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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2016

Commission file number: 000-28508

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒
Non-accelerated filer ☐ Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was $435,055,125 based on the closing sale price of the registrant's American Depositary Shares as reported by the Nasdaq Global Market on June 30, 2016. Such market value excludes 733,328 ordinary shares, $0.01 per share nominal value, held by each officer and director and by shareholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

The number of the registrant's ordinary shares, $0.01 per share nominal value, outstanding as of March 20, 2017 was 41,379,554.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of either (a) a definitive proxy statement involving the election of directors or (b) an amendment to this Form 10-K, either of which will be filed within 120 days after December 31, 2016, are incorporated by reference into Part III of this Form 10-K.

TABLE OF CONTENTS

Cautionary Disclosure Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements. We may make additional written or oral forward-looking statements from time to time in filings with the Securities and Exchange Commission or otherwise. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project" and similar expressions, and the negatives thereof, identify forward-looking statements, which speak only as of the date the statement is made. Such forward-looking statements are within the meaning of that term in Section 27A of the Securities Act of 1933 as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Although we believe that our forward-looking statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results of our research, development and commercialization activities and our results of operations will not differ materially from our expectations. Factors that could cause actual results to differ from expectations in our forward-looking statements include, among others, those specified in "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, including:

- we depend on a small number of products and customers for the majority of our revenues and the loss of any one of these products or customers could reduce our revenues significantly.
- we may depend on partnership arrangements or strategic alliances for the commercialization of some of our products, and the failure of any third party to fulfill its duties under such an arrangement or alliance could have a material adverse effect on our financial condition and results of operation.
- our products may not reach the commercial market for a number of reasons, which would adversely affect our future revenues.
- we must invest substantial sums in research and development ("R&D") in order to remain competitive, and we may not fully recover these investments.
- the development of several of our drug delivery platforms and products depends on the services of a single provider and any interruption of such provider's operations could significantly delay or have a material adverse effect on our product pipeline.
- we depend upon a limited number of suppliers to manufacture our products and to deliver certain raw materials used in our products and the failure of any such supplier to timely deliver sufficient quantities of products or raw materials could have a material adverse effect on our business.
- if our competitors develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do, our commercial opportunity will be diminished or eliminated.
- if third party payors choose not to reimburse our pediatric products our sales and profitability could suffer.
- if we cannot keep pace with the rapid technological change in our industry, we may lose business, and our drug delivery platforms could become obsolete or noncompetitive.
- the impact of the acquisition of FSC on our financial results may be worse than the assumptions we have used.
- if we cannot adequately protect our intellectual property and proprietary information, we may be unable to sustain a competitive advantage.
- our effective tax rate could be highly volatile and could adversely affect our operating results.
- we depend on key personnel to execute our business plan and the loss of any one or more of these key personnel may limit our ability to effectively pursue our business plan.

Forward-looking statements are subject to inherent risks and uncertainties, some of which cannot be predicted or quantified. Future events and actual results could differ materially from those set forth in, contemplated by or underlying the forward-looking statements. We undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise. You should not place undue reliance on these forward-looking statements. Statements in this Annual Report on Form 10-K including those set forth above and in the "Risk Factors" section of this Annual Report on Form 10-K, describe factors, among others, that could contribute to or cause such differences.

PART I

Item 1. Business.

(Amounts in thousands, unless otherwise noted)

General Overview

Avadel Pharmaceuticals PLC ("Avadel," the "Company," "we," "our," or "us") is a specialty pharmaceutical company engaged in identifying, developing, and commercializing niche branded pharmaceutical products mainly in the U.S. Our business model consists of three distinct strategies:

- the development of differentiated, patent protected products through application of the Company's proprietary patented drug delivery platforms, Micropump® and LiquiTime®, that target high-value solid and liquid oral and alternative dosages forms through the U.S. Food and Drug Administration (FDA) 505(b)(2) approval process, which allows a sponsor to submit an application that doesn't depend on efficacy, safety, and toxicity data created by the sponsor. In addition to Micropump® and LiquiTime®, the Company has two other proprietary drug delivery platforms, Medusa™ (hydrogel depot technology for use with large molecules and peptides) and Trigger Lock™ (controlled release of opioid analgesics with potential abuse deterrent properties).

- the identification of Unapproved Marketed Drugs ("UMDs"), which are currently sold in the U.S., but unapproved by the FDA, and the pursuit of approval for these products via a 505(b)(2) New Drug Application (NDA). To date, the Company has received approvals through this "unapproved-to-approved" avenue for three products: Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection) and Akovaz® (ephedrine sulfate injection). As a potential source of near-term revenue growth, Avadel is working on the development of a fourth product for potential NDA submission by year-end 2017, and seeks to identify additional product candidates for development with this strategy.

- the acquisition of commercial and or late-stage products or businesses. The Company markets three branded pediatric-focused pharmaceutical products in the primary care space, and a 510(k) approved device that will launch in the second quarter of 2017, all of which were purchased through the acquisition of FSC Laboratories and FSC Pediatrics on February 5, 2016. We will consider further acquisitions, and the Company continues to look for assets that could fit strategically into its current or potential future commercial sales force.

Corporate Information

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

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

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

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

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

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

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

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

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

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

Further details about the reincorporation, the Merger and the Merger Agreement are contained in our definitive proxy statement filed with the Securities and Exchange Commission (the "SEC") on July 5, 2016, and elsewhere in this Item 1 under the caption "- The Flamel Merger."

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

The Company currently has four direct wholly owned operating subsidiaries: Avadel US Holdings, Inc., Flamel Ireland Limited, trading under the name Avadel Ireland, Avadel Investment Company Limited and Avadel France Holding SAS. Avadel US Holdings, Inc. is a Delaware corporation, and is the holding entity of Avadel Pharmaceuticals (USA), Inc. (Formerly FSC Laboratories, Inc.), Avadel Legacy Pharmaceuticals, LLC (formerly Éclat Pharmaceuticals, LLC), Avadel Management Corporation, and Avadel Operations Company, Inc. 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 the Company's research and development activities take place. A complete list of the Company's subsidiaries can be found in Exhibit 21.1 to this Annual Report on Form 10-K.

Our Business Model

Our three development strategies allow us to develop and/or license or acquire differentiated branded products for FDA approval and commercialization, principally in the United States. The Company is currently able to self-fund most product development opportunities thereby having less reliance on partners. The Company has narrowed its drug delivery focus to center around the Micropump and LiquiTime platforms, and although it currently maintains ownership of Trigger Lock and Medusa, it will assess potential opportunities to divest or partner/license these technology platforms.

Business Strengths and Strategies

Our business strengths and strategies include:

- ***Continued Development of our Drug Delivery Technologies***: Our versatile, proprietary drug delivery platforms (Micropump®, LiquiTime®, Trigger Lock™, Medusa™) allow us to select unique product development opportunities, representing either "life cycle" opportunities, whereby additional intellectual property (IP) can be added to a pharmaceutical to extend the commercial viability of a product, for marketed chemical and biological drugs (via 505(b)(2) approval), or innovative formulation opportunities for new chemical entities (NCE) or new biological entities (NBE) (via NDA regulatory path). Several products formulated using our proprietary drug delivery platforms are currently under various stages of development. These products will be marketed either by the Company and/or by partners via licensing/distribution agreements (see "- Other Products Under Development - Proprietary pipeline to deliver several regulatory filings (US and/or EU) through 2018") in this Part I, Item 1 of this Annual Report on Form 10-K).

- ***Continued exploration and development of additional unapproved to approved drug products:*** Our unapproved to approved drug development process may provide us with near term revenue growth and provide cash flows that can be used to fund R&D and inorganic initiatives.

- ***Inorganic growth through Acquisitions and/or Partnerships***: The Company maintains a strong balance sheet with substantial liquidity and no long-term debt with fixed maturities. The Company intends to explore and pursue appropriate inorganic growth opportunities that complement its drug delivery platforms or to acquire proprietary products that enhance profitability and cash flow. This goal was evidenced in early 2016 with the acquisition of FSC Holdings, LLC and its subsidiaries, specialty pharmaceutical companies which focus on the commercialization of pediatric products and devices. The acquisition of the FSC companies adds to our marketing and licensing knowledge of commercial processes in the U.S, which we believe enhances our ability to identify potential product candidates for development, leverages new opportunities for the application of our drug delivery platforms, and establishes a commercial footprint to license and market products in the U.S.

- ***Divestitures and out licensing:*** We intend to narrow our focus to our two most developed drug delivery platforms, Micropump® and LiquiTime®, and plan to divest or out-license Trigger Lock™, for abuse deterrence, and Medusa™, for extended-release subcutaneous injection. We believe the Trigger Lock™ and Medusa™ platforms are robust and well protected from an IP standpoint; however, their development and FDA approval may require investments in clinical work and infrastructure which we are not currently prepared to support. In 2015, the Company entered into a transaction in which it granted Elan Pharma International Limited an exclusive U.S. license to use the Company's LiquiTime technology for Over-the-Counter ("OTC") products.

Developments in 2016 and 2017

On February 8, 2016, we acquired FSC Holdings, LLC, together with its wholly owned subsidiaries FSC Pediatrics, Inc., FSC Therapeutics, LLC, and FSC Laboratories, Inc. (collectively, "FSC"), from Deerfield CSF, LLC, an affiliate of Deerfield Management, one of the Company's major shareholders. FSC was a Charlotte, NC-based specialty pharmaceutical company that markets three pediatric pharmaceutical products indicated for infection, allergy, gastroesophageal disease (GERD), and a medical device for the administration of aerosolized medication using pressurized Metered Dose Inhalers (pMDIs) for the treatment of asthma. Under the terms of the acquisition, Avadel will pay $21,250 over a five-year period to Deerfield for all of its equity interests in FSC Holdings. Specifically, Avadel will pay $1,050 annually for five years and will make a final payment in January 2021 of $15,000. Avadel will also pay Deerfield a 15% royalty per annum on net sales of the current FSC products, up to $12,500 for a period not exceeding ten years.

On March 31, 2016, we submitted a Special Protocol Assessment (SPA) to the FDA for a Phase III clinical trial of FT218, Avadel's once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy.

In May 2016, the FDA approved our NDA for Akovaz on its PDUFA date of April 30, 2016. Akovaz is the Company's third UMD product and is the first NDA for ephedrine sulfate injection to be approved in the U.S.

In August 2016, we launched our third UMD product, Akovaz, into a market of approximately 7.5 million vials per year, representing the Company's largest market opportunity to date.

In October 2016, we reached an agreement with the FDA for our SPA for our Phase III REST-ON trial to assess the safety and efficacy of FT218, a once-nightly Micropump-based formulation of sodium oxybate, for the treatment of excessive daytime sleepiness (EDS) and cataplexy.

During December 2016, the first patient enrolled in our REST-ON study was dosed.

Lead Products

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 the most frequently used product for the reversal of the effects of other agents used for neuromuscular blocks. There are approximately four million vials sold annually in the U.S. On January 8, 2015 and December 28, 2015, the FDA approved the NDA submitted by Fresenius Kabi USA ("Fresenius") for neostigmine methylsulfate (for both 0.5 mg/1mL and 1 mg/1mL strengths) and an ANDA submitted by Eurohealth International, an affiliate of West-Ward Pharmaceuticals Corp., neostigmine methylsulfate (for both 0.5 mg/1mL and 1 mg/1mL strengths), respectively. In 2016, we recognized total revenues of $82,896 for this product. (for more details, see "- Results of Operations" in Part II, Item 7 of this Annual Report on Form 10-K). In the future, sales of Bloxiverz is dependent upon the competitive market dynamics between Avadel, Fresenius, West-Ward and any subsequent ANDA approvals that may occur. Additionally, an alternative product marketed by Merck, Bridion (sugammadex), was approved in early 2016 and has taken approximately 30% of the neostigmine market away through early February 2017.

Vazculep® (phenylephrine hydrochloride injection) On June 28, 2013, the Company 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. We 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. West-Ward Pharmaceuticals Corp. ("West Ward") commercializes the 1mL single-dose vial, as an approved product in the U.S. In 2016, we recognized total revenues of $39,796 for this product. The volume of sales of Vazculep is dependent upon the competitive landscape in the marketplace.

Akovaz® (ephedrine sulfate injection). On June 30, 2015, the Company announced its third NDA was accepted by the FDA, and was granted approval for Akovaz on April 29, 2016. On August 12, 2016, we launched Akovaz, into a market of approximately 7.5 million vials annually in the U.S. The Company 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. In 2016, we recognized total revenues of $16,831 for this product. On January 27, 2017, Endo International plc's (NASDAQ: ENDP) subsidiary Par Pharmaceuticals, received NDA approval for ephedrine sulfate, packaged in cartons of twenty-five 50mg/mL, 1mL single use vials. On March 2, 2017, Akorn Pharmaceuticals (NASDAQ: AKRX) received FDA approval for its ampule presentation. We expect this market to remain a three-player market.

Karbinal™ER (carbinoxamine maleate extended-release oral suspension). Karbinal ER is an H1 receptor antagonist (antihistamine) indicated for children two years of age and older, is the only first generation extended release oral suspension antihistamine available in U.S. Karbinal ER provides physicians with a new, effective and easy to use treatment option for children with seasonal and perennial allergic rhinitis that need symptomatic relief for runny nose, sneezing, itchy nose or throat and itchy and watery eyes. Karbinal ER was launched in 2015 and is exclusively licensed from Tris Pharma.

AcipHex® Sprinkle™ (rabeprazole sodium). AcipHex Sprinkle is a delayed-release capsule, in dosages of 5 mg and 10 mg, indicated for the treatment of GERD in children 1 to 11 years of age for up to 12 weeks. AcipHex Sprinkle can be sprinkled on a small amount of soft food (e.g., applesauce, fruit or vegetable based baby food, or yogurt) or the capsule granules can be emptied into a small amount of liquid (e.g., infant formula, apple juice, or pediatric electrolyte solution). The U.S. marketing rights for this product were acquired from Eisai Inc. and the product was launched in 2015.

Cefaclor for Oral Suspension, 125 mg/5 mL, 250 mg/5 mL and 375 mg/5 mL. Cefaclor is indicated for the treatment of otitis media, lower respiratory infections, pharyngitis and tonsillitis, urinary tract infections, and skin structure infections, caused by susceptible organisms. It is a second-generation cephalosporin antibiotic used to treat certain infections, caused by susceptible bacteria. Our Cefaclor offering was launched in 2015.

Flexichamber®. Flexichamber, a prescription medical device, is a collapsible holding chamber for use by patients under the care or treatment of a licensed healthcare professional to administer aerosolized medication from most pressurized Metered Dose Inhalers (MDI). Flexichamber is comprised of antistatic materials to help improve delivery of medication from MDIs to the patient, while minimizing the adherence of the medication to the walls of the chamber. Flexichamber can be used with or without a mask. The Company received FDA 510(k) clearance for Flexichamber in October 2014 and the product is expected to produce revenues by the end of the first quarter 2017 and will be actively promoted by our sales force at the onset of the second quarter 2017.

