.8 Waiver; Amendment.** Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. The delay or failure of any Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party’s rights at a later time to enforce the same. This Agreement may be amended, and any term of this Agreement may be modified, only by a written instrument executed by a duly authorized representative of each Party.

**11.9 Binding Effect.** This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

**11.10 Force Majeure.** Neither Party shall be liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Agreement, for delay or failure in the performance of any of its obligations hereunder to the extent, and for so long as, such delay or failure is due to causes beyond its reasonable control, which may include, without limitation, acts of nature, fires, earthquakes, strikes and labor disputes, acts of war, terrorism, or civil unrest (“**Force Majeure**”); provided that the affected Party promptly notifies the other Party and further provided that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall

continue performance with the utmost dispatch whenever such causes are removed. In the event any such Force Majeure event continues for three (3) months or more, the unaffected Party shall have the right to terminate this Agreement, effective as of the date of delivery of notice, which notice shall not be delivered prior to the end of such three (3) month period.

**11.11 Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile and other electronically scanned signatures shall have the same effect as their originals.

**11.12 United States Dollars.** References in this Agreement to “Dollars”, “dollars”, or “\$” shall mean the legal tender of the United States of America.

**11.13 No Strict Construction.** This Agreement has been prepared jointly and shall not be strictly construed against either Party.

**11.14 Responsibility for Affiliates.** The Parties recognize that each Party may perform some or all of its obligations, or exercise its rights, under this Agreement through such Party’s Affiliates, provided, however, that each Party shall remain responsible for the payment and performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement. Any breach of any provision of this Agreement by any Affiliate of a Party shall be deemed a breach hereof by such Party, with such Party being liable hereunder with respect to such breach as if such Party itself had breached this Agreement.

**11.15 Guarantee.** Avadel Seller hereby fully and unconditionally guarantees Avadel’s, and each of Avadel’s Affiliates’, compliance with, and performance of Avadel’s obligations under, this Agreement. Avadel Seller expressly waives any requirement that Cerecor exhaust any right, power or remedy or proceed against Avadel or any Affiliate thereof for any obligation or performance hereunder.

**[SIGNATURE PAGE TO FOLLOW.]**

IN WITNESS WHEREOF, the Parties have executed this Agreement by their proper officers as of the date and year first above written.

**Flamel Ireland Limited**

BY: /s/ Phillandas T. Thompson

NAME: Phillandas T. Thompson

TITLE: Director

**Cerecor, Inc.**

BY: /s/ Robert Moscato

NAME: Robert Moscato

TITLE: President and Director

Solely for purposes of Section 11.15:

**Avadel Pharmaceuticals plc**

BY: /s/ Michael S. Anderson

NAME: Michael S. Anderson

TITLE: Chief Executive Officer

**CONFIDENTIAL TREATMENT REQUESTED**

**THE PORTIONS OF THIS AGREEMENT MARKED WITH ASTERISKS WITHIN BRACKETS (“[\*\*\*]”) HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER 17 C.F.R. SECTIONS 200.80(B)(4), 200.83 AND 230.406. A COMPLETE COPY OF THIS AGREEMENT HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.**

**GUARANTEE**

**GUARANTEE**, dated as of February 16, 2018 (this “**Guarantee**”), made by Avadel US Holdings, Inc. and Avadel Pharmaceuticals plc (the “**Guarantors**”), in favor of Deerfield CSF, LLC, Peter Steelman and James Flynn (each, a “**Guaranteed Party**” and collectively, the “**Guaranteed Parties**”).

WHEREAS, the Guarantors, certain of their affiliated parties and the Guaranteed Parties are parties to that certain Membership Interest Purchase Agreement, dated February 5, 2016 (the “**MIPA**”);

WHEREAS, the Guarantors and its affiliated parties have entered into an Asset Purchase Agreement with Cerecor, Inc. (“**Debtor**”), dated February 12, 2018 (the “**APA**”);

WHEREAS, under the APA, the Guarantors have agreed to assign certain of their rights and obligations under the MIPA to Debtor and Debtor has agreed to assume such rights and obligations and the Guaranteed Parties shall file all necessary documents and instruments with the relevant Governmental authorities on order to effect such release and assignment (the “**Assignment**”);

WHEREAS, in connection with the Assignment, the Guaranteed Parties have requested that the Guarantors provide this Guarantee to the Guaranteed Parties; and

WHEREAS, the Guarantors are willing to provide such Guarantee.

