UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **February 14, 2018**

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland	**001-37977**	**98-1341933**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

Block 10-1 **Blanchardstown Corporate Park,** **Ballycoolin** **Dublin 15, Ireland**	**Not Applicable**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **+353 1 485 1200**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 8.01 Other Events.

Updated Business Description and Risk Factors

Avadel Pharmaceuticals plc (the "Company") has updated its business description and risk factors for purposes of its registration statements and reports filed with the Securities and Exchange Commission pursuant to the Securities Act of 1933 and the Securities Exchange Act of 1934, respectively. The updated business description is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference, and the updated risk factors are filed as Exhibit 99.2 to this Current Report on Form 8-K and are incorporated herein by reference.

This Current Report on Form 8-K and the exhibits incorporated by reference herein contain forward-looking statements. The Company may make additional written or oral forward-looking statements from time to time, including in the Company's filings with the SEC or otherwise. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project" and similar expressions, and the negatives thereof, identify forward-looking statements, each of which speaks 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, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Although we believe that the forward-looking statements contained in this Current Report on Form 8-K are based on reasonable assumptions within the bounds of the Company's knowledge of its business and operations, the Company's business is subject to significant risks and there can be no assurance that actual results of the Company's research, development and commercialization activities and its results of operations will not differ materially from the expectations expressed in the forward-looking statements contained in this Current Report on Form 8-K.

Forward-looking statements are subject to inherent risks (including the risks identified in Exhibit 99.2 to this Current Report on Form 8-K) 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. Except as required by law, we specifically disclaim any obligation to update such forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1		Updated Business Description of Avadel Pharmaceuticals plc dated February 14, 2018
99.2		Updated Risk Factors of Avadel Pharmaceuticals plc dated February 14, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AVADEL PHARMACEUTICALS PLC

By: /s/ Phillandas T. Thompson
Phillandas T. Thompson
Senior Vice President, General Counsel
and Corporate Secretary

Date: February 14, 2018

99.1		Updated Business Description of Avadel Pharmaceuticals plc dated February 14, 2018
99.2		Updated Risk Factors of Avadel Pharmaceuticals plc dated February 14, 2018

BUSINESS OF AVADEL

General Overview

Avadel Pharmaceuticals plc ("Avadel") is a branded specialty pharmaceutical company. Avadel's current revenues are primarily derived from products it markets 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 its urology product, Noctiva™, which it in-licensed in 2017 and will begin marketing in 2018. Avadel also seeks to develop products that utilize its Micropump® drug delivery technology, such as its 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 with an expected NDA filing in 2018. In addition, Avadel is are currently enrolling patients in its 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 UMD and Micropump® based product candidates for development and approval, and will also look for synergistic acquisition targets to grow its company.

Corporate Information

Avadel 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. Its 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, and its website is www.avadel.com. Avadel's website is not incorporated into this Current Report on Form 8-K.

Avadel is the successor to Flamel Technologies S.A., a French *société anonyme* ("Flamel"), as the result of the merger of Flamel with and into Avadel 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, Avadel 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 Avadel continued as the surviving entity and assumed all of the assets and liabilities of Flamel;
- Avadel's authorized share capital is $5,500,000 divided into 500,000,000 ordinary shares with a nominal value of $0.01 each and 50,000,000 preferred shares with a nominal value of $0.01 each, and €25,000 divided into 25,000 deferred ordinary shares with a nominal value of €1.00 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 Avadel, $0.01 nominal value per share. This change in nominal value of Avadel's outstanding shares resulted in its reclassifying $5,936,928 on its balance sheet from ordinary shares to additional paid-in capital;
    - Avadel's 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 authority 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; 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 Avadel.

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

References in this "Business of Avadel" to "Avadel" 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 Avadel'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 Avadel's definitive proxy statement filed with the SEC on July 5, 2016 ("2016 Proxy").

Under Irish law, Avadel can only pay dividends and repurchase shares out of distributable reserves, as discussed further in the 2016 Proxy. Upon completion of the Merger, Avadel did not have any distributable reserves. On February 15, 2017, Avadel filed a petition with the High Court of Ireland seeking the court's confirmation of a reduction of Avadel'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 Avadel's share premium arising pursuant to the Merger by $317.3 million which can be treated as distributable reserves.

Avadel currently has five direct wholly owned subsidiaries: Avadel US Holdings, Inc., Flamel Ireland Limited, trading 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. Avadel Ireland is a corporation organized under the laws of Ireland and is where all intangible 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 research and development activities take place.

Recent Developments

Asset Purchase Agreement with Cerecor. On February 12, 2018, Avadel and certain of its subsidiaries, as sellers, entered into an asset purchase agreement (the "Cerecor Purchase Agreement") with Cerecor, Inc. ("Cerecor") pursuant to which the sellers agreed to divest substantially all of the assets held directly and indirectly by FSC Therapeutics, LLC and FSC Laboratories, Inc (collectively, "FSC"). FSC markets three pediatric pharmaceutical products indicated for infection, allergy and gastroesophageal disease ("GERD"), and a medical device for the administration of aerosolized medication using pressurized Metered Dose Inhalers (pMDIs) for the treatment of asthma. Avadel acquired FSC in February 2016 from Deerfield CSF, LLC ("Deerfield CSF"), an affiliate of Deerfield Management, one of Avadel's major shareholders. The Cerecor Purchase Agreement provides that Cerecor will acquire FSC's business assets and will assume Avadel's remaining payment obligations to Deerfield CSF under the February 2016 membership interest purchase agreement pursuant to which Avadel acquired FSC (the "2016 MIPA"). Avadel will retain responsibility for the interim interest payment of $262,500 per quarter through March 31, 2018. The remaining payment obligations to Deerfield CSF, which were assumed by Cerecor, consist of (a) a quarterly payment of $262,500 beginning July 2018 and ending October 2020 (a total remaining payment obligation of $2.6 million), (b) a payment in January 2021 of $15.3 million, and (c) a 15% royalty per annum on net sales of the FSC products during the period ending February 6, 2026, up to a total royalty of approximately $10.3 million (the "Royalty"). Avadel will pay a make-whole payment to Cerecor in respect of costs incurred in 2018 and 2019 associated with a certain supply contract being assumed by Cerecor.