Other Products Under Development

FT218 is Avadel's 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). It has been described as a therapeutic agent with high medical value; in Europe and the United States it is currently approved in a twice nightly formulation indicated for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy at doses up to 9g/night. In December 2016, the Company initiated patient enrollment and dosing for its REST-ON Phase III clinical trial to assess the safety and efficacy of its once nightly formulation of FT218 for the treatment of excessive daytime sleepiness (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 - 60 clinical sites in the U.S., Canada and western Europe. The Company expects enrollment to be completed by year end 2017. In preparation for its REST-ON trial, Avadel sought and consequently 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. Should the trial reach its primary endpoints of EDS and cataplexy, the Company believes an SPA agreement with the FDA should help to mitigate several risks associated with receiving approval, such as any questions surrounding statistical powering.

Any additional studies, such as pivotal pharmacokinetic (PK) studies, needed for a New Drug Application (NDA) approval, will be run simultaneously, with the trial completion targeted for the first half of 2018. The study provides the potential to demonstrate improved efficacy, safety and patient satisfaction over the standard of care, JAZZ's Xyrem®, a twice nightly sodium oxybate formulation, which is expected to generate revenues of between $1.1 and $1.125 billion in 2016.

We entered into an Exclusive License Agreement on September 30, 2015, with Elan Pharma International Limited, a subsidiary of Perrigo Company plc, for the U.S. rights to our LiquiTime drug delivery platform for the U.S. (OTC) drug market. Under the multi-product license agreement, we received an upfront payment of $6,000 and will be eligible for at least an additional $50,000 in approval and launch milestones. In addition, once commercialized we will receive mid-single digit royalties on net sales of the products. Avadel and Elan believe there is a large market opportunity for other OTC extended release liquid drug formulations, including products containing active ingredient combinations for the US cough/cold market, which analysts have estimated between $6 billion to $8 billion annually.

Avadel currently has four undisclosed products using the Micropump and LiquiTime technologies in proof of concept. These products are focused in the pediatric, psychiatric and central nervous system (CNS) therapeutic areas

Hydromorphone. Avadel also has a Trigger Lock-based abuse-deterrent, extended-release, oral hydromorphone product (FT227) in development. Hydromorphone is used for relief of moderate to severe pain in patients requiring [continuous] around-the-clock opioid treatment for an extended period of time. We announced in June 2015, positive results from two pilot pharmacokinetic (PK) studies in healthy volunteers of FT227. The PK studies were intended to provide sufficient data for the Company to select a preferred prototype formulation to move forward into pivotal studies. The studies compared three FT227 prototypes to the comparator product Jurnista© (sold as Exalgo© in the United States) in both fasted and fed conditions at a dose of 32mg. Under fasted conditions, comparing the AUC and the Cmax of FT227 to Jurnista in 16 subjects, the results identified a FT227 formulation that met the bioequivalence criteria for both parameters. Under fed conditions (14 subjects), the same formulation was bioequivalent in terms of AUC to Jurnista but outside of the Cmax bioequivalence criterion at the lower confidence interval level. Comparing the effect of food on the PK parameters of the FT227 prototypes across the two studies, no notable difference is seen in either AUC or Cmax in fed and fasted conditions. This suggests that administration of FT227 will not be subject to a clinically relevant food effect. In both studies FT227 was well tolerated and no serious adverse events were reported. In addition, Avadel has generated substantial in vitro data comparing the abuse deterrence properties of FT227 compared to other marketed abuse-deterrent opioid products. The Company believes that Trigger Lock is a robust platform for opioids that will set a high standard in terms of abuse deterrence. Further in vitro data have been generated on FT227 by an independent contract research organization which confirmed the effective abuse deterrent properties of the product. FT227 is designed to be filed as a 505(b)(2) New Drug Application (NDA). In the fourth quarter of 2016, the Company completed an alcohol interaction study, and will continue to seek out a licensing partner and or complete divestiture of the Trigger Lock platform. Avadel is currently seeking to divest or license this product candidate in addition to the full Trigger Lock platform and has discontinued spending on this platform.

Exenatide is a once-a-week Medusa-based injectable formulation of exenatide (FT228), a glucagon-like peptide-1 ("GLP-1") agonist for the treatment of type 2 diabetes. The Company received positive results from a Phase 1b clinical trial of FT228, a once-weekly subcutaneous injection formulation of exenatide using its proprietary Medusa™ technology. The study achieved all pharmacokinetic (PK) and pharmacodynamic (PD) objectives throughout four weekly administrations of Medusa™ exenatide (FT228), and assessed the safety, steady-state PK profile and the product's potential effect on biomarkers and surrogate endpoints upon repeated administrations. One dose per week of FT228 at 140mcg was administered to twelve Type 2 Diabetes Mellitus patients over a four-week period. Following each administration, a continuous release of exenatide was observed over a period of up to 14 days and a relative bioavailability exceeding 94% was demonstrated. The PD performance of FT228 was comparable to current marketed products, Victoza® (liraglutide IR) and Bydureon® (exenatide SR). Avadel is currently seeking to divest or license this product candidate in addition to the full Medusa platform, and has discontinued spending on this platform.

Additional Unapproved Marketed Drug Products

The Company intends to develop and seek NDA approval for select products that are currently marketed in the U.S. but are currently not approved by the FDA. The Company is actively developing a fourth unapproved sterile injectable product, for which it is working toward submission of an NDA by year end 2017. One of the Company's principle criteria for the development of commercially viable products is a well-established record of efficacy. We believe this strategy may create opportunities to have the only approved version of products in niche markets, potentially enjoying a period of *de facto* exclusivity through the 505(b)(2) approval pathway. However, this strategy has a limited number of opportunities where a meaningful return on investment is possible given the lack of patent protection from competition. The Company plans to evaluate several other unapproved products for potential development throughout the course of 2017, and will formally announce its intention to move forward with development should a candidate be selected.

Proprietary Product Pipeline

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

Proprietary Product Pipeline

Platform / Strategy	Drug/Product	Indication	Stage
Micropump®	Sodium oxybate	EDS / Cataplexy	Phase III trial ongoing
UMD #4	Sterile Injectable - Drug Undisclosed	Undisclosed	Development ongoing; target filing year end 2017
Pediatrics	*flexichamber*®	Asthma	540(k) approval; launch 1H 2017
LiquiTime®	Guaifenesin	Cough / Cold	Pivotal trial to commence pending stability data 1H 2017
LiquiTime®	Undisclosed	CNS	Proof of concept
LiquiTime®	Undisclosed	Pediatric	Proof of concept
Micropump®	Undisclosed	Pediatric	Proof of concept
Micropump®	Undisclosed	Psychiatric	Proof of concept
Trigger Lock™	Hydromorphone	Pain	PK work complete; seeking divestiture / partner to continue development
Medusa™	Exenatide	Diabetes	Phase 1(b) complete; seeking divestiture / partner to continue development

Competition and Market Opportunities

Competition

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing niche brand or generic specialty pharmaceutical products or drug delivery platforms. Some of these competitors may also be our business partners. There can be no assurance that our competitors will not obtain patent protection or other intellectual property rights that would make it difficult or impossible for us to compete with their products. Furthermore, major technological changes can happen quickly in the pharmaceutical and biotechnology industries. Such rapid technological change, or the development by our competitors of technologically improved or differentiated products, could render our drug delivery platforms obsolete or noncompetitive.

The drug delivery industry landscape has dramatically changed over the past decade and even more so during the past six 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 our pool of potential partners and further accelerated the competition among drug delivery and specialty pharmaceutical companies. Over the past ten years, numerous stand-alone drug delivery companies have been acquired (partly or entirely) by pharmaceutical, biotech, generic or other drug delivery companies. By acquiring drug delivery platforms, those companies are internalizing their previously outsourced R&D efforts while potentially preventing competitors from accessing the acquired technologies. In the meantime, certain drug delivery companies have consolidated their existing positioning or have entered new markets via M&A transactions and/or restructuring.

Just as Avadel has undertaken a strategy of developing and commercializing its own products, few of Avadel's "historical" competitors still pursue a sole drug delivery business model as many others have moved or are moving to the Specialty Pharma model. A few examples include, but are not limited to, Alkermes, Depomed, Ethypharm and Octoplus N.V. (*subsidiary of Dr. Reddy's)*.

Our drug delivery platforms primarily compete with technologies from companies such as:

Avadel's Drug Delivery Platforms	Competition Category*	Selected Competitive Companies*
Micropump® (oral)	Solid sustained release	Alkermes plc; COSMO Pharmaceuticals SpA; Depomed, Inc.; Durect Corp.; Supernus Pharmaceuticals, Inc.; Veloxis Pharmaceuticals A/S (*formerly LifeCycle Pharma*)
LiquiTime® (oral)	Liquid sustained release	Neos Therapeutics, Inc. ("Neos"); Tris Pharma, Inc. ("Tris")
Trigger-Lock™ (oral)	Abuse resistance	Acura Pharmaceuticals, Inc.; Altus Formulation, Cima (Cephalon); Collegium Pharmaceutical, Inc.; Durect Corp.; Egalet Corporation; Elite Pharmaceuticals, Inc.; Ethypharm; Grünenthal Group; Intellipharmaceutics International, Inc.; QRx Pharma, Ltd.; KemPharm, Inc.
Medusa™ (injectable)	Depot (PLA/PLGA microspheres, liposomes and other technologies)	Alkermes plc.; Biodel Inc.; Debiopharm Group; Durect Corp.; LG Life Sciences; InnoCore Pharmaceuticals; Marina Biotech, Inc. (*Novosom AG technology*); MedinCell SA; Octoplus N.V. (*subsidiary of Dr. Reddy's);* Onxeo (*formerly BioAlliance Pharma*); Pacira Pharmaceuticals, Inc.; Q Chip Ltd. (*Midatech*); REcoly N.V.; Soligenix, Inc. (*formerly DOR BioPharma Inc*); Surmodics, Inc.; Xenetic Biosciences plc. (*formerly Lipoxen plc*)

* From companies' web site and/or press releases.

Avadel's Specialty Pharma model (focusing on optimized re-formulations development capabilities) competes with a number of companies, based upon the product being developed. Examples of companies with whom we or future partners would compete, given our current pipeline, include Jazz Pharmaceuticals, Akorn Pharmaceuticals, Tris Pharma and others. Avadel as a specialty pharmaceutical company has various capabilities, including the use of the 505(b)(2) regulatory pathway, the life cycle management of drugs, and direct commercialization of drugs.

Market Opportunities

Drug delivery platforms are of particular interest for managing the life cycle of pharmaceutical products, as they offer many advantages:

- improvements in bioavailability
- pharmacokinetic improvements
- enhanced efficacy
- reduction of adverse events
- improved patient compliance

Application of an improved and patented drug delivery technology to a drug provides differentiation and the potential to add product specific patent protection. Market exclusivity can also be granted for improvements to existing drugs. BCC Research estimated the global drug delivery market to worth an estimated $188 billion in 2014 and that the market grew to $194 billion in 2015. The increased number of geriatric patients and the demand for convenient drug delivery options offer major opportunities for the development of innovative and easy-to-use drug delivery platforms. In 2015, FDA's Center for Drug Evaluation and Research ("CDER") approved 41 novel new drugs, as new molecular entities ("NMEs") under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications ("BLAs") (FDA, Novel New Drugs 2014, Summary, January 2015). Additionally, the FDA approved 82 "first time generic drugs" (FDA, ANDA (Generic) Drug Approvals in 2015, www.fda.gov).

Market opportunities for proprietary pipeline products that Avadel intends to pursue independently are estimated by the Company to be worth at least several hundred million dollars each. For example, Xyrem® (sodium oxybate) recorded $1.1 billion in sales for 2016 (source: Jazz press release Full Year and Fourth Quarter 2016 Financial Results, February 28, 2017) and is expected to generate between $1.2 and $1.25 billion in revenues in 2017; and the U.S. cough, cold, pain and allergy markets targeted by our LiquiTime-based products, is estimated between $6 billion and $8 billion annually (source: Nielsen Data Trend).

The industry faces many challenges. There are five main forces currently affecting all pharmaceutical and drug delivery companies and forcing the industry to adapt and to change: (i) the rise of generics; (ii) the rise in costs for new product development; (iii) the commoditization and acquisition of drug delivery technologies; (iv) the fact that integration of the drug delivery-based formulation development occurs at much earlier stage in the overall pharmaceutical development; and (v) higher regulatory and reimbursement hurdles.

These forces have affected the small molecule space to a greater extent, as biologics currently enjoy higher barriers to entry. In particular, in today's environment, a drug has to demonstrate significant therapeutic efficacy advantage 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. Drug delivery companies must now demonstrate, through costly Phase 3 trials, therapeutic efficacy of their new formulations. The FDA has actually encouraged drug companies developing enhanced formulations to use an abbreviated regulatory pathway: the 505(b)(2) NDA. Most drug delivery 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.

Because the drug delivery industry is highly competitive, participants seek ways to lessen the pressure and increase profitability. Avadel, resulting from the combination of its existing proprietary drug delivery platforms with the established commercial capability of its unapproved to approved product strategy has evolved into a Specialty Pharma company focusing on re-formulations and requiring shorter product development cycles by using a "fast track" NDA mechanism (505(b)(2)). The company's commercial capabilities also differentiate it from some competitors. The pharmaceutical and biotechnology sectors, with an impending "patent cliff", are forcing Big Pharma/Biotech to reorganize and creating niche opportunities for Specialty Pharma companies like Avadel.

Avadel's Drug Delivery Platforms

Avadel owns and develops drug delivery platforms 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 can be applied to a broad range of drugs (novel, already-marketed, or off-patent).

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.

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.

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

We believe the versatility of Micropump which permits us to develop differentiated product profiles (modified/controlled release formulations) under various dosage forms including capsules, tablets, sachets and liquid suspensions (LiquiTime) for oral use, is a competitive advantage. With Trigger Lock potentially addressing the issue of narcotic/opioid analgesics abuse, we have broad and versatile presentations to serve most markets from pediatric to geriatric.

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

We believe that the Medusa platform provides a competitive advantage for developing differentiated injectable product profiles. Medusa-based formulations permit drugs' full activity to be preserved in an extended release format with other potential advantages being, improved solubility, stability, and resistance to aggregation. Overall, Medusa™ can improve the patient experience through a change in the route of administration (e.g. switching from intravenous to subcutaneous injection) and may improve compliance through reduction of administration frequency (e.g. from once-a-day to once-a-week).

The Company will continue to selectively partner its proprietary formulations capabilities and will either commercialize products based on its drug delivery platforms on its own or sell or partner them.

Micropump®: Delivery Platform for the Modified and/or Controlled Release of Solid, Oral Dosage Formulations of Drugs

Avadel's Micropump platform 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.

Because R&D costs for reformulating a drug are typically substantially lower than for developing new chemical entities (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). Avadel currently has additional Micropump-based products in development, including sodium oxybate for EDS and cataplexy, which has been successfully tested in two Phase I clinical studies (see "- Proprietary Product Pipeline" in this Part I, Item 1 of this Annual Report on Form 10-K), and several early-stage feasibility studies of undisclosed drugs.