NOW THEREFORE, for valuable consideration, the receipt and sufficiency of which are hereby conclusively acknowledged by the Guarantors, each Guarantor hereby agrees in favor of the Guaranteed Parties as follows:

1. **Guarantee.** Each Guarantor hereby, jointly and severally, unconditionally and irrevocably, as a primary obligor and not only a surety, guarantees the prompt payment and performance to the Guaranteed Parties when due of any amounts or obligations set forth in Section 1.2(a), Section 1.6(a), Section 1.6(b), and Section 1.6(g) of the MIPA (whether direct or indirect, joint or several, absolute or contingent, matured or unmatured) (collectively, the “**Primary Obligations**”). Each Guarantor further jointly and severally agrees that, with respect to Debtor’s obligation to pay the Deferred Payments pursuant to Section 1.6(a) of the MIPA, if the aggregate of the Deferred Payments



made by Debtor in any full calendar year between (and including) 2018 and 2025 is less than \$[\*\*\*], then the Guarantors shall pay to the Guaranteed Parties the amount of such deficiency (the “**Deferred Obligation**”), it being agreed that the foregoing Deferred Obligation shall be prorated for calendar year 2026, if Debtor's obligation to pay the Deferred Payments is still in effect in such year; provided, however, that if Debtor’s obligation to pay the Deferred Payments terminates because \$12,500 of Deferred Payments has been paid in the aggregate to the Guaranteed Parties, the foregoing obligation of Guarantors shall no longer be in effect. The Deferred Payment Obligation and the Primary Obligations hereinafter collectively referred to as, the “**Obligations**”.

2. **Payment by Guarantor.** If all or any part of the Obligations shall not be punctually paid when due, whether at demand, maturity, acceleration or otherwise, each Guarantor shall, immediately upon demand by the Guaranteed Parties, and without presentment protest, notice of protest, notice of non-payment, notice of intention to accelerate the maturity, notice of acceleration of the maturity, or any other notice whatsoever, but subject to the other terms of this Guarantee, pay in lawful money of the United States of America, the amount then due on the Obligations to each Guaranteed Party at the Guaranteed Party’s address set forth herein. Such demand(s) may be made at any time coincident with or after the time with respect to the same or different items of Obligations. Such demand shall be deemed made, given and received in accordance with the notice provisions hereof.

3. **Release of Security Interests.** Upon payment in full of all of the Obligations by the Guarantors under this Guarantee, the Guaranteed Parties shall release and assign its first priority lien and security interest in the FSC Assets Collateral (as defined in the MIPA) in favor of the Guarantors.

4. **No Duty To Pursue Others.** It shall not be necessary for the Guaranteed Parties (and each Guarantor hereby waives any rights that the Guarantor may have to require the Guaranteed Parties), in order to enforce the obligations of the Guarantor hereunder, first to (i) institute suit or exhaust its remedies against Debtor or any other party that may be liable on the Obligations, (ii) enforce the Guaranteed Parties’ rights against any collateral which shall have been given to secure the Obligations, (iii) enforce the Guaranteed Parties’ rights against any other guarantors of the Obligations, (iv) join Debtor or any other party liable on the Obligations in any action seeking to enforce this Guarantee, or (v) resort to any other means of obtaining payment of the Obligations; provided, however, that if the Guaranteed Parties enforces its rights against collateral given by Debtor or the Guarantor, the Obligations shall be reduced accordingly.

5. **Amount.** The aggregate amount covered by this Guarantee shall not exceed \$[\*\*\*], plus reasonable costs and expenses, if any, including reasonable attorneys’ fees, incurred by the Guaranteed Parties to enforce any of its rights hereunder; provided, however, that such costs and expenses shall be payable by the Guarantors only to the extent the Guaranteed Parties are successful in enforcing this Guarantee (collectively, the “**Guaranteed Cap**”). Each Guarantor’s liability under this Guarantee is specifically limited to the payment and performance of the Obligations (even if such Obligations are deemed to be damages).