The transactions under the Cerecor Purchase Agreement require the consent of Deerfield CSF. Such consent is expected to be delivered at the closing, subject to the delivery by Avadel of its guaranty, in favor of Deerfield CSF, of the payment obligations under the 2016 MIPA being assumed by Cerecor including certain minimum Royalty payments. As a further condition to closing under the Cerecor Purchase Agreement, the majority shareholder of Cerecor will issue a guarantee in favor of Avadel the effect of which is to largely offset any payment obligations Avadel may incur as a result of the Avadel guaranties to Deerfield CSF including any payments in respect of the minimum Royalty payments. In addition, Avadel will enter into a development agreement with Cerecor pursuant to which Avadel will use reasonable diligent efforts to develop and provide to Cerecor four product formulations utilizing Avadel's LiquiTime® technology. Cerecor will reimburse Avadel for any costs associated with the development of the four LiquiTime® products in excess of $1 million in the aggregate. Successful completion of pilot bioequivalence studies with respect to the four LiquiTime® products are to be completed within the first 18 months from the effective date of the development agreement. Upon transfer of these product formulations, Cerecor will assume all remaining development costs and responsibilities for the completion of product development, any required clinical studies, construction of NDA applications and associated filing fees. Upon regulatory approval and commercial launch of any such LiquiTime® products, Cerecor will pay Avadel quarterly royalties based on a percentage of net sales of any products in the mid-single digits.

Avadel believes that the divestiture of its pediatric assets pursuant to the Cerecor Purchase Agreement will be accretive to Avadel's results of operations going forward. However, Avadel is evaluating any gain or loss that it may recognize for financial reporting purposes in the first quarter of 2018 (if a gain) or in the fourth quarter of 2017 (if a loss) as a result of the divestiture pursuant to GAAP.

FT 218 Orphan Drug Designation. In January 2018 Avadel announced that the FDA granted Orphan Drug Designation to its 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., tax credits related to R&D expenditures, 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."

Avadel's Business Model

Avadel executes three primary strategies that allow it 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. Avadel believes that over a thousand unapproved drugs are marketed in the United States today and, while many of these products are outdated therapies, it strategically evaluates those UMD products that are more commonly used as candidates for possible future FDA approval and marketing under its UMD program.

Additional UMD Products. Avadel expects to file its fourth NDA for a UMD in 2018, and intends to develop and seek approval for select UMD products with large existing markets and limited competition.

Avadel believes its strategy to create opportunities to commercialize UMD products in markets with a limited number of competitors may have a limited number of opportunities given the lack of patent protection from competition. Avadel believes this shorter-term strategy may provide it 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 it currently markets 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 its 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, Divestitures and/or Partnerships

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 its urology and hospital products, or its sleep-focused product candidate, FT 218. Avadel in-licensed Noctiva™ in September 2017 from Serenity Pharmaceuticals, 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 "Business of Avadel" under "– 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 its 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 under "– Noctiva™ (desmopressin acetate)" immediately below, and additional information regarding Noctiva may be found elsewhere in this "Business of Avadel" under "– 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 Pharmaceuticals, LLC ("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 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 will provide Serenity with a plan with respect to the commercialization of the Drug in the Field in the Territory.

Within 180 days following the effective date of the License Agreement, the Avadel Licensee will notify Serenity of its 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 $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 as Exhibit 99.2 to this Current Report on Form 8-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 it 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 "Business of Avadel" under "– Other Products Under Development" and "– 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 (GSK) marketed product). In addition to Avadel's FT 218 product, Avadel has several ongoing early-stage feasibility studies of undisclosed drugs that utilize Micropump®.

FT 218 (Micropump® sodium oxybate): Avadel is developing a product which uses its Micropump® drug-delivery technology for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. Avadel currently refers to this product as 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 (GABA). 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 its 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 U.S. rights to its LiquiTime® drug delivery platform 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.

Product Pipeline

Avadel's current product pipeline is detailed in the following table:

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; target filing 2018
LiquiTime®	Guaifenesin	Cough / Cold	Pivotal trial to commence pending stability data
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 it 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 its products, including its drug delivery platforms, obsolete or noncompetitive.

The pharmaceutical industry has dramatically changed over 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 its current marketed products and those in development. Examples of companies with whom Avadel or future partners would compete, given its current 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 its 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 its existing proprietary drug delivery platforms with the established commercial capability of its 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's company 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 it successfully execute its 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 as Exhibit 99.2 to this Current Report on Form 8-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 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 its once nightly formulation of sodium oxybate in FT 218 may have the potential to provide an uninterrupted night's sleep to patients, and may also have an improved safety profile, fewer potential side effects due to a lower Cmax 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 its Micropump® technology permits the development of differentiated product profiles (modified/controlled release formulations) under various dosage forms including capsules, tablets, sachets and liquid suspensions (LiquiTime®) for oral use. In addition, with Trigger Lock™ potentially addressing the issue of narcotic/opioid analgesics abuse, Avadel believes that it has 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 Cmax or peak drug concentration in the plasma, or by reducing intra- and inter-patient variability), and improved patient compliance (by reducing frequency of administration). The platform is applicable to poorly soluble (< 0.01mg/L) as well as highly soluble (> 500g/L) and to low dose (*e.g.*, 4 mg) or high dose (*e.g.*, 1,000 mg) drugs, while providing excellent mouth feel and taste masking properties. Micropump® allows the achievement of extremely precise pharmacokinetic profiles extended (and/or delayed) release of single or combination of drugs, in a variety of formats (such as tablets, capsules, sachet, or liquids (LiquiTime®), while preserving the targeted release rate over the shelf-life of the product.