Micropump (and related products) is patent protected (see "- Proprietary Intellectual Property"). Coreg CR® Micropump-based microparticles are now being manufactured for GSK by Recipharm AB (see "- Strategic Alliances" in this Part I, Item 1 and "- Manufacturing" in this Part I, Item 1 of this Annual Report on Form 10-K).

LiquiTime®: Delivery Platform for the Modified/Controlled Release of Liquid, Oral Dosage Formulations of Drugs

U.S. sales of drugs, both prescription (Rx) and over-the-counter (OTC)) in liquid form for oral administration, exceeded $5.8 billion for the year 2016 (source: IMS). Amongst marketed "extended release" (twice-a-day or once-daily) liquid products areTussionex® (hydrocodone polistirex and chlorpheniramine polistirex) and its branded and generic alternatives, Delsym® and Delsym Children® (dextromethorphan polistirex developed and sold by Reckitt Benckiser plc.), Dyanavel XR (amphetamine, Tris) and Quillivant XR (methylphenidate) marketed by Pfizer. These products totaled almost $299 million sales in 2016 (source: IMS). Avadel has maintained the prescription rights to LiquiTime, as it views prescription products as higher-value opportunities. The Company is currently conducting feasibility studies on two potential prescription products utilizing its LiquiTime technology.

Avadel's LiquiTime platform uses Micropump's competitive advantages to allow us to develop 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. Unlike the other product examples described in the previous paragraph, which are all based on ion exchange resin technology, 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. We believe 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. We believe 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 US for OTC products and we are currently working on an extended release suspension formulation for guaifenesin (see "Proprietary Product Pipeline" in this Part I, Item 1 of this Annual Report on Form 10-K).

LiquiTime (and related products) is patent protected (see "- Proprietary Intellectual Property" in this Part I, Item 1 of this Annual Report on Form 10-K).

Trigger Lock™: Delivery Platform for Abuse-Resistant Modified/Controlled Release Formulations of Narcotic/Opioid Analgesics

A major problem faced by society is the growing abuse and misuse of opioids by drug abusers, who attempt to extract the opioids from the drug products for the purposes of injection or to otherwise achieve the immediate release of the large doses contained in extended release products. The proportion of narcotic/opioid analgesics abuse associated with emergency room admissions has more than tripled in ten years, from 6.8% in 1998 to 26.5% in 2008 (TEDS report, July 15, 2010). Narcotic/opioid analgesics abuse continues to increase as current products remain easy to abuse. In 2010, enough prescription painkillers were prescribed to medicate every American adult every 4 hours for one month (PBS 2013). The number of prescription medicine abusers in 2010 was 8.76 million, 5.1 million of whom abused painkillers (drugabuse.com 2013). The market for opioid drugs, used to treat patients suffering from severe and chronic pain in the seven major markets (USA, Japan, and five European countries), was estimated to exceed $7.4 billion in 2010, dominated by oxycodone. In 2016, the U.S. sales of oral opioid drugs (hydrocodone, hydromorphone, morphine, oxycodone and oxymorphone, including combination products) exceeded $5.9 billion (source: IMS).

Avadel's Trigger Lock platform utilizes the Micropump technology and additional formulation techniques resulting in abuse-resistant modified/controlled release formulations of narcotics and other drugs susceptible to abuse.

Trigger Lock has the potential to provide products that are either bioequivalent to or have improved pharmacokinetics over marketed narcotic/opioid analgesics. We believe that the FDA's moves to restrict the prescribing of extended-release opioid analgesics should benefit abuse-resistant formulations, such as Trigger Lock. The FDA issued a "Draft Guidance for Abuse Deterrent Opioids" on January 9, 2013.

We believe that Trigger Lock could potentially satisfy the FDA Draft Guidance for Abuse Deterrent Opioids for the following reasons:

- Laboratory-based in vitro manipulation and extraction studies (Category 1) - Success with Trigger Lock
- Pharmacokinetic studies (Category 2) - Success with Trigger Lock
- Clinical abuse potential studies (Category 3) - To be required prior to marketing
- Analysis of post marketing data to assess the impact of an abuse-resistant formulation on actual abuse in a community setting (Category 4) - To be performed post marketing

Avadel has one Trigger Lock-based internal product, hydromorphone, developed for which certain PK and independent in-vitro abuse resistance data was gathered in 2015. The Company will consider the sale or out-license of its Trigger-Lock platform to a third party. (see "- Proprietary Product Pipeline" in this Part I, Item 1 of this Annual Report on Form 10-K). Trigger Lock (and related products) is patent protected (see "- Proprietary Intellectual Property" in this Part I, Item 1 of this Annual Report on Form 10-K).

Medusa™ Delivery Platform for the Modified/Controlled Release of Injectable Dosage Formulations of Drugs

U.S. sales for injectable products in 2016 exceeded $150 billion, including more than $18 billion for "long-acting" products (source: IMS). Global sales of biologics were between $190 to $222 billion in 2014 according to various analysts, and are expected to exceed $386 billion by 2019 (source: BCC Research).

Avadel's Medusa, a proprietary hydrogel depot platform, enables less frequent injections by extending the release profile of subcutaneously delivered drugs. Importantly, Medusa is able to do this without modifying the drug substance thereby offering a potentially faster and less risky regulatory pathway to approval.

The Medusa platform consists of proprietary and versatile drug carrier polymers that form hydrogel depots after injection. Medusa polymers are made of glutamic acid, a naturally occurring amino acid, and alpha tocopherol (Vitamin E). These polymers are amphiphilic and spontaneously form stable hydrogels in water. These hydrogels contain hydrophobic nanodomains rich in Vitamin E and hydrophilic polyglutamate that are exposed to water. The hydrogels are robust over a wide range of pH values and can be stored, in particular as a stable freeze-dry form, that can be easily reconstituted in water for injection. Those polymers have been proven to be safe and biodegradable. A comprehensive absorption, distribution, metabolism and excretion (ADME) and regulatory toxicology package for the key Medusa polymer was completed in 2014 in order to update the Type IV Drug Master File ("DMF") filed with the FDA in February 2011.

The drug is loaded in the hydrogel (nano- or micro-gel) via non-covalent, hydrophobic and electrostatic bonds. Once in the body, the hydrogel releases the drug in a controlled manner with no initial burst effect, a lower Cmax, and uniform plasma concentration over an extended period of time. Both drug loading (in fully aqueous solution, and usually, under solvent- and surfactant-free conditions) and release (essentially by displacement of the loaded drug by circulating endogenous proteins) are non-denaturing, which preserves structural integrity - and hence activity of the drug. The transient, non-covalent interactions dictate the pharmacokinetic parameters (Cmax and bioavailability in particular) of the released drugs.

We believe that Medusa is best suited for "biobetter" development opportunities, which can be summarized as follows:

- Proven biologic drugs with established markets and proven clinical development approaches;
- Product differentiation e.g. improvement of pharmacokinetic (and potentially pharmacodynamics) parameters;
- Protection of market position through product differentiation and/or patent extension; and,
- Ability to grow market share and resist price competition.

Avadel had one Medusa-based internal product in development (see "- Proprietary Product Pipeline" in this Part I, Item 1 of this Annual Report on Form 10-K). Avadel completed a Phase 1(a) study of its once-a-week Medusa exenatide product in 2015 and a Phase 1(b) study in second quarter of 2016. The Company is currently looking to divest this platform in order to more narrowly focus on its most developed technology platforms, Micropump and LiquiTime.

Medusa is patent protected until June 2031 in the United States (see "- Proprietary Intellectual Property" in this Part I, Item 1 of this Annual Report on Form 10-K).

Proprietary Intellectual Property

Patents and other proprietary rights are essential to our business. A substantial part of our proprietary product pipeline and our strategic alliances are dependent on our drug delivery platforms and related products (formulation, process, etc.) being patent protected. As a matter of policy, we seek patent protection of our inventions and trademarks and also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and develop our competitive position.

On a case-by-case basis, an invention developed jointly by Avadel and a partner may be assigned to and prosecuted by the partner. The information provided in this section herein, does not refer to such patent applications.

As of December 31, 2016, we owned the following patent and patent applications:

	US	EUROPE	ROW*	TOTAL
Granted patents	19	194	112	325
Pending patent applications	18	12	37	67
Patents granted in 2016	3	21	9	33
Patent applications filed in 2016	5	—	—	5

* ROW: Rest of the World

The Company's granted patents protecting its drug delivery platforms have the following latest dates of expiration by technology platform:

Drug Delivery Platforms	Date of expiration of granted patents	
	U.S.	Europe
Micropump®	July 2027	May 2030
LiquiTime®	September 2025	April 2023
Trigger Lock™	April 2027	May 2026
Medusa™	June 2031	November 2024

Avadel's key patents include protection for the following:

- **Micropump® platform** is patented under multiple granted patents. Among them is Avadel's Micropump®-related key patent, WO 2003/030878, which discloses an efficacious coating formulation for providing delayed and sustained release of an active ingredient with absorption limited to the upper part of intestinal tract. It is granted in the U.S. as US Patent 8,101,209 and will expire on October 2025. Equivalent patents are granted in China, Hong Kong, Israel, India, Singapore, Japan, South Korea, Canada, South Africa, Mexico (expiry date: October 2022) and in France (expiry date: October 2021). Patent applications are pending in Brazil and Europe; and, would expire on October 2022.
- **LiquiTime® platform** is protected by Avadel's patent granted in the U.S. (US 7,906,145; expiry date: September 2025) and in South Korea, Canada, Israel, Japan, Australia, China, Austria, Belgium, Switzerland, Liechtenstein, Germany, Spain, France, United Kingdom, Italy, Ireland, Luxembourg, Netherlands, Portugal, Sweden, Turkey, India, Mexico, South Africa that expire in April 2023. A patent application is pending in Brazil and 3 continuation application are pending in the U.S.
- **Trigger Lock platform** is protected by 7 (seven) Avadel patent application families. Within these patent families, 12 (twelve) patents are granted in the U.S., Europe and Japan; and, 20 (twenty) patent applications are pending including other countries and will expire between November 2025 and December 2033.
- **Medusa platform** is patented under Avadel's key patent WO 2003/104303 granted in the U.S. and which will expire in July 2023. Equivalent patents to WO 2003/104303 are granted in China, Israel, Mexico, Australia, Japan, South Korea, Canada, Europe, India and South Africa. A patent application is pending in Brazil. These patents will expire in June 2023.
    - Medusa-based nanogels are protected by issued patents from WO 2005/051416' family in the U.S., Australia, China, Israel, Japan, South Korea, Mexico, South Africa, India, Canada and Europe expiring on November 2024. Corresponding patent application is pending in Brazil

- Medusa-based microgels are protected by granted patents from WO 2007/141344' patents family in the U.S., Australia, Japan, Canada, China, Israel, South Korea, Mexico and South Africa. Patent applications are pending in Europe, India and Brazil. This patents family will expire on June 2027

Manufacturing

The manufacturing facilities for our drug delivery platforms are located in Pessac, France, near Bordeaux (hereinafter referred as the "Pessac Facility"). The Pessac Facility, which was previously owned by Flamel Technologies SA, provided us with two commercial scale production lines for the manufacture of Coreg CR ® microparticles, and another production line used for other Micropump, and LiquiTime/Trigger Lock-based formulations (*i.e.* the production of certain pharmaceutical products, including commercial scale quantities of our intermediate formulated products). During 2014, our commercial manufacturing capacity utilization ranged from 50% to 65% of total capacity.

On December 1, 2014, the Pessac Facility was divested to Recipharm. This divestiture agreement allows Avadel to retain access to the development and manufacturing capabilities of Pessac Facility for all its drug delivery platforms. In particular, this facility can support, like any CDMO, certain of our needs for scale-up activities and clinical batch manufacturing for our Micropump, LiquiTime and Trigger Lock platforms, as well as for the synthesis of Medusa's polymers and technical batch manufacturing for non-clinical studies pertaining to our Medusa-based formulations. In addition, this agreement permits us to utilize other Recipharm manufacturing facilities for the development and/or manufacture of our proprietary pipeline if needed.

The Pessac Facility was never used for the production of finished products commercialized by our US operations. The manufacture of the UMDs marketed by the Company's US operations is outsourced to cGMP compliant and FDA-audited CDMOs in accordance with supply agreements.

Avadel intends to continue to outsource to third party contract manufacturing companies like Recipharm when appropriate. For example, in 2014, Avadel transferred the scale up of certain of its own proprietary products to CDMOs in the U.S. This will be beneficial to the Company for products that will ultimately be marketed in the United States.

Government Regulation

The design, testing, manufacturing and marketing of certain new or substantially modified drugs, biological products or medical devices must be approved, cleared or certified by regulatory agencies, regulatory authorities and Notified Bodies under applicable laws and regulations, the requirements of which may vary from country to country. This regulatory process is lengthy, expensive and uncertain. In the United States, the FDA regulates such products under various federal statutes, including the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Public Health Service Act. Similar requirements exist in the Member States of the European Union and are imposed by the European Commission and the competent authorities of EU Member States. There can be no assurance that we or our collaborative partners will be able to obtain such regulatory approvals or clearances or certification of conformity on a timely basis, if at all, for any products under development. Delays in receipt or failure to receive such approvals, clearances, or certifications of conformity, the revocation of previously received approvals or clearances, or certifications of conformity, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Any finished product that we develop, either inclusive or not of our drug delivery platforms, is subject to regulatory approval in the respective country where we intend to market the product. In the United States and the European Union, biological products, such as therapeutic proteins and peptides, generally are subject to the same FDA and EU regulatory requirements as other drugs, although some differences exist. For example, a biologic license application (BLA) is submitted for approval for commercialization of some biological products instead of the New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") used for other drugs. Also, unlike other drug products, some biological products are subject to FDA lot-by-lot release requirements and those approved under a BLA currently cannot be the subject of ANDAs. However, the FDA is working on a variety of issues pertaining to the possible development of biosimilars and there can be no assurance that this type of submission will continue to be unavailable for biological products. Additionally, our delivery platforms likely will be regulated by the FDA as 'combination products' if they are used together with a biologic or medical device. 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. In the European Union, applications for marketing authorization of innovative drugs, which are essentially products that are neither generics nor biosimilars, are addressed on a case-by-case basis by the European Medicines Agency ("EMA"), followed by a decision of the European Commission, or by the competent authorities of the EU Member States.

New Drug and Biological Product Development and Approval Process

United States and European Union

Regulation by governmental authorities in the United States and other countries has a significant impact on the development, manufacture, and marketing of biological and drug products and on ongoing research and product development activities. The products of all of our pharmaceutical and biotechnology partners as well as our 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 cGMP quality principles, 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 and biological products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources.