6. **Release of Obligations.** This Guarantee will remain in full force and effect until all of the Obligations are irrevocably and unconditionally performed and paid in full or Debtor ceases to have any obligations in respect thereof in accordance with the terms of the Agreement.
7. **Nature of Guarantee.** This Guarantee may not be revoked by the Guarantors and shall continue to be effective with respect to any Obligations arising or created after any attempted revocation by the Guarantors. In the event that any payment of the Debtor to the Guaranteed Parties in respect of any Obligations is rescinded or must otherwise be returned to the Debtor or surrendered to any person for any reason whatsoever, then the Obligations or part thereof intended to be satisfied shall be reinstated or returned by the Guaranteed Parties to the Guarantors, and this Guarantee shall continue to be effective as if such payment had not been made or value received notwithstanding any revocation thereof; provided, however, that the Guaranteed Cap shall be reduced by the amount of such rescinded or returned payment.
8. **Obligations Not Reduced by Offset.** The Obligations and the liabilities and obligations of Guarantors to the Guaranteed Parties hereunder shall not be reduced, discharged, or released because or by reason of any existing or future offset, claim or defense of Debtor, or any other party, against a Guaranteed Party or against payment of the Obligations, whether such offset, claim or defense arises in connection with the Obligations (or the transactions creating the Obligations) or otherwise; provided, however, that if a Guaranteed Party proceeds against the Guarantors under the Obligations, the Guarantors shall be afforded all rights and defenses against such claim as would be available to the Debtor in connection with such claim.
9. **Liability Absolute.** Without limiting the generality of the foregoing, the liability of the Guarantors will not be released, discharged, diminished, limited or otherwise affected by: (i) any change in the name, existence, structure, powers, business, constitution, objects, capital, constating documents, by-laws, control or ownership of the Debtor, the Guarantor or any other person, or (ii) any insolvency, bankruptcy, reorganization or other similar proceeding affecting the Debtor, it being the intention of the Debtor and the Guarantor that the Guarantor's obligations hereunder shall not be discharged except by (a) the Guarantor's or Debtor's performance of such obligations, and then only to the extent of such performance, or (b) any other termination of such obligations, and then only to the extent of such termination.
10. **Waivers.** Guarantor agrees to the provisions of the Agreement, and hereby waives notice of (i) acceptance of this Guarantee, (ii) any amendment of the Agreement, (iii) the execution and delivery by Debtor and the Guaranteed Parties of any other agreement arising under or in connection with the Agreement, (iv) the occurrence of any breach by Debtor or an event of default; (v) the Guaranteed Parties' transfer or disposition of the Obligations, or any part thereof, (vi) protest, proof of non-payment or default by Debtor, or (vii) any other action at any time taken or omitted by a Guaranteed Party, and, generally, all demands and notices of every kind in connection with this Guarantee or the Agreement, any documents or agreements evidencing, securing or relating to any of the Obligations and the obligations hereby guaranteed. Each Guarantor waives (a) diligence, presentment, protest, demand for payment and notice of default or nonpayment to or upon Buyer or any of the them with respect to the Obligations, (b) notice of the existence or creation or non-

payment of all or any of the Obligations, and (c) all diligence in collection or protection of or realization upon any Obligations or any guaranty of any Obligations.