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

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 it views prescription products as higher-value opportunities. Avadel is currently conducting feasibility studies on two potential prescription products utilizing its 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 its licensor's ability to obtain and maintain patent protection for Noctiva™. In addition, parts of Avadel's product pipeline and strategic alliances utilize its 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 its 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 it is 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 its intellectual property and proprietary information, Avadel may be unable to sustain a competitive advantage" in the "Risk Factors" included as Exhibit 99.2 to this Current Report on Form 8-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 its 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 it 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 Food and Drug Administration ("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 its 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 its 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 infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

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

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

For a brief discussion of potential marketing exclusivity that could be available under certain conditions with respect to Avadel's product candidate 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 as Exhibit 99.2 to this Current Report on Form 8-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 active pharmaceutical ingredients (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 its 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.

Properties

Avadel Research SAS, Avadel's 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 Avadel's 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.

Avadel previously owned manufacturing facilities, of approximately 103,900 square feet, located in Pessac, France ("Pessac Facility"), which included (i) approximately 6,800 square feet used for the manufacture of Coreg CR® microparticles for GSK as well as other Micropump®, and LiquiTime®/Trigger Lock™-based formulations (up to commercial scale) and housed two suites of equipment, as well as a dedicated warehouse, analytical control laboratory and a technical area with air compressor units, refrigeration units for solvents, and a heat boiler. This facility was divested to Recipharm on December 1, 2014.

Avadel has commercial and administrative activities located in Chesterfield, Missouri. In November 2015, it relocated to new office space in Chesterfield, Missouri. The office space consists of 17,065 square feet, and the lease expires in 2022. Avadel still maintains the lease on its former office space which expires in 2018. Additionally, Avadel still maintains the lease on the former headquarters of FSC Laboratories, Inc. located in Charlotte, North Carolina. This office space consists of 6,300 square feet, and the lease expires in 2020.

Avadel has 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.

During 2016, Avadel expended $1.2 million on property primarily for maintenance and investment in a global ERP.

Employees

As of December 31, 2017, Avadel had approximately 192 employees, of which approximately 165 were full-time. None of Avadel's employees are subject to a union or other collective bargaining agreement. Employees at Avadel's French subsidiaries (approximately 101 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. Avadel believes that its relations with its employees are satisfactory.

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 as Exhibit 99.2 to this Current Report on Form 8-K. While Avadel may be engaged in various other claims and legal proceedings in the ordinary course of business, it is not involved (whether as a defendant or otherwise) in, and, it has 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 its consolidated financial position, results of operations or liquidity.

RISK FACTORS

An investment in Avadel Pharmaceuticals plc ("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 Current Report on Form 8-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 Current Report on Form 8-K, where we describe additional uncertainties associated with Avadel's business and the forward-looking statements included or incorporated by reference in this Current Report on Form 8-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 Related to Avadel's Business and Industry

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

Avadel derives a majority of its revenues from sales of three products, Bloxiverz®, Vazculep® and Akovaz®. Additionally, Avadel depends on a small number of customers for the majority of its revenues from these products. Four customers, accounted for approximately 93% of total revenues in 2016, and approximately 94% of total revenues for the nine months ended September 30, 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 Avadel 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. Avadel expects that continuing consolidation may cause competitive pressures on pharmaceutical companies. The loss of any one of these products or the termination of Avadel's relationship with any of these customers or Avadel's failure to broaden its customer base could cause its revenues to decrease significantly and result in losses from its operations. Further, Avadel may be unable to negotiate favorable business terms with customers that represent a significant portion of its revenues, and any such inability could have a material adverse effect on Avadel's business, results of operations, financial condition and prospects.

Avadel expects to rely on collaborations with third parties to commercialize certain of its products in development, in particular products using Avadel's drug delivery technologies, and such strategy involves risks that could impair Avadel's prospects for realizing profits from such products.

Avadel expects that the commercialization of some its products in development which utilize Avadel's drug delivery technologies will involve third-party collaboration partners for strategic alliances, licenses, product divestitures or other arrangements to commercialize these products, as Avadel did with respect to the license to Elan for the OTC rights for LiquiTime® (see the discussion under the caption "– Products in Development with Partners" in the "Business of Avadel" included as Exhibit 99.1 to this Current Report on Form 8-K). Avadel may not be successful in entering into such collaborations on favorable terms, if at all, or its collaboration partners may not adequately perform under such arrangements, and as a result its ability to commercialize these products will be negatively affected and its prospects will be impaired.

Avadel's products may not gain market acceptance.

Avadel's 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 Avadel 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 Avadel's products or technologies fails to achieve market acceptance, Avadel's ability to generate additional revenue will be limited, which would have a material adverse effect on its business.

Avadel's 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 research and development ("R&D") of pharmaceutical products is difficult, expensive and time consuming. Many product candidates fail to reach the market. Avadel's success will depend on the development and the successful commercialization of additional previously Unapproved Marketed Drug ("UMD") products, development of products that utilize Avadel's drug delivery technologies. If any of Avadel's additional UMD products or products incorporating Avadel's drug delivery technologies fails to reach the commercial market, Avadel's future revenues would be adversely affected.

Even if Avadel's 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 Avadel's partners may delay or halt applicable clinical trials;
- Avadel or its partners may face slower than expected rate of patient recruitment and enrollment in clinical trials, or may devote insufficient funding to the clinical trials;
- Avadel's 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;
- Avadel or its partners may find certain products cannot be manufactured on a commercial scale and, therefore, may not be economical or feasible to produce; or
- Avadel's 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.