The FDA and European Union's statutes, regulations, or policies may change and additional statutes or government regulations may be enacted which could prevent or delay regulatory approvals of biological or drug products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

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

The process for new drug and biological 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 or biological 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 requirements. 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 biological or 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 US 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

USA: 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 or biological 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 matters 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 or Biological License Application

After the completion of the clinical trial phases of development, if the sponsor concludes that there is substantial evidence that the drug or biological candidate is effective and that the drug is safe for its intended use, an NDA or "BLA" ("Biological License Application") may be submitted to the FDA. The application must contain all of the information on the drug or biological candidate gathered to that date, including data from the pre-clinical and clinical trials, information pertaining to the preparation of the drug

or biologic, analytical methods, product formulation, details on the manufacture of finished products, proposed product packaging, labeling and stability (shelf-life). NDAs and BLAs 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 or BLA does not assure FDA approval for marketing.

The FDA reviews all submitted NDAs and BLAs 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 or BLA 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 or BLA 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, we do not anticipate it applying to any of our products or our 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 or BLA 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 or BLA 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 or BLA. For instance, FDA may require us to provide data from additional preclinical studies or clinical trials to support approval of certain development products acquired from Éclat. Among the conditions for NDA or BLA 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 inspections prior to NDA or BLA approval to assure compliance with cGMPs and with 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, we intend to submit 505(b)(2) NDAs, relying solely on published scientific literature. We do not plan to conduct additional preclinical studies or clinical trials for these 505(b)(2) NDAs; and, if we 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. Because it takes time for the FDA to review and approve an application once it has been accepted for filing, five-year NCE exclusivity usually effectively means the ANDA or 505(b)(2) application is not approved for a period well beyond five years from approval of the RLD.

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.

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. When any of our products is approved, we intend to seek patent term restoration for an applicable patent when it is appropriate.

Other Countries

Whether or not FDA approval has been obtained, approval of a pharmaceutical product by regulatory authorities must be obtained in any other country prior to the commencement of marketing of the product in that country. The approval procedure may vary from country to country, can involve additional testing, and the time required may differ from that required for FDA approval. Under European Union legislation, product authorization is granted for an initial period of five years. The authorization may subsequently be renewed for an unlimited period on the basis of a re-evaluation of the risk-benefit balance by the competent authorizing authority. In the EU, marketing authorization of drugs is according to either a centralized, decentralized or mutual recognition procedure, generally depending on the nature and type of drug. Certain designated drugs may be authorized only in accordance with the centralized procedure by the European Commission following an opinion by the European Medicines Agency ("EMA"). The centralized procedure is mandatory for pharmaceutical products developed by means of biotechnological processes (recombinant DNA, controlled expression of genes coding, hybridoma and monoclonal antibody methods), products containing new actives substances indicated for the treatment of AIDS, cancer, diabetes and neuro-degenerative diseases, orphan designated medicinal products and advanced therapy products. Other pharmaceutical products may be authorized in accordance with the centralized procedure where it is demonstrated that they contain new active substances or are demonstrated to have a significant therapeutic benefit, or where they constitute a scientific or technical innovation, or are in the interest of patients at Community level. Where authorization is in accordance with the decentralized or mutual recognition procedures, approval is either by "mutual

recognition," whereby the authorization granted by the competent authorities of one EU Member States are recognized by the authorities of other EU Member States, or where the competent authorities of each EU Member State authorize a product on the basis of an identical dossier, with one national authority taking care of the dossier intensively and coordinating activities. To the extent possible, clinical trials of our products are designed to develop a regulatory package sufficient for the grant of marketing authorization in the EU approval according to the Community Code on medicinal products.

Regulatory approval of prices for certain drugs is required in many other countries outside the United States. In particular, many EU Member States make the reimbursement of a product within the national social security system conditional on the agreement by the seller not to sell the product above a fixed price in that country. Also common is the unilateral establishment of a reimbursement price by the national authorities, often accompanied by the inclusion of the product on a list of reimbursable products. Related pricing discussions and ultimate governmental approvals can take several months to years. Some countries require periodic pricing updates and renewals at intervals ranging from two to five years. Some countries also impose price freezes or obligatory price reductions. We cannot assure you that, if regulatory authorities establish lower prices for any product incorporating our technology in any one EU Member State, this will not have the practical effect of requiring our collaborative partner correspondingly to reduce its prices in other EU Member States. We can offer no assurance that the resulting prices would be sufficient to generate an acceptable return on our investment in our products.

Regulation of Combination Drugs

Medical products containing a combination of drugs or biological 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 our delivery platforms, when coupled with a drug, biologic 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.

In the European Union, drug combinations, that is, drug products containing two or more drug substances each of which has to contribute a proven advantage of therapy (*e.g.* synergism, less adverse reactions), are subject to drug regulations like all others. Products combining drug substances or drugs with a device may be subject to device and/or drug regulations, or may be classified as medical devices, depending on the individual case.

Marketing Approval and Reporting Requirements

If the FDA approves an NDA or BLA, 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, with respect to Vazculep, the FDA has required the Company to conduct post-marketing clinical and non-clinical studies to be completed between 2016 and 2019.

Drug and biologics 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 the Company or our licensees to comply with FDA's cGMP regulations or other requirements could have a significant adverse effect on the Company'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 or BLA holder. In addition, later discovery of previously unknown problems may result in restrictions on the product, manufacturer or NDA or BLA holder, including withdrawal of the product from the market. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of our 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.

Biologics Price Competition and Innovation Act of 2009

The Hatch-Waxman construct applies only to conventional chemical drug compounds, sometimes referred to as small molecule compounds approved under an NDA. On March 23, 2010, however, the "Biologics Price Competition and Innovation Act" of 2009, or "BPCIA", was signed into law. It creates an abbreviated approval pathway for biological products that are "biosimilar" to a previously approved biological product, which is called the "reference product." This abbreviated approval pathway is intended to permit a biosimilar product to come to market more quickly and less expensively than if a "full" BLA were submitted, by relying to some extent on FDA's previous review and approval of the reference product to which the proposed product is similar. If a proposed biosimilar product meets the statutory standards for approval (which include demonstrating that it is highly similar to the reference product and there are no clinically meaningful differences in safety, purity or potency between the products), the proposed biosimilar may be approved on the basis of an application that is different than the standard BLA. In addition, a biosimilar

product may be approved as interchangeable with the reference product if the proposed product application meets standards intended to ensure that the biosimilar product can be expected to produce the same clinical result as the reference product.

Other Regulation

Controlled Substances Act. Our Trigger Lock delivery platform is designed to control the release of narcotics and other active ingredients subject to abuse. Narcotics 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. The company 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. Our manufacturing facilities and laboratories are subject to inspection and regulation by French regulatory authorities in accordance with applicable EU provisions governing cGMP and may also be subject to the United States' and other countries' regulatory agencies. Mutual recognition agreements for government inspections exist between the United States, the EU, Canada, Australia and New Zealand.

In addition to regulations enforced by the FDA, we are 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. Our R&D involves the controlled use of hazardous materials, chemicals, viruses and various radioactive compounds. Although we believe that our 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. We are 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 our 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. Our sales and marketing activities relating to our 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 us or our executive officers of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions. In addition to the reasons noted above, our 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, our reporting actions could be subject to the penalty provisions of the pertinent authorities.

Healthcare Privacy and Security Laws. We may be subject to, or our marketing activities may be limited by, 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 our sales, marketing, and other activities with respect to our medicines in the United States by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or otherwise comply with these laws, we 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, we have 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). We are 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 our prices, or offer required discounts or rebates could subject us 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 our potential products as well as products of pharmaceutical and biotechnology companies that incorporate our 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 us to maintain price levels sufficient to realize an appropriate return on our product development investment. Legislation and regulations affecting the pricing of pharmaceuticals may change before our proposed products are approved for marketing and any such changes could further limit reimbursement for medical products and services.

Employees

As of December 31, 2016, we had approximately 192 employees, of which approximately 165 were full-time. None of the Company's employees are subject to a union or other collective bargaining agreement. Employees at our French subsidiaries

(approximately 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. The Company believes that its relations with its employees are satisfactory.

Item 1A. Risk Factors.

Our business faces many risks. The risks described below may not be the only risks we face. Additional risks that we do not yet know of or that we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occur, our business, financial condition or results of operations could suffer, and the trading price of our securities could decline. As a result, you should consider all of the following risks, together with all of the other information in this Annual Report on Form 10-K, before making an investment decision regarding our securities.

Risks Relating to Our Business and Industry

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

We derive a majority of our revenues from sales of three products, Bloxiverz, Vazculep and Akovaz. Additionally, we depend on a small number of customers for the majority of our revenues from these products. Four customers, accounted for approximately 93% of revenues from sales of these products in 2016. 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 resulting in lower revenues or loss of business. This distribution network is also continuing to undergo consolidation marked by mergers and acquisitions among wholesale distributors and retail drug store chains. As a result, a small number of large wholesale distributors and large chain drug stores control a significant share of the market. We expect that continuing consolidation may cause competitive pressures on pharmaceutical companies. The loss of any one of these products or the termination of our relationship with any of these customers or our failure to broaden our customer base could cause our revenues to decrease significantly and result in losses from our operations. Further, we may be unable to negotiate favorable business terms with customers that represent a significant portion of our revenues, and any such inability could have a material adverse effect on our business, results of operations, financial condition and prospects.

We expect to rely on collaborations with third parties to commercialize certain of our products in development, in particular products using our drug delivery platforms, and such strategy involves risks that could impair our prospects for realizing profits from such products.

The commercialization of some of our products in development which utilize our drug delivery platforms, such as Trigger Lock based-hydromorphone and Medusa based-exenatide, will require resources and expertise that we currently do not have. Therefore, we expect to seek third-party collaboration partners for strategic alliances, licenses, product divestitures or other arrangements to commercialize these products, as we did with respect to the license to Elan for the OTC rights for LiquiTime (see "- Products in Development with Partners" in this Part I, Item 1 of this Annual Report on Form 10-K). We may not be successful in entering into such collaborations on favorable terms, if at all, or our collaboration partners may not adequately perform under such arrangements, and as a result our ability to commercialize these products will be negatively affected and our prospects will be impaired.

Our products may not gain market acceptance.

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

- the scope of regulatory approvals, including limitations or warnings in a product's regulatory-approved labeling;
- in the case of any new "unapproved-marketed-drug" product we may successfully pursue, whether and the extent to which the FDA removes competing products from the market;
- demonstration of the clinical safety and efficacy of the product or technology;
- the absence of evidence of undesirable side effects of the product or technology that delay or extend trials;
- the lack of regulatory delays or other regulatory actions;
- its cost-effectiveness;
- its potential advantage over alternative treatment methods;
- the availability of third-party reimbursement; and
- the marketing and distribution support it receives.

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

Our products may not reach the commercial market for a number of reasons.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Successful research and development ("R&D") of pharmaceutical products is difficult, expensive and time consuming. Many product candidates fail to reach the market. Our success will depend on the development and the successful commercialization of additional previously Unapproved Marketed Drug ("UMD") products, development of products that utilize our drug delivery platforms, and the continued development and marketing of the products we obtained in the FSC acquisition in February 2016. If any of our additional UMD products, products incorporating our drug delivery platforms, or FSC products fails to reach the commercial market, our future revenues would be adversely affected.

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

- the FDA, the European Medicines Agency ("EMA"), the competent authority of an EU Member State or an Institutional Review Board ("IRB"), or an Ethics Committee (EU equivalent to IRB), or our partners may delay or halt applicable clinical trials;
- we or our partners may face slower than expected rate of patient recruitment and enrollment in clinical trials, or may devote insufficient funding to the clinical trials;
- our drug delivery platforms and drug products may be found to be ineffective or cause harmful side effects, or may fail during any stage of pre-clinical testing or clinical trials;
- we or our partners may find certain products cannot be manufactured on a commercial scale and, therefore, may not be economical or feasible to produce;
- managed care providers may be unwilling or unable to reimburse patients at an economically attractive level for our products; or
- our products could fail to obtain regulatory approval or, if approved, fail to achieve market acceptance, fail to be included within the pricing and reimbursement schemes of the U.S. or EU Member States, or be precluded from commercialization by proprietary rights of third parties.

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

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to R&D in order to develop new products and enhance our technologies. In 2016, we spent $34,611 on R&D. Our ongoing investments in R&D for future products could result in higher costs without a proportionate increase, or any increase, in revenues. The R&D process is lengthy and carries a substantial risk of failure. If our R&D does not yield sufficient products that achieve commercial success, our future operating results will be adversely affected.

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

As part of the divestiture of our development and manufacturing facility located in Pessac, France to Recipharm AB ("Recipharm") in December 2014, we entered into certain agreements with Recipharm for the development, supply of clinical materials and potentially the supply of commercial batches for several of our products incorporating our drug delivery platforms, as well as our Medusa polymer(s); for details see "Business - Information on the Company" in this Part I, Item 1 of this Annual Report on Form 10-K. Any disruption in the operations of Recipharm or if Recipharm fails to supply acceptable quantity and quality materials or services to us for any reason, such disruption or failure could delay our product development and could have a material adverse effect on our business, financial condition and results of operations. In case of a disruption, we may need to establish alternative manufacturing sources for our drug delivery products, and this would likely lead to substantial production delays as we build or locate replacement facilities and seek to satisfy necessary regulatory requirements.

We depend on a limited number of suppliers for the manufacturing of our products and certain raw materials used in our products and any failure of such suppliers to deliver sufficient quantities of supplies of product or these raw materials could have a material adverse effect on our business.

Currently, we depend on a single contract manufacturing organization for three products, Bloxiverz, Vazculep and Akovaz, from which we derive a majority of our revenues. Additionally, we purchase certain raw materials used in our products from a limited number of suppliers, including a single supplier for certain key ingredients. If the supplies of these products or materials were interrupted for any reason, our manufacturing and marketing of certain products could be delayed. These delays could be extensive

and expensive, especially in situations where a substitution was not readily available or required variations of existing regulatory approvals and certifications or additional regulatory approval. For example, an alternative supplier may be required to pass an inspection by the FDA, EMA or the competent authorities of EU Member States for compliance with current Good Manufacturing Practices ("cGMP") requirements before supplying us with product or before we may incorporate that supplier's ingredients into the manufacturing of our products by our contract, development, and manufacturing organizations ("CDMOs"). Failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

If our competitors develop and market technologies or products that are safer or more effective than ours, or obtain regulatory approval and market such technologies or products before we do, our commercial opportunity will be diminished or eliminated.

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures and other pharmaceutical and biotechnology companies, including other companies developing drug delivery platforms or niche brand or generic specialty pharmaceutical products. Some of these competitors may also be our business partners.

Our drug delivery platforms compete with technologies provided by several other companies (for details see "Business - Competition and Market Opportunities" in this Part I, Item 1 of this Annual Report on Form 10-K). In particular, New Biological or Chemical Entities ("NBEs" or "NCEs") could be developed that, if successful, could compete against our drug delivery platforms or products. Among the many experimental therapies being tested in the U.S. and in the EU, there may be some that we do not now know of that may compete with our drug delivery platforms or products in the future. These new biological or chemical products may be safer or may work better than our products.