11. **Governing Law; Attornment.** This Guarantee shall be governed by and construed in accordance with the domestic laws of the State of Delaware without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of Delaware. Any action, suit or other proceeding, at law or in equity, arising out of or relating to this Agreement or any agreements or transactions contemplated hereby shall only be brought in any state or federal court located in Delaware. THE PARTIES AGREE THAT JURISDICTION AND VENUE IN ANY ACTION BROUGHT BY ANY PARTY PURSUANT TO THIS AGREEMENT SHALL PROPERLY AND EXCLUSIVELY LIE IN SUCH COURTS. BY EXECUTION AND DELIVERY OF THIS AGREEMENT, EACH PARTY IRREVOCABLY AND EXCLUSIVELY SUBMITS TO THE JURISDICTION OF SUCH COURTS FOR ITSELF AND IN RESPECT OF ITS PROPERTY WITH RESPECT TO SUCH ACTION. THE PARTIES IRREVOCABLY AGREE THAT VENUE WOULD BE PROPER IN SUCH COURT, AND HEREBY WAIVE ANY OBJECTION THAT SUCH COURT IS AN IMPROPER OR INCONVENIENT FORUM FOR THE RESOLUTION OF SUCH ACTION. THE PARTIES FURTHER AGREE THAT THE MAILING BY CERTIFIED OR REGISTERED MAIL, RETURN RECEIPT REQUESTED, OF ANY PROCESS REQUIRED BY ANY SUCH COURT SHALL CONSTITUTE VALID AND LAWFUL SERVICE OF PROCESS AGAINST THEM, WITHOUT NECESSITY FOR SERVICE BY ANY OTHER MEANS PROVIDED BY STATUTE OR RULE OF COURT. EACH PARTY HERETO HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT TO ANY PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (I) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (II) IT UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF SUCH WAIVER, (III) IT MAKES SUCH WAIVER VOLUNTARILY, AND (IV) IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN PARAGRAPH.

12. **Successors and Assigns.** The provisions of this Guarantee will be binding upon and inure to the benefit of the Guaranteed Parties and will be binding upon each Guarantor and its successors. This Guarantee may not be assigned by the Guarantors or the Guaranteed Parties without the prior written consent of the other.

13. **Severability.** Wherever possible, any provision in this Guarantee which is held invalid or unenforceable by a court of competent jurisdiction from which no further appeal has or is taken shall, as to such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating the remaining provisions of this Guarantee, and any such invalidity or unenforceability in any one jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

14. **Notice.** All notices, requests, claims, demands and other communications hereunder shall be given (and shall be deemed to have been duly given upon receipt) by hand delivery, by prepaid overnight courier (providing written proof of delivery), by transmission-mail (with confirmation of transmission other than by means of an automatically-generated reply) or by certified or registered mail (return receipt requested and first class postage prepaid), addressed as follows (or at such other address for a party as shall be specified by like notice):

If to the Guaranteed Parties:

780 Third Avenue  
37th Floor  
New York, NY 10017  
Fax: (212) 573-8111  
E-mail:  
Attention: James E. Flynn

Peter Steelman  
David J. Clark

with a copy to (which shall not constitute notice):

Robinson, Bradshaw & Hinson, P.A.  
101 North Tryon Street, Suite 1900  
Charlotte, NC 28246  
Fax: (704) 339-3428  
E-mail:  
Attention: Mark O. Henry

If to the Guarantor:

Avadel US Holdings, Inc.  
16640 Chesterfield Grove Rd.  
Suite 200  
Chesterfield, MO 63005

Attn: Chief Financial Officer

with a copy (which shall not constitute notice) to:

General Counsel

and with a copy (which shall not constitute notice) to:

Orrick, Herrington & Sutcliffe LLP  
51 W. 52nd St.  
New York, NY 10019  
Attn: R. King Milling, Jr.; Tal Hacohen

e-mail:

provided that any notice received at the addressee's location on any business day after 5:00 p.m. (addressee's local time) shall be deemed to have been received at 9:00 a.m. (addressee's local time) on the next business day.

15. **Amendment.** No term or provision of this Guarantee shall be amended, modified, altered, waived or supplemented except in a writing signed by Guarantors and the Guaranteed Parties.

**[The remainder of this page has been intentionally left blank.]**

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[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

**THIS GUARANTEE** executed effective the date first written above.

Avadel US Holdings, Inc.