Avadel must invest substantial sums in R&D in order to remain competitive, and it may not fully recover these investments.

To be successful in the highly competitive pharmaceutical industry, Avadel must commit substantial resources each year to R&D in order to develop new products and enhance Avadel's technologies. In 2016, Avadel spent $34.6 million on R&D, and for the nine months ended September 30, 2017, it spent $22.1 million on R&D. Avadel's 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 Avadel's R&D does not yield sufficient products that achieve commercial success, Avadel's future operating results will be adversely affected.

The development of several of Avadel's 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 Avadel's 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 Avadel's products incorporating its drug delivery technologies. For details, see the discussion in the "Business of Avadel" included as Exhibit 99.1 to this Current Report on Form 8-K under "– Supplies and Manufacturing". Any disruption in the operations of this provider or if this provider fails to supply acceptable quantity and quality materials or services to Avadel for any reason, such disruption or failure could delay Avadel's product development and could have a material adverse effect on Avadel's business, financial condition and results of operations. In case of a disruption, Avadel may need to establish alternative manufacturing sources for its drug delivery products, and this would likely lead to substantial production delays as Avadel builds or locates replacement facilities and seeks to satisfy necessary regulatory requirements.

Avadel depends on a limited number of suppliers for the manufacturing of Avadel's products and certain raw materials used in Avadel's 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 Avadel's business.

Currently, Avadel depends on a limited number of contract manufacturing organizations for three products, Bloxiverz®, Vazculep® and Akovaz®, from which Avadel derives a majority of its revenues, and a single contract manufacturer for Noctiva™. Additionally, Avadel purchases certain raw materials used in its 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, Avadel's 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 Avadel with product or before Avadel may incorporate that supplier's ingredients into the manufacturing of Avadel's products by its contract, development, and manufacturing organizations ("CDMOs"). Failure to obtain adequate supplies in a timely manner could have a material adverse effect on Avadel's business, financial condition and results of operations.

If Avadel's competitors develop and market technologies or products that are safer or more effective than Avadel's, or obtain regulatory approval and market such technologies or products before Avadel does, Avadel's commercial opportunity will be diminished or eliminated.

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 drug delivery technologies or niche brand or generic specialty pharmaceutical products. Some of these competitors may also be Avadel's business partners.

Avadel's drug delivery technologies compete with technologies provided by several other companies (for details, see the discussion in the "Business of Avadel" included as Exhibit 99.1 to this Current Report on Form 8-K under "– Competition and Market Opportunities"). In particular, New Biological Entities or NCEs could be developed that, if successful, could compete against Avadel's 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 Avadel does not now know of that may compete with Avadel's drug delivery technologies or products in the future. These new biological or chemical products may be safer or may work better than Avadel's products.

With respect to Avadel's UMD drug products, the FDA could approve generic versions or previously filed NDAs of Avadel's marketed products.

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

Avadel's revenues may be negatively affected by healthcare reforms and increasing pricing pressures.

Future prices for Avadel's 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 Avadel's contracts with the drug wholesalers who distribute Avadel's 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 Avadel's financial condition and results of operations.

If Avadel cannot keep pace with the rapid technological change in its industry, it may lose business, and its products and technologies could become obsolete or noncompetitive.

Avadel's 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 Avadel cannot maintain competitive products and technologies, Avadel's competitors may succeed in developing competing technologies or obtaining regulatory approval for products before Avadel, and the products of Avadel's competitors may gain market acceptance more rapidly than Avadel's products. Such rapid technological change, or the development by Avadel's competitors of technologically improved or different products, could render Avadel's products or technologies obsolete or noncompetitive.

Avadel may fail to effectively execute its business strategy.

Avadel's business strategy is to commercially launch Noctiva™ during 2018, continue its UMD program, including by obtaining FDA approval for, and commercialize, its 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 its drug delivery technologies, and develop and identify and acquire additional businesses or new product opportunities. There can be no assurance that Avadel will be successful in any of these objectives; and a failure in any of these objectives could negatively impact Avadel's business and operating results.

In particular, Avadel 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 Avadel acquires could be expensive and time consuming, and could disrupt Avadel's ongoing business and distract Avadel's management. If Avadel fails to complete these acquisitions or successfully integrate any acquired businesses, products or technologies, its business will suffer. In addition, any amortization or charges resulting from the costs of acquisitions could negatively impact Avadel's operating results.

If Avadel cannot adequately protect its intellectual property and proprietary information, Avadel may be unable to sustain a competitive advantage.

Avadel's success depends, in part, on its ability to obtain and enforce patents and other intellectual property rights for its products and technology, including its drug delivery platforms, and to preserve its trade secrets and other proprietary information. If Avadel cannot do so, Avadel's competitors may exploit its technologies and deprive Avadel of the ability to realize revenues and profits from its 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. Avadel's patents may not be exclusive, valid or enforceable. For example, Avadel's patents may not protect it 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 Avadel may attempt to compete, in particular where such applications rely, at least in part, on safety and efficacy data from Avadel's products or Avadel's business partners' products. In addition, Avadel's competitors may obtain patents that may have an adverse effect on Avadel's ability to conduct business, or they may discover ways to circumvent Avadel's patents. The scope of any patent protection may not be sufficiently broad to cover Avadel's products or to exclude competing products. Any patent applications that Avadel has made or may make relating to its 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 Avadel. 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.

Avadel's partnerships with third parties expose Avadel to risks that they will claim intellectual property rights on Avadel's inventions or fail to keep Avadel's unpatented products or technology confidential. Avadel also relies on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen its competitive position.