With respect to our UMD drug products, the FDA could approve generic versions or previously filed NDAs of our marketed products, as was the case with the approval of APP's (a division of Fresenius Kabi USA, LLC) and Eurohealth International's (an affiliate of West-Ward Pharmaceuticals Corp.) neostigmine methylsulfate products, competitive products to Bloxiverz in January and December 2015 respectively.

With respect to our pediatric products acquired in our acquisition of FSC, third parties offer competing products in both the OTC and the prescription markets.

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

If third party payors choose not to reimburse the use of our pediatric products our sales and profitability could suffer.

Because certain products in several of the categories in which we participate are available on an over-the-counter basis (OTC) some insurance programs may drive consumers to those products by requiring large co-pays for our products. In some cases, this could require a patient failure with OTCs before our products are allowed to be used. Additionally, some health plans may prefer generic alternatives in our therapeutic categories, which is manifested by requiring higher copays for our products. Other health plans could omit coverage for our products altogether. Any of these types of dynamics could negatively impact the sale of our products.

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

Future prices for our pharmaceutical products and medical devices will be substantially affected by reimbursement policies of third-party payors such as government healthcare programs, private insurance plans and managed care organizations; by our contracts with the drug wholesalers who distribute our products; and by competitive market forces generally. In recent years, third-party payors have been exerting downward pressure on prices at which products will be reimbursed, and the drug wholesale industry has been undergoing consolidation which gives greater market power to the remaining, larger drug wholesalers. In the U.S., the new administration has made public and social media statements causing uncertainty as to future federal U.S. government policies regulating drug prices. And the trend toward increased availability of generic products has contributed to overall pricing pressures in the pharmaceutical industry. Any future changes in laws, regulations, practices or policies, in the drug wholesale industry, or in the prevalence of generic products may adversely affect our financial condition and results of operations.

If we cannot keep pace with the rapid technological change in our industry, we may lose business, and our drug delivery platforms could become obsolete or noncompetitive.

Our success also depends, in part, on maintaining a competitive position in the development of products and technologies in a rapidly evolving field. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries. If we cannot maintain competitive products and technologies, our competitors may succeed in developing competing technologies or obtaining regulatory approval for products before us, and the products of our competitors may gain market acceptance more rapidly than our products. Such rapid technological change, or the development by our competitors of technologically improved or different products, could render our drug delivery platforms obsolete or noncompetitive.

We may fail to effectively pursue our business strategy.

Our business strategy is to obtain FDA approval and commercialize certain UMD product candidates, continue to develop and commercialize our drug delivery platforms, develop and market the FSC products and identify and acquire additional businesses or new product opportunities. There can be no assurance that we will be successful in any of these objectives; and a failure in any of these objectives could negatively impact our business and operating results.

In particular, we may be unable to successfully identify attractive acquisition candidates or complete any acquisitions, successfully integrate any acquired business, product or technology or retain any key employees of acquired businesses. Integrating any business, product or technology we acquire could be expensive and time consuming, and could disrupt our ongoing business and distract our management. If we fail to complete these acquisitions or successfully integrate any acquired businesses, products or technologies, our business would suffer. In addition, any amortization or charges resulting from the costs of acquisitions could negatively impact our operating results.

The impact of the acquisition of FSC on our financial results may be worse than the assumptions we have used.

We made certain assumptions relating to the impact on our financial results from the acquisition of FSC. These assumptions relate to numerous matters, including:

- the amount of intangible assets that will result from the acquisition;
- the impact of fair value adjustments to related party payables as a result of changes in estimated probability and timing of achieving the targets;
- acquisition costs, including transaction and integration costs, as well as operating costs going forward;
- the impact of impairment and other charges if the FSC products are unsuccessful; and
- other financial and strategic risks of the acquisition.

If one or more of these assumptions are incorrect, it could have an adverse effect on our business and operating results, and the perceived benefits from the acquisition may not be realized. In addition, we may encounter general economic and business conditions that adversely affect us following the acquisition.

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

Our success depends, in part, on our ability to obtain and enforce patents for our products and technology, including our drug delivery platforms, and to preserve our trade secrets and other proprietary information. If we cannot do so, our competitors may exploit our inventions and deprive us of the ability to realize revenues and profits from our products and technologies.

Any patent applications that we have made or may make relating to our potential products or technologies may not result in patents being issued. Patent law relating to the scope of claims in the pharmaceutical and biotechnology fields is continually evolving and can be the subject of uncertainty and may change in a way that would limit protection. Our patents may not be exclusive, valid or enforceable. For example, our patents may not protect us against challenges by companies that submit drug marketing applications to the FDA, the EMA, or the competent authorities of EU Member States, that rely, at least in part, on safety and efficacy data from our products or our business partners' products. In addition, competitors may obtain patents that may have an adverse effect on our ability to conduct business or discover ways to circumvent our patents. The scope of any patent protection may not be sufficiently broad to cover our products or to exclude competing products. Our partnerships with third parties expose us to risks that they will claim intellectual property rights on our inventions or fail to keep our unpatented products or technology confidential.

Further, patent protection once obtained is limited in time, after which competitors may use the covered product or technology without obtaining a license from us. Because of the time required to obtain regulatory marketing approval, the period of effective patent protection for a marketed product is frequently substantially shorter than the duration of the patent.

We also rely on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen our competitive position. To protect our products, trade secrets and proprietary technologies, we rely, in part, on confidentiality agreements with our employees, consultants, advisors and partners. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information. If these agreements are breached, we cannot be certain that we will have adequate remedies. Further, we cannot guarantee that third parties will not know, discover or independently develop equivalent proprietary information or technologies, or that they will not gain access to our trade secrets or disclose our trade secrets to the public. Therefore, we cannot guarantee that we can maintain and protect unpatented proprietary information and trade secrets. Misappropriation or other loss of our intellectual property would adversely affect our competitive position and may cause us to incur substantial litigation or other costs.

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

The Leahy-Smith America Invents Act of 2011 ("AIA") changes the current U.S. "first-to-invent" system to a system that awards a patent to the "first-inventor-to-file" for an application for a patentable invention. This change alters the pool of available materials that can be used to challenge patents in the U.S. and eliminates the ability to rely on prior research to lay claim to patent rights. Disputes will be resolved through new derivation proceedings and the AIA creates mechanisms to allow challenges to newly issued patents in reexamination proceedings. New bases and procedures may make it easier for competitors to challenge our patents, which could result in increased competition and have a material adverse effect on our business and results of operations. The AIA may also make it harder to challenge third-party patents and place greater importance on being the first inventor to file a patent application on an invention. The AIA amendments to patent filing and litigation procedures in the U.S. my result in litigation being more complex and expensive and divert the efforts of our technical and management personnel.

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

Third parties may claim, that the manufacture, use, import, offer for sale or sale of our drug delivery platforms or our other products infringes on their patent rights. In response to such claims, we may have to seek licenses, defend infringement actions or challenge the validity of those patent rights in court. If we cannot obtain required licenses, are found liable for infringement or are not able to have such patent rights declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from the manufacture, use, import, offer for sale or sale of products or methods of drug delivery covered by the patents of others. We may not have identified, or be able to identify in the future, U.S. or foreign patents that pose a risk of potential infringement claims.

Any claims, with or without merit, that our products or drug delivery platforms infringe proprietary rights of third parties could be time-consuming, result in costly litigation or divert the efforts of our technical and management personnel, any of which could disrupt our relationships with our partners and could significantly harm our operating results.

If we or our partners are required to obtain licenses from third parties, our revenues and royalties on any commercialized products could be reduced.

The development of some of our drug delivery platforms-based products may require the use of raw materials (*e.g.* proprietary excipient), active ingredients, drugs (*e.g.* proprietary proteins) or technologies developed by third parties. The extent to which efforts by other researchers have resulted or will result in patents and the extent to which we or our partners are forced to obtain licenses from others, if available, on commercially reasonable terms is currently unknown. If we or our partners must obtain licenses from third parties, fees must be paid for such licenses, which could reduce the net revenues and royalties we may receive on commercialized products that incorporate our drug delivery platforms.

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

In the ordinary course of our business, we collect and store proprietary data, including intellectual property, as well as our proprietary business information and that of our customers, suppliers and business partners, on our networks. The secure maintenance and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information systems and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, investigations by regulatory authorities in the U.S. and EU Member States, disruption to our operations and damage to our reputation, any of which could adversely affect our business.

Failure to comply with domestic and international privacy and security laws could result in the imposition of significant civil and criminal penalties.

The costs of compliance with privacy and security laws, including protecting electronically stored information from cyber-attacks, and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). 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.

Fluctuations in foreign currency exchange rates may cause fluctuations in our financial results.

For the year ended December 31, 2016, we derived 100% of our total revenues from continuing operations from transactions in U.S. dollars, but have a majority of our expenses denominated in Euros. Up through December 30, 2016 our functional currency was the Euro and our reporting currency is the U.S. Dollar. As a result, both our actual and reported financial results could be significantly affected by fluctuations of the Euro relative to the U.S. dollar. We do not currently engage in substantial hedging activities with respect to the risk of exchange rate fluctuations.

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

Our 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 our management report annually on the effectiveness of the Company's internal control over financial reporting. Among other things, our management must conduct an assessment of the Company's internal control over financial reporting to allow management to report on, and our independent registered public accounting firm to audit, the effectiveness of the Company's internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act.

In our annual report on Form 10-K for the year ended December 31, 2015, our management identified material weaknesses in the Company'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 our internal control systems.

During 2015 and 2016 we implemented steps intended to remediate these material weaknesses in the Company's internal control over financial reporting. As disclosed in Part II, Item 9A, "Controls and Procedures" of this Annual Report on Form 10-K, our management has determined that, while such steps have successfully remediated certain of the material weaknesses that existed as of December 31, 2015, material weaknesses in the Company's internal control over financial reporting continued to exist as of December 31, 2016 in three areas: (1) Personnel - our 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.

The Company has identified and implemented additional processes, procedures and controls to improve the effectiveness of our 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." However, we cannot assure you that our efforts will prove wholly successful in remediating these material weaknesses. In addition, we cannot assure you that we have identified all existing material weaknesses, or that other material weaknesses will not arise in the future. If we are unable to successfully identify and remediate any material weakness that may exist in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected, we 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 our ADSs may decline, and we could be subject to shareholder litigation.

Our effective tax rate could be highly volatile and could adversely affect our operating results.

Our future effective tax rate may be adversely affected by a number of factors, many of which are outside of our control, including:

- the jurisdictions in which profits are determined to be earned and taxed;
- increases in expenses not deductible for tax purposes, including increases in the fair value of related party payables, write-offs of acquired in-process R&D and impairment of goodwill in connection with acquisitions;
- changes in domestic or international tax laws or the interpretation of such tax laws;
- adjustments to estimated taxes upon finalization of various tax returns;
- changes in available tax credits;
- changes in share-based compensation expense;
- changes in the valuation of our deferred tax assets and liabilities;
- the resolution of issues arising from tax audits with various tax authorities; and
- the tax effects of purchase accounting for acquisitions that may cause fluctuations between reporting periods.

Any significant increase in our future effective tax rates could impact our results of operations for future periods adversely.

We outsource important activities to consultants, advisors and outside contractors.

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

We depend on key personnel to execute our business plan. If we cannot attract and retain key personnel, we may not be able to successfully implement our business plan.

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

Risks Relating to Regulatory and Legal Matters

Products that incorporate our drug delivery platforms and other products we may develop are subject to regulatory approval. If we or our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our revenues may be adversely affected.

Products in development for utilizing our drug delivery platforms and other products we may develop may not gain regulatory approval and reach the commercial market for a variety of reasons.

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

Applicants for FDA approval often must submit to the FDA extensive clinical and pre-clinical data, as well as information about product manufacturing processes and facilities and other supporting information. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. The FDA also may require us, or our partners to conduct additional pre-clinical studies or clinical trials. For instance, the FDA may require additional toxicology tests and clinical trials to confirm the safety and effectiveness of Medusa-based product candidates, which would impact development plans for product candidates. In addition, although we have submitted a Drug Master File (“DMF”) for our lead Medusa polymer, the FDA may require additional information prior to the conduct of clinical trials or for commercialization of any product that uses our Medusa polymer and cross-references our DMF.

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

Changes in FDA approval policy during the development period, or changes in regulatory review for each submitted new product application, also may delay an approval or result in rejection of an application. For instance, under the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), we or our partners may be required to develop Risk Evaluations and Mitigation Strategies ("REMS"), to ensure the safe use of product candidates. If the FDA disagrees with such REMS proposals, it may be more difficult and costly to obtain regulatory approval for our product candidates. Similarly, FDAAA provisions may make it more likely that the FDA will refer a marketing application for a new product to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. This review may add to the time for approval, and, although the FDA is not bound by the recommendation of an advisory committee, objections or concerns expressed by an advisory committee may cause the FDA to delay or deny approval.

The FDA has substantial discretion in the approval process and may disagree with our or our partners' interpretations of data and information submitted in an application, which also could cause delays of an approval or rejection of an application. Even if the FDA approves a product, the approval may limit the uses or indications for which the product may be marketed, restrict distribution of the product or require further studies. With respect to Vazculep, the FDA has required the Company to conduct post-marketing non-clinical and clinical studies to be completed between 2016 and 2019.

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

Our products are subject to continuing regulation, and we on our own, and in conjunction with our pharmaceutical and biotechnology partners, may be subject to adverse consequences if we or they fail to comply with applicable regulations.

We on our own and in conjunction with our pharmaceutical and biotechnology partners will be subject to extensive regulatory requirements for our and the co-developed products and product candidates that incorporate our drug delivery platforms, 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 our product candidates are safe and effective in clinical trials, or to generate data in clinical trials to support expansion of the therapeutic uses for our existing products, could materially and adversely affect our business, financial condition, results of operations and growth prospects.

We have made significant investments in our REST-ON Phase III clinical trial. Clinical trials are expensive and can take many years to complete, and the outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of

preclinical studies and early clinical trials of potential medicine candidates may not be predictive of the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical testing. Any failure or delay in completing our REST-ON Phase III clinical trial would prevent or delay the commercialization of our sodium oxybate product, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

In addition to issues relating to the results generated in clinical trials, clinical trials can be delayed or halted for a variety of reasons, including:

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

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the medicine candidate being studied in relation to other available therapies, including any new drugs or biologics that may be approved for the indications we are investigating. Furthermore, we rely and expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our future clinical trials and while we have and intend to have agreements governing their committed activities, we will have limited influence over their actual performance.

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

We rely on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials, including with respect to site selection, contract negotiation and data management. We do not control these third parties and, as a result, they may not treat our clinical studies as a high priority, which could result in delays. We are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol, as well as the FDA's and non-U.S. regulatory agencies' requirements, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA and non-U.S. regulatory agencies enforce good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. If we, contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or its non-U.S. counterparts may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or non-U.S. regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the U.S. Our failure, or the failure of our product suppliers, to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process.

If third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols, including dosing requirements, or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates or succeed in our efforts to create approved line extensions for certain of our existing products or generate additional useful clinical data in support of these products.