By: /s/ Phillandas T. Thompson  
Name: Phillandas T. Thompson  
Title: Secretary

Avadel Pharmaceuticals plc

By: /s/ Michael S. Anderson  
Name: Michael S. Anderson  
Title: Chief Executive Officer

[Signature Page to Avadel Guarantee]

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

Acknowledged and Accepted:

Deerfield CSF, LLC

By: /s/ David J. Clark

Name: David J. Clark

Title: Manager

/s/ Peter Steelman

Peter Steelman

/s/ James Flynn

James Flynn

[Signature Page to Avadel Guarantee]

[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

**CONFIDENTIAL TREATMENT REQUESTED**

**THE PORTIONS OF THIS AGREEMENT MARKED WITH ASTERISKS WITHIN BRACKETS (“[\*\*\*]”) HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT UNDER 17 C.F.R. SECTIONS 200.80(B)(4), 200.83 AND 230.406. A COMPLETE COPY OF THIS AGREEMENT HAS BEEN FILED SEPARATELY WITH THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION.**

**GUARANTEE**

**GUARANTEE**, dated as of February 16, 2018 (this “**Guarantee**”), by Armistice Capital Master Fund, Ltd. (the “**Guarantor**”), in favor of Avadel US Holdings, Inc. (the “**Guaranteed Party**”).

WHEREAS, Deerfield CSF, LLC, Peter Steelman and James Flynn (each, a “**Deerfield Party**” and collectively, the “**Deerfield Parties**”), the Guaranteed Party, and certain of its affiliated parties are parties to that certain Membership Interest Purchase Agreement, dated February 5, 2016 (the “**MIPA**”);

WHEREAS, the Guaranteed Party and certain of its affiliated parties have entered into an Asset Purchase Agreement with Cerecor, Inc. (“**Debtor**”), dated February 12, 2018 (the “**APA**”);

WHEREAS, under the APA, the Guaranteed Party has agreed to assign certain of its rights and obligations under the MIPA to Debtor and Debtor has agreed to assume such rights and obligations (the “**Assignment**”);

WHEREAS, notwithstanding the Assignment, the Guaranteed Party remains obligated to the Deerfield Parties under such assigned rights and obligations;

WHEREAS, in connection with the Assignment, the Guaranteed Party has requested that the Guarantor provide this Guarantee to the Guaranteed Party; and

WHEREAS, the Guarantor will benefit from the transactions contemplated by the APA and is willing to provide such Guarantee covering all of the obligations set forth in this Guarantee.

NOW THEREFORE, for valuable consideration, the receipt and sufficiency of which are hereby conclusively acknowledged by the Guarantor, the Guarantor hereby agrees in favor of the Guaranteed Party as follows:

1. **Guarantee.** The Guarantor hereby unconditionally and irrevocably guarantees, for the direct third party benefit of the Guaranteed Party, the prompt payment and performance by Debtor to the Deerfield Parties of any amounts set forth in Section 1.2(a), Section 1.6(a), Section 1.6(b), and Section 1.6(g) of the MIPA (whether direct or indirect, joint or several, absolute or contingent,



matured or unmatured). The Guarantor hereby irrevocably and unconditionally covenants and agrees that it is liable for the Obligations as a primary obligor, subject to the terms of this Guarantee (collectively, the “**Primary Obligations**”). The Guarantor further agrees in connection with the foregoing guarantee that, if the Guaranteed Party becomes obligated to pay to the Deerfield Party (1) all or any part of the Obligations or (2) the difference between (x) the aggregate Deferred Payments pursuant to Section 1.6(a) of the MIPA in any full calendar year between (and including) 2018 and 2025 and (y) \$[\*\*\*] (or the prorated portion of such amount for 2026), then the Guarantor shall pay to the Guaranteed Party the amount of such difference (the “**Deferred Obligation**”). The Deferred Payment Obligation and the Primary Obligations hereinafter collectively referred to as, the “**Obligations**”.

2. **Payment by Guarantor.** If all or any part of the Obligations shall not be punctually paid when due, whether at demand, maturity, acceleration or otherwise, the Guarantor shall, without presentment protest, notice of protest, notice of non-payment, notice of intention to accelerate the maturity, notice of acceleration of the maturity, or any other notice whatsoever, but subject to the other terms of this Guarantee, pay in lawful money of the United States of America, the amount then due on the Obligations to the Guaranteed Party at the Guaranteed Party’s address set forth herein. Such demand(s) may be made at any time coincident with or after the time any of the Obligations become due. Such demand shall be deemed made, given and received in accordance with the notice provisions hereof.