To protect its products, trade secrets and proprietary technologies, Avadel relies, in part, on confidentiality agreements with its employees, consultants, advisors and partners. These agreements may not provide adequate protection for Avadel's 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, Avadel cannot be certain that it will have adequate remedies. Further, Avadel cannot guarantee that third parties will not know, discover or independently develop equivalent proprietary information or technologies, or that they will not gain access to Avadel's trade secrets or disclose Avadel's trade secrets to the public. Therefore, Avadel cannot guarantee that it can maintain and protect unpatented proprietary information and trade secrets. Misappropriation or other loss of Avadel's intellectual property would adversely affect Avadel's competitive position and may cause Avadel to incur substantial litigation or other costs.

The implementation of the Leahy-Smith America Invents Act of 2011 may adversely affect Avadel's 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 Avadel's patents, which could result in increased competition and have a material adverse effect on Avadel's 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 Avadel's technical and management personnel.

Third parties may claim that Avadel's products infringe their rights, and Avadel may incur significant costs resolving these claims.

Third parties may claim, that the manufacture, use, import, offer for sale or sale of Avadel's drug delivery technologies or Avadel's other products infringes on their patent and other intellectual property rights. For example, in connection with Avadel 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 Avadel to prevent it from commercializing FT 218. In response to any claim of infringement, Avadel may have to seek licenses, defend infringement actions or challenge the validity or enforceability of those patent rights in court. If Avadel cannot obtain required licenses, is found liable for infringement or is not able to have such patent rights declared invalid or unenforceable. Avadel 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. Avadel 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 Avadel's products or drug delivery technologies infringe proprietary rights of third parties could be time-consuming, result in costly litigation or divert the efforts of Avadel's technical and management personnel, any of which could disrupt Avadel's relationships with its partners and could significantly harm Avadel's operating results.

If Avadel or its partners are required to obtain licenses from third parties, Avadel's revenues and royalties on any commercialized products could be reduced.

The development of certain products based on Avadel's 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 Avadel or its partners are forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If Avadel or its partners must obtain licenses from third parties, fees must be paid for such licenses, which could reduce the net revenues and royalties Avadel may receive on commercialized products that incorporate its drug delivery technologies.

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

In the ordinary course of Avadel's business, it collects and stores proprietary data, including intellectual property, as well as Avadel's proprietary business information and that of its customers, suppliers and business partners, on Avadel's networks. The secure maintenance and transmission of this information is critical to Avadel's operations and business strategy. Despite Avadel's security measures, its 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 Avadel's 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 Avadel's operations and damage to its reputation, any of which could adversely affect Avadel's 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 Avadel's business, financial condition and results of operations. Avadel is subject to various domestic and international privacy and security regulations, including but not limited to HIPAA. Additionally, Avadel 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, it will face significant fines and penalties that could adversely affect its business, financial condition and results of operations.

Material weaknesses in Avadel's internal control over financial reporting have occurred in the past and could occur in the future.

Avadel's management is responsible for establishing and maintaining adequate internal control over financial reporting, and the Sarbanes-Oxley Act of 2002 and SEC rules require that Avadel's management report annually on the effectiveness of Avadel's internal control over financial reporting. Among other things, Avadel's management must conduct an assessment of its internal control over financial reporting to allow management to report on, and its independent registered public accounting firm to audit, the effectiveness of Avadel's internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act.

In Avadel's annual report on Form 10-K for the year ended December 31, 2015, its management identified material weaknesses in Avadel's internal control over financial reporting as of December 31, 2015 related to lack of sufficient personnel, resulting in, among other things, a failure to implement a proper segregation of duties; ineffective controls over the revenue, income tax, and financial close processes; ineffective controls over information technology and key spreadsheets used in preparing financial statements; and ineffective monitoring of Avadel's internal control systems.

During 2016 and 2017, Avadel implemented steps intended to remediate these material weaknesses in Avadel's internal control over financial reporting. As disclosed in Part II, Item 9A, "Controls and Procedures" of Avadel's most recently filed annual report on Form 10-K, Avadel's management determined that, while such steps have successfully remediated certain of the material weaknesses that existed as of December 31, 2015, material weaknesses in Avadel's internal control over financial reporting continued to exist as of December 31, 2016 in three areas: (1) Personnel - Avadel's added personnel need to have more time in their roles to have an impact on internal controls 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 information used in the control, key assumptions utilized in accounting estimates, and accounting for significant non-routine and complex transactions; (2) Financial Close Process - the previously reported material weakness remains unremediated specifically related to the data and assumptions used in accounting for significant non-routine and complex transactions associated with the financial close process; and (3) Rebates and Expired Product Reserves - the previously reported material weakness continues to exist related to the data and assumptions utilized in accounting for rebate and expired product reserves.

Avadel has identified and implemented additional processes, procedures and controls to improve the effectiveness of its internal control over financial reporting and disclosure controls and procedures in the areas where material weaknesses continued to exist as of December 31, 2016. See Item 9A, "Controls and Procedures - Actions related to unremediated material weaknesses" of Avadel's most recently filed annual report on Form 10-K and Item 4 of Avadel's quarterly report on form 10-Q filed November 9, 2017. However, we cannot assure you that Avadel's efforts will prove wholly successful in remediating these material weaknesses. In addition, we cannot assure you that Avadel has identified all existing material weaknesses, or that other material weaknesses will not arise in the future. If Avadel is unable to successfully identify and remediate any material weakness that may exist in Avadel's internal control over financial reporting, the accuracy and timing of Avadel's financial reporting may be adversely affected, Avadel may be unable to maintain compliance with securities law requirements and applicable stock exchange listing requirements regarding timely filing of periodic reports, the market price of Avadel's American Depositary Shares ("ADSs") may decline, and Avadel could be subject to shareholder litigation.

Avadel's effective tax rate could be highly volatile and could adversely affect its operating results.

- Avadel's future effective tax rate may be adversely affected by a number of factors, many of which are outside of its 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 Avadel's 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 Avadel's future effective tax rates could impact its results of operations for future periods adversely.

Avadel outsources important activities to consultants, advisors and outside contractors.