If we or our partners, including any CDMOs that we use, fail to comply with these laws and regulations, the FDA, the European Commission, competent authorities of EU Member States, or other regulatory organizations, may take actions that could significantly restrict or prohibit commercial distribution of our products and products that incorporate our technologies. If the FDA, the European Commission or competent authorities of EU Member States determine that we are not in compliance with these laws and regulations, they could, among other things:

- issue warning letters;
- impose fines;
- seize products or request or order recalls;
- issue injunctions to stop future sales of products;
- refuse to permit products to be imported into, or exported out of, the United States or the European Union;
- suspend or limit our production;
- withdraw or vary approval of marketing applications;
- order the competent authorities of EU Member States to withdraw or vary national authorization; and
- initiate criminal prosecutions.

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

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

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

Our ability to successfully commercialize our products and technologies may depend on the extent to which the government health administration authorities, the health insurance funds in the EU Member States, private health insurers and other third party payers in the U.S. will reimburse consumers for the cost of these products, which would affect the volume of drug products sold by pharmaceutical and biotechnology companies that incorporate our technology into their products. Third party payers are increasingly challenging both the need for, and the price of, novel therapeutic drugs and uncertainty exists as to the reimbursement status of newly approved therapeutics. The commercial success of our products depends in part on the conditions under which products incorporating our technology are reimbursed. Adequate third party reimbursement may not be available for such drug products to enable us to maintain price levels sufficient to realize an appropriate return on our investments in research and product development, which could materially and adversely affect our business. We cannot predict the effect that changes in the healthcare system, especially cost containment efforts, may have on our business. In particular, it is difficult to predict the effect of health care reform legislation enacted in the U.S. in 2010, certain provisions of which are still subject to regulatory implementation, further legislative change and ongoing judicial review. Any such changes or changes due to future legislation governing the pricing and reimbursement of healthcare products in the EU Member States may adversely affect our business.

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

From time to time, the US Congress, the Council of the European Union and the European Parliament, as well as the legislators of the EU Member States, adopt changes to the statutes that the FDA, the European Commission and the competent authorities of the EU Member States enforce in ways that could significantly affect our business. In addition, the FDA, the European Commission and the competent authorities of the EU Member States often issue new regulations or guidance, or revise or reinterpret their current regulations and guidance in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA, EU or EU Member State's regulations, guidance or interpretations changed, and what the impact of any such changes may be.

Any such changes could have a significant impact on the path to approval of products incorporating our drug delivery platforms, our products or of competing products, and on our obligations and those of our pharmaceutical and biotechnology company partners.

We and companies to which we have licensed, or will license our products or drug delivery platforms and subcontractors we engage for services related to the development and manufacturing of our products are subject to extensive regulation by the FDA and other regulatory authorities. Our and their failure to meet strict regulatory requirements could adversely affect our business.

We, and companies to which we license our products or drug delivery platforms, as well as companies acting as subcontractors for our product developments, including but not limited to non-clinical, pre-clinical and clinical studies, and manufacturing, are subject to extensive regulation by the FDA, other domestic regulatory authorities and equivalent foreign regulatory authorities, particularly the European Commission and the competent authorities of EU Member States. Those regulatory authorities may conduct periodic audits or inspections of the applicable facilities to monitor compliance with regulatory standards and we remain responsible for the compliance of our subcontractors. If the FDA or another regulatory authority finds failure to comply with applicable regulations, the authority may institute a wide variety of enforcement actions, including:

- warning letters or untitled letters;
- fines and civil penalties;
- delays in clearing or approving, or refusal to clear or approve, products;
- withdrawal, suspension or variation of approval of products; product recall or seizure;
- orders to the competent authorities of EU Member States to withdraw or vary national authorization;
- orders for physician notification or device repair, replacement or refund;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

Any adverse action by a competent regulatory agency could lead to unanticipated expenditures to address or defend such action and may impair our ability to produce and market applicable products, which could significantly impact our revenues and royalties that we receive from our customers.

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

The testing, including through clinical trials, manufacturing and marketing, and the use of our products may expose us to potential product liability and other claims. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from Contract Research Organizations ("CROs") or pharmaceutical and biotechnology companies or hospitals conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Insurance coverage is expensive and difficult to obtain, and we may be unable to obtain coverage in the future on acceptable terms, if at all. We currently maintain general liability insurance with a limit of €10 million and product liability and recall insurance with a limit of €10 million. We cannot be certain that the coverage limits of our insurance policies or those of our strategic partners will be adequate. If we are unable to obtain sufficient insurance at an acceptable cost, a product liability claim or recall could adversely affect our financial condition. Similarly, any indemnification we have obtained, or may obtain, from pharmaceutical and biotechnology companies with whom we are developing, or will develop, our products may not protect us from product liability claims from the consumers of those products or from the costs of related litigation.

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

Our R&D activities involve the controlled use of potentially harmful biological and/or chemical materials, and are subject to U.S., state, EU, national and local laws and regulations governing the use, storage, handling and disposal of those materials and specified waste products. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials, including fires and/or explosions, storage tank leaks and ruptures and discharges or releases of toxic or hazardous substances. These operating risks can cause personal injury, property damage and environmental contamination, and may result in the shutdown of affected facilities and the imposition of civil or criminal penalties. The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results.

We currently maintain property, business interruption and casualty insurance with aggregate maximum limits of €60 million, which are limits that we believe to be commercially reasonable, but may be inadequate to cover any actual liability or damages.

Risks Relating to Ownership of Our Securities

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

The trading price of our shares has been, and is likely to continue to be, highly volatile. The market value of an investment in our shares may fall sharply at any time due to this volatility. During the year ended December 31, 2016, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $7.85 to $14.89. During the year ended December 31, 2015, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from $11.50 to $25.69. The market prices for securities of drug delivery, specialty pharma, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our share price include, among others:

- fluctuations in our operating results;
- announcements of technological partnerships, innovations or new products by us or our competitors;
- actions with respect to the acquisition of new or complementary businesses;
- governmental regulations;
- developments in patent or other proprietary rights owned by us or others;
- public concern as to the safety of drug delivery platforms developed by us or drugs developed by others using our platform;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- adverse events related to our products or products developed by pharmaceutical and biotechnology company partners that use our drug delivery platforms;
- lack of efficacy of our products;
- litigation;
- decisions by our pharmaceutical and biotechnology company partners relating to the products incorporating our technologies;
- the perception by the market of specialty pharma, biotechnology, and high technology companies generally; and
- general market conditions, including the impact of the current financial environment.

If we are not profitable in the future, the value of our shares may fall.

We have a history of operating losses and have accumulated aggregate net losses from our inception of approximately $319,800 through December 31, 2016. If we are unable to earn a profit in future periods, the market price of our stock may fall. The costs for R&D of our products and drug delivery platforms and general and administrative expenses have been the principal causes of our net losses in recent years. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

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

We may require additional financing, which may not be available on favorable terms or at all, and which may result in dilution of the equity interest of the holders of our ADSs.

We may require additional financing to fund the development and possible acquisition of new products and businesses. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. If we cannot obtain financing when needed, or obtain it on favorable terms, we may be required to curtail our plans to continue to develop drug delivery platforms, develop new products, or acquire additional products and businesses. Other factors that will affect future capital requirements and may require us to seek additional financing include:

- the development and acquisition of new products and drug delivery platforms;
- the progress of our research and product development programs;
- results of our partnership efforts with potential pharmaceutical and biotechnology company partners; and

- the timing of, and amounts received from, future product sales, product development fees and licensing revenue and royalties.

If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in loss of sales, increased costs and reduced revenues. Alternatively, to obtain needed funds for acquisitions or operations, we may choose to issue additional ADSs representing our ordinary shares, or we may choose to issue shares of preferred stock, in either case through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of such equity financings, may result in dilution to the holders of our ADSs.

We have broad discretion in the use of our cash and may not use it effectively.

Our management has broad discretion in the use of our cash, and may not apply our cash in ways that ultimately increase the value of any investment in our securities. We currently intend to use our cash to fund marketing activities for our commercialized products, to fund certain clinical trials for product candidates, to fund research and development activities for potential new product candidates, to acquire assets or businesses that we may identify as potentially beneficial to our business strategies, to repurchase our ordinary shares represented by ADSs of up to $25,000 in connection with the program approved by our Board of Directors in March 2017, and for working capital, capital expenditures and general corporate purposes. As in the past we expect to invest our cash in available-for-sale marketable securities, including corporate bonds, U.S. government securities, other fixed income securities and equities; and these investments may not yield a favorable return. If we do not invest or apply our cash effectively, our financial position and the price of our ADSs may decline.

We currently do not intend to pay dividends and cannot assure the holders of our ADSs that we will make dividend payments in the future.

We have never declared or paid a cash dividend on any of our ordinary shares or ADSs and do not anticipate declaring cash dividends in the foreseeable future. Declaration of dividends will depend upon, among other things, future earnings, if any, the operating and financial condition of our business, our capital requirements, general business conditions and such other factors as our Board of Directors deems relevant.

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

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

- permit our board of directors to issue preferred shares with such rights and preferences as they may designate, subject to applicable law;
- impose advance notice requirements for shareholder proposals and director nominations to be considered at annual shareholder meetings; and
- require the approval of a supermajority of the voting power of the shares of our share capital entitled to vote generally at a meeting of shareholders to amend or repeal certain provisions of our articles of association.

We believe these provisions will provide some protection to holders of our ADSs from coercive or otherwise unfair takeover tactics. These provisions are not intended to make us immune from takeovers. However, these provisions will apply even if some holders of our ADSs consider an offer to be beneficial and could delay or prevent an acquisition that our Board of Directors determines is in the best interest of the holders of our ADSs. These provisions may also prevent or discourage attempts to remove and replace incumbent directors.

In addition, several mandatory provisions of Irish law could prevent or delay our acquisition by a third party. For example, Irish law does not permit shareholders of an Irish public limited company to take action by written consent with less than unanimous consent. In addition, an effort to acquire us may be subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in our ADSs in certain circumstances.

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

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

Holders of our ADSs could have more difficulty protecting their interests than would the shareholders of a U.S. corporation. As an Irish company, we are governed by the Irish Companies Act 2014, which differs in some significant, and possibly material, respects from provisions set forth in various U.S. state laws applicable to U.S. corporations and their shareholders, including provisions relating to interested directors, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors.

The duties of directors and officers of an Irish company are generally owed to the company only. Therefore under Irish law shareholders of Irish companies do not generally have a right to commence a legal action against directors or officers, and may only do so in limited circumstances. Directors of an Irish company must act with due care and skill, honestly and in good faith with a view to the best interests of the company. Directors must not put themselves in a position in which their duties to the company and their personal interests conflict and must disclose any personal interest in any contract or arrangement with the company or any of its subsidiaries. A director or officer can be held personally liable to the company in respect of a breach of duty to the company.

Judgments of United States courts, including those predicated on the civil liability provisions of the federal securities laws of the United States, may not be enforceable in Irish courts.

An investor in the U.S. may find it difficult to:

- Effect service of process within the U.S. against us and our non-U.S. resident directors and officers;
- enforce United States court judgments based upon the civil liability provisions of the United States federal securities laws against us and our non-U.S. resident directors and officers in Ireland; or
- bring an original action in an Irish court to enforce liabilities based upon the U.S. federal securities laws against us and our non-U.S. resident directors and officers.

Holders of ADSs have fewer rights than shareholders and have to act through the Depositary to exercise those rights.

Holders of ADSs do not have the same rights as shareholders and, accordingly, cannot exercise rights of shareholders against us. The Bank of New York Mellon, as depositary, or the "Depositary", is the registered shareholder of the deposited shares underlying the ADSs. Therefore, holders of ADSs will generally have to exercise the rights attached to those shares through the Depositary. We will use reasonable efforts to request that the Depositary notify the holders of ADSs of upcoming votes and ask for voting instructions from them. If a holder fails to return a voting instruction card to the Depositary by the date established by the Depositary for receipt of such voting instructions, or if the Depositary receives an improperly completed or blank voting instruction card, or if the voting instructions included in the voting instruction card are illegible or unclear, then such holder will be deemed to have instructed the Depositary to vote its shares, and the Depositary shall vote such shares in favor of any resolution proposed or approved by our Board of Directors and against any resolution not so proposed or approved.

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

As of February 16, 2017, Broadfin Capital and certain of its affiliates beneficially owned approximately 10.7% of our outstanding shares (in the form of ADRs), Janus Capital Management, LLC and certain of its affiliates beneficially owned 5.5% of our outstanding shares (in the form of ADRs) and Deerfield Capital and certain of its affiliates beneficially owned approximately 9.98% of our outstanding shares (in the form of ADRs). To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, they will remain in a position to exert heightened influence in the election of the directors of the Company and in other corporate actions that require shareholder approval, including change of control transactions.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

(Amounts in thousands, except per square foot amounts)

Avadel Research SAS, our research center, is located in Venissieux, France (a suburb of Lyon) in three adjacent leased facilities totaling approximately 51,600 square feet. One building of approximately 12,800 square feet houses administrative offices and analytical research laboratories. The lease on this facility expires in March 2019. A second facility comprising approximately 12,800 square feet houses equipment dedicated to our Micropump, LiquiTime and Trigger Lock platforms has a lease which expires in March 2019. The third facility of approximately 26,000 square feet houses research and biochemistry (Medusa) laboratories and quality/regulatory affairs and the lease may be terminated by the end of 2018.

We 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; altogether the "Micropump Pilot Development facilities") 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 (for more detail, see *Note 19: Discontinued Operations* to the consolidated financial statements in Item II, Part 8 of this Annual Report on Form 10-K).

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

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

During 2016, we expended $1,201 on property and equipment essentially limited to maintenance and investment in a global ERP.

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

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

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

As described in Item 1. of this Annual Report on Form 10-K under the caption "Business - General Overview," the Company is an Irish public limited company, or plc, and is the successor to Flamel Technologies S.A., a French *société anonyme* ("Flamel"), as the result of the merger of Flamel with and into the Company which was completed at 11:59:59 p.m., Central Europe Time, on December 31, 2016 (the "Merger") pursuant to the agreement between Flamel and the Company entitled Common Draft Terms of Cross-Border Merger dated as of June 29, 2016 (the "Merger Agreement"). Immediately prior to the Merger, the Company was a wholly owned subsidiary of Flamel. In accordance with the Merger Agreement, as a result of the Merger Flamel ceased to exist as a separate entity and the Company continued as the surviving entity and assumed all of the assets and liabilities of Flamel.

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

Common Stock Data (per share) (Unaudited):

The principal trading market for the Company's securities in ADSs is the NASDAQ Global Market. There is no foreign trading market for the Company's ordinary shares, ADSs or any other equity security issued by the Company. Each ADS represents one ordinary share, nominal value $0.01. Each ADS is evidenced by an ADR. The Bank of New York Mellon is the Depositary for the ADRs.

As of March 20, 2017, there were 41,379,554 ADSs outstanding, and the closing stock price of the Company was $9.73 per share.