3. **No Duty To Pursue Others.** It shall not be necessary for the Guaranteed Party (and the Guarantor hereby waives any rights that the Guarantor may have to require the Guaranteed Party), in order to enforce the obligations of the Guarantor hereunder, first to (i) institute suit or exhaust its remedies against Debtor or any other party that may be liable on the Obligations, (ii) enforce the Guaranteed Party’s rights against any collateral which shall have been given to secure the Obligations, (iii) enforce the Guaranteed Party’s rights against any other guarantors of the Obligations, (iv) join Debtor or any other party liable on the Obligations in any action seeking to enforce this Guarantee, (v) exhaust any remedies available to the Guaranteed Party against any collateral which shall ever have been given to secure the Obligations, or (vi) resort to any other means of obtaining payment of the Obligations. Without limiting the generality of the foregoing, and notwithstanding anything to the contrary contained herein, the Guaranteed Party shall be entitled to claim against Guarantor as primary obligor under the Obligations if and when the Guaranteed Party becomes liable for them, without first having to make any claims against the Debtor.

4. **Release of Obligations.** This Guarantee will remain in full force and effect until the Obligations are irrevocably and unconditionally performed and paid in full or Debtor ceases to have any obligations in respect thereof in accordance with the terms of the APA.

5. **Representations and Warranties.** Guarantor represents and warrants that: (a) Guarantor is a duly organized and validly existing Cayman Islands exempt company in good standing under the laws of the jurisdiction of its organization; (b) this Guarantee has been duly executed and delivered by the Guarantor and constitutes a legal, valid and binding obligation of the Guarantor, enforceable against the Guarantor in accordance with its terms; (c) the execution, delivery and performance of this Guarantee have been duly authorized by all necessary action and will not violate

(i) the organizational documents of Guarantor, (ii) any order, judgment or decree to which Guarantor or any of its assets may be subject, (iii) any contract to which Guarantor is a party, or (iv) any law applicable to Guarantor; and (d) Guarantor is currently solvent and will not be rendered insolvent by providing this Guarantee.

6. **Nature of Guarantee.** This Guarantee is an irrevocable, absolute, continuing guarantee of payment and performance and not a guarantee of collection. This Guarantee may not be revoked by the Guarantor and shall continue to be effective with respect to any Obligations arising or created after any attempted revocation by the Guarantor. The fact that at any time or from time to time the Obligations may be increased or reduced shall not release or discharge the obligation of Guarantor to the Guaranteed Party and shall not be discharged by the assignment or negotiation of all or part of the Obligations. In the event that any payment of the Debtor to the Deerfield Parties in respect of any Obligations is rescinded or must otherwise be returned to the Debtor or surrendered to any person for any reason whatsoever, then the Obligations or part thereof intended to be satisfied shall be reinstated or returned by the Deerfield Parties to the Guaranteed Party, and this Guarantee shall continue to be effective as if such payment had not been made or value received notwithstanding any revocation thereof; provided, however, that the Guaranteed Cap shall be reduced by the amount of such rescinded or returned payment.

7. **Obligations Not Reduced by Offset.** The Guarantor agrees to be bound by the Assignment as though Guarantor were a party to the APA with respect to the provisions thereof relating to the Assignment. The Obligations and the liabilities and obligations of Guarantor to the Guaranteed Party hereunder shall not be reduced, discharged, or released because or by reason of any existing or future offset, claim or defense of Debtor, or any other party, against the Guaranteed Party or against payment of the Obligations, whether such offset, claim or defense arises in connection with the Obligations (or the transactions creating the Obligations) or otherwise; provided, however, that if the Guaranteed Party proceeds against the Guarantor under the Obligations, the Guarantor shall be afforded all rights and defenses against such claim as would be available to the Debtor in connection with such claim.