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

Avadel depends on key personnel to execute its business plan. If Avadel cannot attract and retain key personnel, it may not be able to successfully implement its business plan.

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

The Asset Purchase Agreement dated February 12, 2018, by and among Avadel and certain of its subsidiaries and Cerecor, Inc. (the "Cerecor Purchase Agreement") contains conditions to closing, some of which are beyond Avadel's control, and Avadel may be unable to consummate the divestiture of its pediatric assets.

The Cerecor Purchase Agreement contains certain closing conditions, including the delivery of certain third-party guarantees and consents. It is possible that one or more of the conditions in the Cerecor Purchase Agreement will not be satisfied, and Avadel may be unable or unwilling to consummate divestiture of its pediatric assets. If the divestiture of Avadel's pediatric assets is not closed on account of a failure by third-parties to deliver guarantees or consents, Avadel would be obligated to continue making payments to Deerfield CSF, LLC under the February 2016 membership interest purchase agreement pursuant to which Avadel acquired such pediatric assets.

If the divestiture of Avadel's pediatric assets is not closed, it may adversely affect Avadel's business, financial results and stock price. As a result, if the divestiture of Avadel's pediatric assets is not consummated, holders of our capital stock would be exposed to the risks described above and various other risks.

Even if the divestiture of Avadel's pediatric assets closes, the divestiture of the pediatric assets may not be accretive to Avadel's results of operations going forward. In addition, Avadel may recognize a gain or loss as a result of the divestiture pursuant to United States generally accepted accounting principles.

Risks Related to Avadel's Exclusive License Agreement for Noctiva™

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

Avadel anticipates 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 Avadel cannot guaranty the availability or levels of any such reimbursements for Noctiva™. Avadel does 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, Avadel's 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 Avadel 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 Avadel's 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 Avadel conducts its Noctiva™ business and could have a material adverse effect on Avadel's commercialization efforts for Noctiva™.

Avadel may have overestimated the market opportunity for Noctiva™ or it may not effectively exploit such market opportunity.

Avadel's internal analyses may overstate the market opportunity in the United States for the drug desmopressin acetate, which Avadel has licensed from Serenity and which Avadel intends to market under the brand name "Noctiva™". If one or more of the assumptions underlying its internal analyses are incorrect, the benefits Avadel anticipates from the Serenity License Agreement for Noctiva™ may not be realized or may be smaller than expected. Avadel may also fail to effectively exploit the market opportunity for Noctiva™, and such failure could have a material adverse effect on Avadel's 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 Avadel licenses from Serenity under the Serenity License Agreement are subject to litigation and if Serenity is unsuccessful in defending this litigation, Avadel may lose its 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 Avadel's business.

Patents covering Noctiva™ that Avadel has 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. Trial on defendants' counterclaims is currently scheduled for February 2018. 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 Nocdurna 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, Avadel 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 Avadel would no longer have any rights to such patents and Avadel 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 Avadel was unable to obtain any license to any of the Patents-In-Suit, it may be required to cease its development and commercialization of Noctiva™. Avadel could also be liable for damages to Ferring, which may be significant. Even if Avadel were able to obtain such a license, it may only be non-exclusive and in such case Avadel would not be able to enforce any of the Patents-in-Suit against competitors or other third parties, which may materially impair Avadel's 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 Avadel would no longer have exclusive rights to such patents. In such case, if Avadel was 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 Avadel's competitors or other third parties. Moreover, Avadel 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, Avadel would lose its ability to enforce such patents against third parties, which may materially impair Avadel's 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 Nocdurna product does not infringe the Patents-in-Suit, then Avadel would not be able to enforce the Patents-In-Suit to prevent the development and commercialization of Ferring's Nocdurna product.

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

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

Avadel's ability to establish effective marketing and advertising campaigns for Noctiva™ will be key to its success in commercializing the drug. If Avadel is 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™, Avadel's efforts to build a substantial customer base for the drug may not be successful. In addition, Avadel's overall marketing activities or pricing strategies may not be successful in promoting or selling Noctiva™. If Avadel's marketing and advertising programs are not adequate to support future growth of Noctiva™ sales, its expected results may experience a material adverse effect.

Avadel depends 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 Avadel's business.

Avadel will depend on a single contract manufacturing organization, Renaissance Lakewood, LLC, for the manufacturing and supply of Noctiva™. If the supplies of Noctiva™ are interrupted for any reason, Avadel's 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 Avadel's business, financial condition and results of operations.

Avadel's costs to commercialize Noctiva™ could exceed its estimates or such costs may not provide the intended results.

Avadel's 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 Avadel adequately controls such costs, its expenditures in developing and commercializing Noctiva™ may not yield the desired results. Further, Avadel may incur higher than expected operating costs, and it 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 Avadel's business and adversely affect its financial results.

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

Risks Related to Regulatory and Legal Matters

Avadel's products will generally be subject to regulatory approval. If Avadel or its pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, Avadel's revenues may be adversely affected.

Although Noctiva has FDA approval (as described in the "Business of Avadel" included as Exhibit 99.1 to this Current Report on Form 8-K), Avadel's fourth UMD product and its FT 218 product, as well as products that Avadel 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 Avadel or its pharmaceutical and biotechnology partners can control whether Avadel obtains 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 Avadel's technologies. If Avadel or its partners are not successful in timely obtaining such approvals, Avadel's 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 Avadel or its partners to conduct additional pre-clinical studies or clinical trials.

Similarly, although Avadel anticipates submitting applications for approval for its development products that rely on existing data to demonstrate safety and effectiveness, the FDA may determine that additional studies particular to Avadel's 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"), Avadel or its 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 Avadel's 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 Avadel or its 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, Avadel's revenues, operating results and liquidity may decline and earnings may be negatively impacted.