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

	2016 Price Range		2015 Price Range	
	High	Low	High	Low
First quarter	$ 12.92	$ 7.85	$ 18.47	$ 11.50
Second quarter	13.32	8.83	22.32	13.88
Third quarter	14.89	11.01	25.69	15.37
Fourth quarter	13.16	9.26	19.27	12.21

Holders

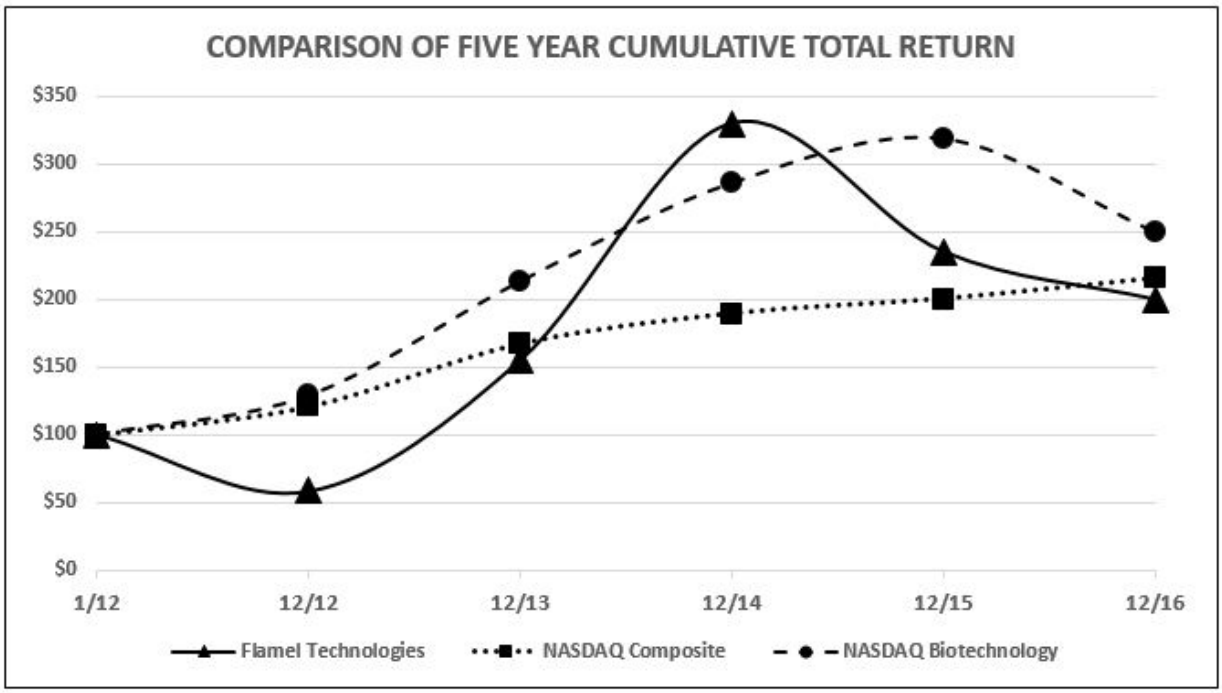
As of March 20, 2017, there were 244 holders of record of our ordinary shares and 20 accounts registered with The Bank of New York Mellon, the depositary of our ADS program, as holders of ADSs, one of which ADS accounts is registered to the Depositary Trust Corporation (DTC). Because our ADSs are generally held of record by brokers, nominees and other institutions as participants in DTC on behalf of the beneficial owners of such ADSs, we are unable to estimate the total number of beneficial owners of the ADSs held by these record holders.

Dividends

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

Stock Performance Graph

The following graph compares the cumulative 5-year return provided to shareholders of Avadel's ADSs relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. We believe these indices are the most appropriate indices against which the total shareholder return of Avadel should be measured. The NASDAQ Biotechnology Index has been selected because it is an index of U.S. quoted biotechnology and pharmaceutical companies. An investment of $100 (with reinvestment of all dividends) is assumed to have been made in our ADSs and in each of the indexes on January 1, 2012 and its relative performance is tracked through December 31, 2016. The comparisons shown in the graph are based upon historical data and we caution that the stock price performance shown in the graph is not indicative of, or intended to forecast, the potential future performance of our stock.



This performance graph shall not be deemed "filed" for purposes of Section 18 of the Exchange Act. Notwithstanding any statement to the contrary set forth in any of our filings under the Securities Act of 1933 or the Exchange Act that might incorporate future filings, including this Annual Report on Form 10-K, in whole or in part, this performance graph shall not be incorporated by reference into any such filings except as may be expressly set forth by specific reference in any such filing.

Item 6. Selected Financial Data (in thousands, except per share amounts).

Annual Financial Data:

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

Statement of Income (Loss) Data:	**2016**	**2015** [b]	**2014** [b]	**2013** [b]	**2012** [b]
Revenues	$ 150,246	$ 173,009	$ 14,975	$ 4,179	$ 7,534
Gross profit [a]	136,998	161,599	11,592	3,617	7,134
Operating income (loss)	(4,965)	70,758	(93,657)	(53,700)	(9,913)
Net income (loss) from continuing operations	(41,276)	41,798	(89,487)	(46,176)	(4,380)
Net income from discontinued operations	—	—	4,018	3,584	1,512
Net income (loss)	(41,276)	41,798	(85,469)	(42,592)	(2,868)
Earnings (loss) per share - basic:					
Continuing operations	(1.00)	1.03	(2.47)	(1.81)	(0.17)
Discontinued operations	—	—	0.11	0.14	0.06
Net income (loss) per share - basic	(1.00)	1.03	(2.36)	(1.67)	(0.11)
Earnings (loss) per share - diluted:					
Continuing operations	(1.00)	0.96	(2.47)	(1.81)	(0.17)
Discontinued operations	—	—	0.11	0.14	0.06
Net income (loss) per share - diluted	(1.00)	0.96	(2.36)	(1.67)	(0.11)

Balance Sheet Data:	**2016**	**2015** [b]	**2014** [b]	**2013**	**2012**
Cash and cash equivalents	$ 39,215	$ 65,064	$ 39,760	$ 6,636	$ 2,742
Marketable securities	114,980	79,738	53,074	401	6,413
Goodwill	18,491	18,491	18,491	18,491	18,491
Intangible assets, net	22,837	15,825	28,389	40,139	41,589
Total assets	245,482	215,081	174,382	116,252	117,311
Long-term debt (incl. current portion)	815	1,118	3,717	30,249	10,409
Long-term related party payable (incl. current portion)	169,347	122,693	114,750	55,265	26,220

[a] Gross profit is computed by subtracting cost of products and services sold from total revenues.

[b] The consolidated financial statements for prior periods contain certain reclassifications to conform to the presentation used in 2016. Additionally, the Company has identified certain immaterial errors related to prior reporting periods. Refer to *Note 1: Summary of Significant Accounting Policies* in the notes to the consolidated financial statements.

Quarterly Financial Data (Unaudited):

The following tables present certain unaudited consolidated quarterly financial information for each quarter of 2016 and 2015. Year-to-date earnings (loss) per share amounts may be different than the sum of the applicable quarters due to differences in weighted average shares outstanding for the respective periods.

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

2015:	**March 31 [b]**	**June 30 [b]**	**September 30 [b]**	**December 31 [b]**
Revenues	$ 32,526	$ 48,602	$ 47,313	$ 44,568
Gross profit [a]	28,896	45,846	45,226	41,631
Operating income (loss)	10,014	(2,370)	(14,486)	77,600
Net income (loss)	13,213	(16,857)	(28,076)	73,518
Net income (loss) per share - basic	0.33	(0.42)	(0.69)	1.79
Net income (loss) per share - diluted	0.31	(0.42)	(0.69)	1.69

[a] Gross profit is computed by subtracting cost of products and services sold from total revenues.

[b] The consolidated financial statements for prior periods contain certain reclassifications to conform to the presentation used in 2016. Additionally, the Company has identified certain immaterial errors related to prior reporting periods. Refer to *Note 1: Summary of Significant Accounting Policies* in the notes to the consolidated financial statements and Item 5 in the second quarter 2016 Form 10-Q filing.

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

MANAGEMENT'S DISCUSSION AND ANALYSIS

(In thousands, except per share data)

You should read the discussion and analysis of our financial condition and results of operations set forth in this Item 7 together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties, and reference is made to the "Cautionary Disclosure Regarding Forward-Looking Statements" set forth immediately following the Table of Content of this Annual Report on Form 10-K for further information on the forward looking statements herein. In addition, you should read the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this Annual Report on Form 10-K.

Overview

Nature of Operations

Avadel Pharmaceuticals PLC ("Avadel," the "Company," "we," "our," or "us") is a specialty pharmaceutical company engaged in identifying, developing, and commercializing niche branded pharmaceutical products mainly in the U.S. Our business model consists of three distinct strategies:

- the development of differentiated, patent protected products through application of the Company's proprietary patented drug delivery platforms, Micropump® and LiquiTime®, that target high-value solid and liquid oral and alternative dosages forms through the U.S. Food and Drug Administration (FDA) 505(b)(2) approval process, which allows a sponsor to submit an application that doesn't depend on efficacy, safety, and toxicity data created by the sponsor. In addition to Micropump® and LiquiTime®, the Company has two other proprietary drug delivery platforms, Medusa™ (hydrogel depot technology for use with large molecules and peptides) and Trigger Lock™ (controlled release of opioid analgesics with potential abuse deterrent properties).

- the identification of Unapproved Marketed Drugs ("UMDs"), which are currently sold in the U.S., but unapproved by the FDA, and the pursuit of approval for these products via a 505(b)(2) New Drug Application (NDA). To date, the Company has received approvals through this "unapproved-to-approved" avenue for three products: Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection) and Akovaz® (ephedrine sulfate injection). As a potential source of near-term revenue growth, Avadel is working on the development of a fourth product for potential NDA submission by year-end 2017, and seeks to identify additional product candidates for development with this strategy.

- the acquisition of commercial and or late-stage products or businesses. The Company markets three branded pediatric-focused pharmaceutical products in the primary care space, and a 510(k) approved device that will launch in the second quarter of 2017, all of which were purchased through the acquisition of FSC Laboratories and FSC Pediatrics on February 5, 2016. We will consider further acquisitions, and the Company continues to look for assets that could fit strategically into its current or potential future commercial sales force.

The Company was incorporated in Ireland on December 1, 2015 as a private limited company, and re-registered as an Irish public limited company on November 21, 2016. Its headquarters are in Dublin, Ireland and it has operations in St. Louis, Missouri, United States, and Lyon, France.

The Company is an Irish public limited company, or plc, and is the successor to Flamel Technologies S.A., a French *société anonyme* ("Flamel"), as the result of the merger of Flamel with and into the Company which was completed at 11:59:59 p.m., Central Europe Time, on December 31, 2016 (the "Merger") pursuant to the agreement between Flamel and Avadel entitled Common Draft Terms of Cross-Border Merger dated as of June 29, 2016 (the "Merger Agreement"). Immediately prior to the Merger, the Company was a wholly owned subsidiary of Flamel. As a result of the Merger Agreement:

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

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

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

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

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

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

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

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

Further details about the reincorporation, the Merger and the Merger Agreement are contained in our definitive proxy statement filed with the Securities and Exchange Commission on July 5, 2016, and within the Annual Report on Form 10-K of which these financial statements are a part in Item 1 thereof under the caption “Business - The Flamel Merger.”

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

Strategy

The Company's business strategy is designed to drive overall sales and earnings growth while maintaining a return on invested capital at an appropriate premium above the Company's cost of capital. Our key areas of focus address the most significant opportunities and challenges we face, including:

- ***Unapproved Marketed Drug Development***: The Company derives a majority of its revenues and cash flow from its UMD products. During the twelve months ended December 31, 2016 the Company generated $147,222 of sales from the UMD products compared to $172,288 in the same period of 2015.

    - The first UMD product, Bloxiverz, which had sales of $82,896 and $150,083 for the twelve months ended December 31, 2016 and 2015, respectively, was approved by the FDA on May 31, 2013, and is currently being marketed in the U.S.

    - The second UMD product, Vazculep, which had sales of $39,796 and $20,151 for the twelve months ended December 31, 2016 and 2015, respectively, was approved by the FDA on September 27, 2014 and launched in October 2014 in the U.S.

    - The third UMD product, Akovaz, which had sales of $16,831 for the twelve months ended December 31, 2016, was approved by the FDA April 29, 2016. The Company began marketing this product in August 2016.

Each of the above products is currently sold in the United States by Avadel’s subsidiary Avadel Legacy Pharmaceuticals, LLC (formerly Éclat). Through our acquisition of Éclat, we obtained marketing and licensing knowledge of the commercial and regulatory processes in the U.S. and E.U. We believe this knowledge has enhanced our ability to identify product candidates for development, leverage new opportunities for the application of our drug delivery platforms, and license and market products in

the U.S and E.U. The cash flow generated from these UMD products, among other things, is used to fund our second strategy, the development and commercialization of drug delivery products.

- ***Development and Commercialization of the Company's Drug Delivery Pipeline Products***: In addition to the UMD strategy, the Company is continuing to advance the development of its innovative drug delivery platforms. We have enhanced our ability to identify new product candidates and to pursue commercial opportunities associated with our drug delivery platforms. The Company's drug delivery platforms allow the creation of competitive and differentiated drug product profiles (e.g., with improved pharmacokinetics, efficacy and/or safety). We own and develop drug delivery platforms 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 can be applied to a broad range of drugs (novel, already-marketed, or off-patent). Application of these technologies to pharmaceuticals allows us to protect our potential products through patent protection and product differentiation. As a result of developing our own drug delivery platforms our business is now less dependent on the development activities performed by partners, and relies more on the development of our own, self-funded, products. Our proprietary drug delivery platforms include:

    - **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. and in the E.U., respectively).

    - **LiquiTime®** allows development of modified/controlled release oral products in a liquid suspension formulation particularly suited to children or patients having issues swallowing tablets or capsules. Unlike most liquid pharmaceuticals, LiquiTime® technology is not limited to ionic drugs as with resin-complex based technologies and can be applied to the development of combination products.

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

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

Several products formulated using our proprietary drug delivery platforms are currently under various stages of development for possible marketing either by the Company and/or by partners via licensing/distribution agreements. In particular, the Company has started a Phase III trial, titled *"A Double-blind, Randomized, Placebo Controlled, Two Arm Multi-Center Study to Assess the Efficacy and Safety of a Once Nightly Formulation of Sodium Oxybate for Extended-Release Oral Suspension (FT218) for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Subjects with Narcolepsy,"* We have branded this trial REST-ON. On October 6, 2016, the Company announced that its Irish subsidiary, Avadel Ireland Holdings, has reached agreement with the U.S. Food and Drug Administration (FDA) for the design and planned analysis of the noted Phase III clinical trial of FT218, a once nightly formulation of sodium oxybate utilizing the Company's proprietary drug delivery platform, Micropump®. The agreement was reached through the Special Protocol Assessment (SPA) process. A SPA is an acknowledgment by FDA that the design and planned analysis of the Company's pivotal clinical trial of FT218 adequately addresses the objectives necessary to support a regulatory submission. In December 2016, the Company initiated patient enrollment and dosing for its REST-ON Phase III clinical trial to assess the safety and efficacy of its once nightly formulation of Micropump® sodium oxybate (FT218) for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. The sole-source market for sodium oxybate, dosed twice nightly, is estimated at $1.1 billion in 2016. We believe that our product could offer significant advantages over the existing product to narcolepsy patients. Our objective is to complete enrollment for this study by year-end 2017.