8. **Liability Absolute.** Without limiting the generality of the foregoing, the liability of the Guarantor will not be released, discharged, diminished, limited or otherwise affected by: (i) any change in the name, existence, structure, powers, business, constitution, objects, capital, constating documents, by-laws, control or ownership of the Debtor, the Guarantor or any other person, or (ii) any insolvency, bankruptcy, reorganization or other similar proceeding affecting the Debtor, it being the intention of the Debtor and the Guarantor that the Guarantor's obligations hereunder shall not be discharged except by (a) the Guarantor's or Debtor's performance of such obligations, and then only to the extent of such performance, or (b) any other termination of such obligations, and then only to the extent of such termination.

9. **Waivers.** Guarantor agrees to the relevant provisions of the APA, and hereby waives notice of (i) acceptance of this Guarantee, (ii) any amendment of the APA, (iii) the execution and delivery by Debtor and the Guaranteed Party of any other agreement arising under or in connection with the APA, (iv) the occurrence of any breach by Debtor or an event of default; (v) the Guaranteed Party's transfer or disposition of the Obligations, or any part thereof, (vi) protest, proof of non-payment or

default by Debtor, or (vii) any other action at any time taken or omitted by a Guaranteed Party, and, generally, all demands and notices of every kind in connection with this Guarantee or the APA, any documents or agreements evidencing, securing or relating to any of the Obligations and the obligations hereby guaranteed.

10. **Limitation of Liability.** Notwithstanding anything to the contrary in this Guarantee, the Guarantor shall not be liable for special, consequential, incidental, punitive, exemplary, equitable or indirect damages (whether or not arising from a party's negligence), lost profits or other business interruption damages, by statute, in tort or contract, under any indemnity provision or otherwise.

11. **Governing Law; Attornment.** This Guarantee shall be governed by and construed in accordance with the domestic laws of the State of New York without giving effect to any choice or conflict of law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New York. Any action, suit or other proceeding, at law or in equity, arising out of or relating to this Agreement or any agreements or transactions contemplated hereby shall only be brought in any federal court located in New York County, New York State. THE PARTIES AGREE THAT JURISDICTION AND VENUE IN ANY ACTION BROUGHT BY ANY PARTY PURSUANT TO THIS AGREEMENT SHALL PROPERLY AND EXCLUSIVELY LIE IN SUCH COURTS. BY EXECUTION AND DELIVERY OF THIS AGREEMENT, EACH PARTY IRREVOCABLY AND EXCLUSIVELY SUBMITS TO THE JURISDICTION OF SUCH COURTS FOR ITSELF AND IN RESPECT OF ITS PROPERTY WITH RESPECT TO SUCH ACTION. THE PARTIES IRREVOCABLY AGREE THAT VENUE WOULD BE PROPER IN SUCH COURT, AND HEREBY WAIVE ANY OBJECTION THAT SUCH COURT IS AN IMPROPER OR INCONVENIENT FORUM FOR THE RESOLUTION OF SUCH ACTION. THE PARTIES FURTHER AGREE THAT THE MAILING BY CERTIFIED OR REGISTERED MAIL, RETURN RECEIPT REQUESTED, OF ANY PROCESS REQUIRED BY ANY SUCH COURT SHALL CONSTITUTE VALID AND LAWFUL SERVICE OF PROCESS AGAINST THEM, WITHOUT NECESSITY FOR SERVICE BY ANY OTHER MEANS PROVIDED BY STATUTE OR RULE OF COURT. EACH PARTY HERETO HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT TO ANY PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY. EACH PARTY CERTIFIES AND ACKNOWLEDGES THAT (I) NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (II) IT UNDERSTANDS AND HAS CONSIDERED THE IMPLICATIONS OF SUCH WAIVER, (III) IT MAKES SUCH WAIVER VOLUNTARILY, AND (IV) IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN PARAGRAPH.

12. **Successors and Assigns.** The provisions of this Guarantee will be binding upon and inure to the benefit of the Guaranteed Party and will be binding upon the Guarantor and its successors.

This Guarantee may not be assigned by the Guarantor or the Guaranteed Party without the prior written consent of the other.