Avadel's products are subject to continuing regulation, and Avadel on its own, and in conjunction with its pharmaceutical partners, may be subject to adverse consequences if Avadel or they fail to comply with applicable regulations.

Avadel on its own and in conjunction with its pharmaceutical partners will be subject to extensive regulatory requirements for Avadel's 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;
- active pharmaceutical ingredients 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 Avadel's product candidates are safe and effective in clinical trials, or to generate data in clinical trials to support expansion of the therapeutic uses for Avadel's existing products, could materially and adversely affect its business, financial condition, results of operations and growth prospects.

Avadel has made significant investments in its 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 Avadel's REST-ON Phase III clinical trial would prevent or delay the commercialization of its sodium oxybate product, which could materially and adversely affect its 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 Avadel is investigating. Furthermore, Avadel relies and expects to rely on CROs and clinical trial sites to ensure the proper and timely conduct of its future clinical trials and while Avadel has and intends to have agreements governing their committed activities, Avadel will have limited influence over their actual performance.

Avadel relies on third parties to conduct its clinical trials, and if they do not properly and successfully perform their contractual, legal and regulatory duties, Avadel may not be able to obtain regulatory approvals for or commercialize its drug product candidates.

Avadel relies on CROs and other third parties to assist it in designing, managing, monitoring and otherwise carrying out its clinical trials, including with respect to site selection, contract negotiation and data management. Avadel does not control these third parties and, as a result, they may not treat Avadel's clinical studies as a high priority, which could result in delays. Avadel is responsible for confirming that each of its 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 Avadel, CROs or other third parties assisting Avadel or its study sites fail to comply with applicable good clinical practices, the clinical data generated in Avadel's clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require Avadel to perform additional clinical trials before approving its marketing applications. Avadel cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies will determine that any of Avadel's clinical trials comply with good clinical practices. In addition, Avadel's clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the U.S. Avadel's failure, or the failure of its product suppliers, to comply with these regulations may require Avadel 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 Avadel, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to Avadel's clinical protocols, including dosing requirements, or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, Avadel's clinical trials may not meet regulatory requirements. If Avadel's clinical trials do not meet regulatory requirements or if these third parties need to be replaced, Avadel's clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, Avadel may not be able to obtain regulatory approval of its product candidates or succeed in its efforts to create approved line extensions for certain of its existing products or generate additional useful clinical data in support of these products.

If Avadel or its partners, including any CDMOs that Avadel uses, 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 Avadel's products and products that incorporate its technologies. If the FDA, the European Commission or competent authorities of EU Member States determine that Avadel is 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 Avadel's 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, Avadel 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.

Avadel's 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 Avadel's 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 Avadel's 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.

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

Avadel is 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 Avadel to incur substantial costs associated with compliance or to alter one or more of Avadel's sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt Avadel's business and result in a material adverse effect on Avadel's 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 U.S. 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 Avadel, and Avadel is not successful in defending ourselves or asserting its rights, those actions could have a significant impact on Avadel's business, including the imposition of significant fines or other sanctions.

Healthcare reform and restrictions on reimbursements may limit Avadel's financial returns.

Avadel's ability to successfully commercialize its 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 Avadel's 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 Avadel's products depends in part on the conditions under which products incorporating Avadel's technology are reimbursed. Adequate third party reimbursement may not be available for such drug products to enable Avadel to maintain price levels sufficient to realize an appropriate return on its investments in research and product development, which could materially and adversely affect its business. Avadel cannot predict the effect that changes in the healthcare system, especially cost containment efforts, may have on its 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 Avadel's business.

Regulatory reforms may adversely affect Avadel's ability to sell its 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 Avadel's 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 Avadel's business and its 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 Avadel's proposed products or of competing products, and on Avadel's obligations and those of its pharmaceutical industry partners.

Avadel and companies to which it has licensed, or will license its products or drug delivery technologies and subcontractors Avadel engages for services related to the development and manufacturing of its products are subject to extensive regulation by the FDA and other regulatory authorities. Avadel's and their failure to meet strict regulatory requirements could adversely affect Avadel's business.

Avadel, and companies to which it licenses Avadel's products or drug delivery technologies, as well as companies acting as subcontractors for Avadel's 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 Avadel remains responsible for the compliance of its 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 Avadel's ability to produce and market applicable products, which could significantly impact Avadel's revenues and royalties that it receives from its customers.

Avadel may face product liability claims related to clinical trials for its products or their misuse.

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

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

Avadel's 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. Avadel 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 Avadel's operating results.

Avadel currently maintains property, business interruption and casualty insurance with limits that Avadel believes to be commercially reasonable, but may be inadequate to cover any actual liability or damages.

Risks Related to Ownership of Avadel's Securities

Avadel's share price has been volatile and may continue to be volatile.

The trading price of Avadel's shares has been, and is likely to continue to be, highly volatile. The market value of an investment in Avadel's shares may fall sharply at any time due to this volatility. During the period from January 1, 2018 to February 7, 2018, the closing sale price of Avadel's ADSs as reported on the Nasdaq Global Market ranged from $8.80 to $11.70. During the period from January 1, 2017 to December 31, 2017, the closing sale price of Avadel's ADSs as reported on the Nasdaq Global Market ranged from $8.03 to $11.57. During the period from January 1, 2016 to December 31, 2016, the closing sale price of Avadel's ADSs as reported on the Nasdaq Global 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 Avadel's share price include, among others:

· fluctuations in Avadel's operating results;

- announcements of technological partnerships, innovations or new products by Avadel or its competitors;
- actions with respect to the acquisition of new or complementary businesses;
- governmental regulations;
- developments in patent or other proprietary rights owned by Avadel or others;
- public concern as to the safety of drug delivery technologies developed by Avadel or drugs developed by others using Avadel's platform;
- the results of pre-clinical testing and clinical studies or trials by Avadel or its competitors;
- adverse events related to Avadel's products or products developed by pharmaceutical and biotechnology company partners that use Avadel's drug delivery technologies;
- lack of efficacy of Avadel's products;
- litigation;
- decisions by Avadel's pharmaceutical and biotechnology company partners relating to the products incorporating Avadel's 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 Avadel may issue.