13. **Severability.** Wherever possible, any provision in this Guarantee which is held invalid or unenforceable by a court of competent jurisdiction from which no further appeal has or is taken shall, as to such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating the remaining provisions of this Guarantee, and any such invalidity or unenforceability in any one jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

14. **Notice.** All notices, requests, claims, demands and other communications hereunder shall be given (and shall be deemed to have been duly given upon receipt) by hand delivery, by prepaid overnight courier (providing written proof of delivery), by transmission-mail (with confirmation of transmission other than by means of an automatically-generated reply) or by certified or registered mail (return receipt requested and first class postage prepaid), addressed as follows (or at such other address for a party as shall be specified by like notice):

If to the Guaranteed Party:

Avadel US Holdings, Inc.  
16640 Chesterfield Grove Rd.  
Suite 200  
Chesterfield, MO 63005

Attn: Chief Financial Officer

with a copy (which shall not constitute notice) to:

General Counsel

and with a copy (which shall not constitute notice) to:

Orrick, Herrington & Sutcliffe LLP  
51 W. 52nd St.  
New York, NY 10019  
Attn: R. King Milling, Jr.; Tal Hacohen  
e-mail:

If to the Guarantor:

Armistice Capital Master Fund, Ltd.  
510 Madison Avenue; 22nd Floor  
New York, NY 10022  
Attn: Steve Boyd  
E-mail:

provided that any notice received at the addressee's location on any business day after 5:00 p.m. (addressee's local time) shall be deemed to have been received at 9:00 a.m. (addressee's local time) on the next business day.

15. **Entire Agreement.** This Guarantee embodies the entire agreement and understanding between Guarantor and the Guaranteed Party and supersedes all prior agreements and understandings relating to the subject matter of this Guarantee. No term or provision of this Guarantee shall be amended, modified, altered, waived or supplemented except in a writing signed by Guarantor and the Guaranteed Party. This Guarantee supersedes and replaces all other guarantees issued by the Guarantor in favour of the Guaranteed Party, and all other obligations and liabilities guaranteed by the Guarantor under the previous guarantees shall be considered Obligations hereunder as of the effective date of this Guarantee.

**[The remainder of this page has been intentionally left blank.]**

**THIS GUARANTEE** executed effective the date first written above.

**Armistice Capital Master Fund, Ltd.**

By: /s/ Steven Boyd  
Name: Steven Boyd  
Title: Chief Investment Officer

Acknowledged and accepted:

**Avadel US Holdings, Inc.**

By: /s/ Michael F. Kanan  
Name: Michael F. Kana  
Title: Treasurer

*[Project Spartan – Guarantee (Armistice Capital)]*

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[CONFIDENTIAL TREATMENT REQUESTED BY AVADEL PHARMACEUTICALS PLC]

## List of Subsidiaries

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

CONSENT OF  
INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-219016, 333-177591, 333-212585, 333-213154) and on Form S-3 (No. 333-183961) of Avadel Pharmaceuticals plc (formerly Flamel Technologies S.A.) of our report dated March 15, 2016, except for the effects of the revisions discussed in Note 1 (not presented herein) to the consolidated financial statements appearing under Item 8 of the Company's 2016 annual report on Form 10-K, as to which the date is March 28, 2017, relating to the financial statements and financial statement schedule, which appears in this Form 10-K.

Lyon, France,  
March 16, 2018

/s/ PricewaterhouseCoopers Audit

Represented by  
/s/ Frédéric Charcosset  
Frédéric Charcosset



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 16, 2018, 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, 2017.

/s/ Deloitte and Touche LLP

St. Louis, Missouri

March 16, 2018

**Exhibit 31.1**  
**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**

I, Michael S. Anderson, 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 16, 2018

/s/ Michael S. Anderson

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Michael S. Anderson

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 16, 2018

/s/ Michael F. Kanan

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Michael F. Kanan

Senior Vice President and Chief Financial Officer

**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, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael S. Anderson, 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/ Michael S. Anderson

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Michael S. Anderson  
Chief Executive Officer  
Avadel Pharmaceuticals plc  
March 16, 2018

**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, 2017, 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

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Michael F. Kanan

Senior Vice President and Chief Financial Officer

Avadel Pharmaceuticals plc

March 16, 2018