If Avadel is not able to sustain profitability in the future, the value of its shares may fall.

Avadel reported net loss of $41.3 million for the year ended December 31, 2016 and net income of $76.5 million for the nine months ended September 30, 2017. Avadel cannot predict if it will be able to sustain profitability. If Avadel is unable to maintain a profit in future periods, the market price of Avadel's shares may fall. Avadel's ability to operate profitably depends upon a number of factors, many of which are beyond its direct control. These factors include:

- the demand for Avadel's drug delivery technologies and products;
- the level of product and price competition;
- Avadel's ability to develop new partnerships and additional commercial applications for its products;
- Avadel's ability to control its costs;
- Avadel's ability to broaden its customer base;
- the effectiveness of Avadel's marketing strategy;
- its effective tax rate;
- the launch costs of Noctiva™

- the effectiveness of Avadel's partners' marketing strategy for products that use Avadel's technology; and

- general economic conditions.

Avadel 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 its ADSs.

Avadel may require additional financing to fund the development and possible acquisition of new products and businesses. Avadel may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. If Avadel cannot obtain financing when needed, or obtain it on favorable terms, it may be required to curtail its 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 Avadel to seek additional financing include:

- the development and acquisition of new products and drug delivery technologies;

- the progress of Avadel's 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, Avadel may be required to significantly reduce or refocus its product development efforts, resulting in loss of sales, increased costs and reduced revenues. Alternatively, to obtain needed funds for acquisitions or operations, Avadel may choose to issue additional ADSs representing its ordinary shares, or issue equity-linked debt, or Avadel 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 Avadel and, in the case of such equity financings, may result in dilution to the holders of Avadel's ADSs.

Avadel has broad discretion in the use of its cash and may not use it effectively.

Avadel's management has broad discretion in the use of its cash, and may not apply its cash in ways that ultimately increase the value of any investment in its securities. Avadel currently intends to use its cash to fund marketing activities for Avadel's commercialized products, to fund certain clinical trials for product candidates, to fund research and development activities for potential new product candidates, to acquire assets or businesses that Avadel may identify as potentially beneficial to its business strategies, and for working capital, capital expenditures and general corporate purposes. As in the past, Avadel expects to invest its 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 Avadel does not invest or apply its cash effectively, its financial position and the price of its ADSs may decline.

Avadel currently does not intend to pay dividends and cannot assure the holders of its ADSs that it will make dividend payments in the future.

Avadel has never declared or paid a cash dividend on any of its ordinary shares or ADSs and does 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 Avadel's business, its capital requirements, general business conditions and such other factors as Avadel's Board of Directors deems relevant.

Provisions of Avadel's articles of association could delay or prevent a third-party's effort to acquire Avadel.

Avadel's articles of association could delay, defer or prevent a third-party from acquiring us or Avadel, even where such a transaction would be beneficial to the holders of Avadel's ADSs, or could otherwise adversely affect the price of Avadel's ADSs. For example, certain provisions of Avadel's articles of association:

- permit Avadel's 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 Avadel's share capital entitled to vote generally at a meeting of shareholders to amend or repeal certain provisions of Avadel's articles of association.

Avadel believes these provisions may provide some protection to holders of Avadel's ADSs from coercive or otherwise unfair takeover tactics. These provisions are not intended to make Avadel immune from takeovers. However, these provisions will apply even if some holders of Avadel's ADSs consider an offer to be beneficial and could delay or prevent an acquisition that Avadel's Board of Directors determines is in the best interest of the holders of Avadel's 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 Avadel's 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 Avadel 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 Avadel's ADSs in certain circumstances.

These provisions may discourage potential takeover attempts, discourage bids for Avadel's 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, Avadel's ADSs. These provisions could also discourage proxy contests and make it more difficult for holders of Avadel's ADSs to elect directors other than the candidates nominated by Avadel's board of directors, and could depress the market price of Avadel's ADSs.

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

Holders of Avadel's ADSs could have more difficulty protecting their interests than would the shareholders of a U.S. corporation. As an Irish company, Avadel is 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 Avadel 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 Avadel. Directors must not put themselves in a position in which their duties to Avadel and their personal interests conflict and must disclose any personal interest in any contract or arrangement with Avadel or any of its subsidiaries. A director or officer can be held personally liable to Avadel in respect of a breach of duty to Avadel.

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 Avadel and its 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 Avadel and its 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 Avadel and its 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 recognise 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 recognise 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 Avadel. 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. Avadel 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 Avadel’s Board of Directors and against any resolution not so proposed or approved.

Avadel’s largest shareholders own a significant percentage of the share capital and voting rights of Avadel.

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 Avadel’s 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 Avadel’s outstanding shares (in the form of ADRs). To the extent these shareholders continue to hold a large percentage of Avadel’s share capital and voting rights, they will remain in a position to exert heightened influence in the election of the directors of Avadel and in other corporate actions that require shareholder approval, including change of control transactions.

Risks Related to Recent Tax Legislation

The effect of comprehensive U.S. tax reform legislation on Avadel, 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 Avadel's analysis of the Tax Act's impact on its cash tax liability and financial condition has not identified any overall material adverse effect, Avadel is still evaluating the effects of the Tax Act on it 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, Avadel will use what it believes are reasonable interpretations and assumptions in interpreting and applying the Tax Act for purposes of determining its cash tax liabilities and results of operations, which may change as it receives 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 Avadel previously made, which could have a material adverse effect on Avadel's cash tax liabilities, results of operations and financial condition. You are urged to consult your tax adviser regarding the implications of the Tax Act.