- **The key elements of our pipeline strategy include:**

    - Continuing to build commercially successful products utilizing Micropump;

    - Identifying opportunities and optimizing time-to-market for our LiquiTime drug delivery platform;

    - Maximizing the technical potential of our existing drug delivery platforms for developing new and proprietary products; and

    - Developing and validating improved and complementary drug delivery platforms related to our current drug delivery capabilities.

- ***Inorganic growth through Acquisitions and/or Partnerships***: The Company maintains a strong balance sheet with substantial liquidity and no long-term debt with fixed maturities. As part of its overall enterprise strategy, the Company

expects to explore and pursue appropriate inorganic growth opportunities that complement its drug delivery platforms or to acquire proprietary products that enhance profitability and cash flow. This was evidenced in early 2016 with the acquisition of FSC, a specialty pharmaceutical company dedicated to providing innovative solutions to unmet medical needs for pediatric patients. Additionally, the Company will leverage the capabilities of its existing and future proprietary products and/or drug delivery platforms with pharmaceutical and biotechnology partnerships or licensing transactions. In 2015, the Company completed a licensing transaction for exclusive U.S. rights to its LiquiTime technology-based Over-the-Counter ("OTC") products which was licensed to Elan Pharma International Limited.

- **Divestitures and out licensing:** We have a stated objective to narrow our focus to our two most developed platforms, Micropump® and LiquiTime®. As a result, we are pursuing the divestiture or out licensing of Trigger Lock™ for abuse deterrence, and Medusa™ for extended-release subcutaneous injection. We believe both platforms are robust and well protected from an IP standpoint; however, their development and FDA approval will likely require substantial investments in clinical work and infrastructure, which we are not currently prepared to support.

Key Business Trends and Highlights

In operating our business and monitoring our performance, we consider a number of performance measures, as well as trends affecting our industry as a whole, which include the following:

- **Healthcare and Regulatory Reform**: Various health care reform laws in the U.S. may impact our ability to successfully commercialize our products and technologies. The success of our commercialization efforts may depend on the extent to which the government health administration authorities, the health insurance funds in the E.U. Member States, private health insurers and other third party payers in the U.S. will reimburse consumers for the cost of healthcare products and services.

- **Competition and Technological Change:** Competition in the pharmaceutical and biotechnology industry continues to be intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing niche brand or generic specialty pharmaceutical products or drug delivery platforms. Furthermore, major technological changes can happen quickly in the pharmaceutical and biotechnology industries. Such rapid technological change, or the development by our competitors of technologically improved or differentiated products, could render our drug delivery platforms obsolete or noncompetitive.

- **Pricing Environment for Pharmaceuticals**: The pricing environment continues to be in the political spotlight in the U.S. As a result, the need to obtain and maintain appropriate pricing and reimbursement for our products may become more challenging due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide.

- **Generics Playing a Larger Role in Healthcare**: Generic pharmaceutical products will continue to play a large role in the U.S. healthcare system. Specifically, we have seen, or likely will see, additional generic competition to our current and future products and we continue to expect generic competition in the future.

- **Access to and Cost of Capital**: The cost of raising capital has recently become more expensive. If the need were to arise to raise more capital our cost will be more expensive and may create challenges for the Company. Currently, the Company has no need to raise capital.

Highlights of our consolidated results for the twelve months ended December 31, 2016 are as follows:

- Revenue was $150,246 for the twelve months ended December 31, 2016 compared to $173,009 in the same period last year. This decrease was primarily the result of a decrease in Bloxiverz revenues as a result of additional competition, partially offset by the August 2016 launch of Akovaz, which added $16,831 of revenue.

- Operating loss was $4,965 for the twelve months ended December 31, 2016 compared to operating income of $70,758 for the twelve months ended December 31, 2015. This decline in profitability was largely driven by the lower gross profit (revenues minus cost of goods sold) as a result of the decrease in revenues noted above, increases in SG&A and R&D and higher non-cash charges related to the adjustments to the fair value of our related party payables.

- Net loss was $41,276 for the twelve months ended December 31, 2016 compared to net income of $41,798 in the same period last year. The decline to a net loss in 2016 from net income in 2015 was due to the same reasons noted above.

- Diluted net loss per share was $1.00 for the twelve months ended December 31, 2016 compared to net income per share of $0.96 in the same period last year.

- Cash and marketable securities increased $9,393 to $154,195 at December 31, 2016 from $144,802 at December 31, 2015.

Critical Accounting Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to use judgment in making estimates and assumptions that affect the reported amounts of assets and liabilities, disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the periods presented. Actual results could differ from those estimates under different assumptions or conditions.

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

Revenue

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

Product Sales and Services

Revenue is generally realized or realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the seller's price to the buyer is fixed or determinable, and collectability is reasonably assured. The Company records revenue from product sales when title and risk of ownership have been transferred to the customer, which is typically upon delivery to the customer and when the selling price is determinable. As is customary in the pharmaceutical industry, the Company's gross product sales are subject to a variety of deductions in arriving at reported net product sales. These adjustments include estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

For generic and branded products sold in mature markets where the ultimate net selling price to the customer is estimable, the Company recognizes revenues upon shipment to the wholesaler. For new product launches, we recognize revenue once sufficient data is available to determine product acceptance in the marketplace such that product returns and other deductions may be estimated based on historical data and there is evidence of reorders and consideration is made of wholesaler inventory levels. In connection with the third quarter 2016 launch of Akovaz, we determined that sufficient data was available to determine the ultimate net selling price to the customer, and therefore, we began to recognize revenue upon shipment to our wholesaler customers.

Prior to the second quarter 2016, we did not have sufficient historical data to estimate certain revenue deductions. As such, we could not accurately estimate the ultimate net selling price of our Avadel Legacy Pharmaceuticals (formerly Éclat) portfolio of products. As a result, we delayed revenue recognition on these products until the wholesaler sold the product through to its customers.

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

License and Research Revenue

Our license and research revenues consist of fees and milestone payments. Non-refundable fees where we have continuing performance obligations are deferred and are recognized ratably over the projected performance period. We recognize milestone payments, which are typically related to regulatory, commercial or other achievements by us or our licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. For the year ended December 31, 2016, we recognized $3,024 of revenue from license agreements.

Research and Development

Research and development expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, and other research and development expenses. Clinical studies and outside services costs relate primarily to services performed by clinical research organizations and related clinical or development manufacturing costs, materials and supplies, filing fees, regulatory support, and other third party fees. Personnel expenses relate primarily to salaries, benefits and stock-based

compensation. Other research and development expenses primarily include overhead allocations consisting of various support and facilities-related costs. R&D expenditures are charged to operations as incurred.

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

Stock-based Compensation

The Company accounts for stock-based compensation based on grant-date fair value estimated in accordance with ASC 718. The fair value of stock options and warrants is estimated using Black-Scholes option-pricing valuation models ("Black-Scholes model"). As required by the Black-Sholes model, estimates are made of the underlying volatility of AVDL stock, a risk-free rate and an expected term of the option or warrant. We estimated the expected term using a simplified method, as we do not have enough historical exercise data for a majority of such options and warrants upon which to estimate an expected term. The Company recognizes compensation cost, net of an estimated forfeiture rate, using the accelerated method over the requisite service period of the award.

Income Taxes

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

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

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in a multitude of jurisdictions across our global operations. ASC 740 states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

We (1) record unrecognized tax benefits as liabilities in accordance with ASC 740 and (2) adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available.

We have not recorded a deferred tax liability for any income or withholding taxes that may arise as the result of the distribution of unremitted earnings within our Company. While the Company has no unremitted earnings as measured on a US GAAP basis, the measure of earnings for purposes of taxation of a distribution may differ for tax purposes and would become subject to income tax if they were remitted as dividends. Based on our estimates that future domestic cash generation will be sufficient to meet future domestic cash needs along with our specific plans for reinvestment, we have not recorded a deferred tax liability for any income or withholding taxes that may arise from a distribution that would qualify as a dividend for tax purposes. It is not practicable to estimate the amount of deferred tax liability on such remittances, if any.

Goodwill

Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. The Company has determined that it operates in a single segment and has a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then, in the second step, the loss is measured as the excess of recorded goodwill over the implied fair value of the goodwill. Implied fair value of goodwill is the excess of the fair value of the reporting unit as a whole over the fair value of all separately identified assets and liabilities within the reporting unit. The Company tests goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. The Company uses projections of future discounted cash flows and takes into account assumptions regarding the evolution of the market and the Company's ability to successfully develop and commercialize its products. Changes in market conditions could have a major impact on the valuation of these assets and

could result in potential associated impairment. During the fourth quarter of 2016, we performed our required annual impairment test of goodwill and have determined that no impairment of goodwill existed at December 31, 2016 or 2015.

Long-Lived Assets

Long-lived assets include fixed assets and intangible assets. Intangible assets consist primarily of purchased licenses, in-process R&D and intangible assets recognized as part of the Éclat and FSC acquisitions. Acquired IPR&D has an indefinite life and is not amortized until completion and development of the project, at which time the IPR&D becomes an amortizable asset. Amortization of acquired IPR&D is computed using the straight-line method over the estimated useful life of the assets.

Long-lived assets are reviewed for impairment whenever conditions indicate that the carrying value of the assets may not be fully recoverable. Such impairment tests are based on a comparison of the pretax undiscounted cash flows expected to be generated by the asset to the recorded value of the asset. If impairment is indicated, the asset value is written down to its market value if readily determinable or its estimated fair value based on discounted cash flows. Any significant changes in business or market conditions that vary from current expectations could have an impact on the fair value of these assets and any potential associated impairment. The Company has determined that no indications of impairment existed at December 31, 2016 or 2015.

Acquisition-related Contingent Consideration

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

Financing-related Royalty Agreements

We also entered into two royalty agreements with related parties in connection with certain financing arrangements. We elected the fair value option for the measurement of the financing-related contingent consideration payable associated with the royalty agreements with certain Deerfield and Broadfin entities, both of whom are related parties (see *Note 10: Long-Term Related Party Payable*). The fair value of financing-related royalty agreements is estimated using many of the components used to determine the fair value of the acquisition-related contingent consideration noted above. Changes to these components can also have a material impact on our consolidated statements of income (loss), balance sheets and statements of cash flows. Changes in the fair value of this liability are recorded in the consolidated statements of income (loss) as other expense - changes in fair value of related party payable.

Foreign Currency Translation

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

Results of Operations

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

				Increase / (Decrease)			
	Years Ended December 31,			2016 vs. 2015		2015 vs. 2014	
Comparative Statements of Income (Loss):	**2016**	**2015** [(a)]	**2014** [(a)]	**$**	**%**	**$**	**%**
Product sales and services	$ 147,222	$ 172,288	$ 12,193	$ (25,066)	(14.5)%	$ 160,095	1,313.0 %
License and research revenue	3,024	721	2,782	2,303	319.4 %	(2,061)	(74.1)%
Total	150,246	173,009	14,975	(22,763)	(13.2)%	158,034	1,055.3 %
Operating expenses:							
Cost of products and services sold	13,248	11,410	3,383	1,838	16.1 %	8,027	237.3 %
Research and development	34,611	25,608	17,298	9,003	35.2 %	8,310	48.0 %
Selling, general and administrative	44,179	21,712	15,698	22,467	103.5 %	6,014	38.3 %
Intangible asset amortization	13,888	12,564	11,749	1,324	10.5 %	815	6.9 %
Changes in fair value of related party contingent consideration	49,285	30,957	57,491	18,328	59.2 %	(26,534)	(46.2)%
Loss on early repayment of related party acquisition-related note	—	—	3,013	—	*n/a*	(3,013)	(100.0)%
Total	155,211	102,251	108,632	52,960	51.8 %	(6,381)	(5.9)%
Operating income (loss)	(4,965)	70,758	(93,657)	(75,723)	(107.0)%	164,415	(175.6)%
Investment and other income	1,635	1,236	927	399	32.3 %	309	33.3 %
Interest expense	(963)	—	(5,747)	963	*n/a*	(5,747)	(100.0)%
Other expense - changes in fair value of related party payable	(6,548)	(4,883)	(3,525)	1,665	34.1 %	1,358	38.5 %
Foreign exchange gain	1,123	10,594	11,871	(9,471)	(89.4)%	(1,277)	(10.8)%
Income (loss) before income taxes	(9,718)	77,705	(90,131)	(87,423)	(112.5)%	167,836	(186.2)%
Income tax provision (benefit)	31,558	35,907	(644)	(4,349)	(12.1)%	36,551	(5,675.6)%
Net income (loss) from continuing operations	(41,276)	41,798	(89,487)	(83,074)	(198.8)%	131,285	(146.7)%
Net income from discontinued operations	—	—	4,018	—	*n/a*	(4,018)	(100.0)%
Net income (loss)	$ (41,276)	$ 41,798	$ (85,469)	$ (83,074)	(198.8)%	$ 127,267	(148.9)%
Earnings (loss) per share - diluted:	$ (1.00)	$ 0.96	$ (2.36)	$ (1.96)	(204.2)%	$ 3.32	(140.7)%

[(a)] The consolidated financial statements for prior periods contain certain reclassifications to conform to the presentation used in 2016. Additionally, the Company has identified certain immaterial errors related to prior reporting periods. Refer to *Note 1: Summary of Significant Accounting Policies* in the notes to the consolidated financial statements and Item 5 in the second quarter 2016 Form 10-Q filing.

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

				Increase / (Decrease)			
	Years Ended December 31,			2016 vs. 2015		2015 vs. 2014	
Revenues:	**2016**	**2015**	**2014**	**$**	**%**	**$**	**%**
Bloxiverz	$ 82,896	$ 150,083	$ 10,411	$ (67,187)	(44.8)%	$ 139,672	1,341.6 %
Vazculep	39,796	20,151	—	19,645	97.5 %	20,151	*n/a*
Akovaz	16,831	—	—	16,831	*n/a*	—	*n/a*
Other	7,699	2,054	1,782	5,645	274.8 %	272	15.3 %
Total product sales and services	147,222	172,288	12,193	(25,066)	(14.5)%	160,095	1,313.0 %
License and research revenue	3,024	721	2,782	2,303	319.4 %	(2,061)	(74.1)%
Total revenues	$ 150,246	$ 173,009	$ 14,975	$ (22,763)	(13.2)%	$ 158,034	1,055.3 %

2016 Compared to 2015

Product sales and services revenues were $147,222 for the year ended December 31, 2016, compared to $172,288 for the same prior year period. Revenues for the year ended December 31, 2016 include $5,981 in additional revenue as a result of our change in accounting estimate previously described under *"Critical Accounting Estimates."* Excluding the impact of this revenue change, total product sales and services for the year ended December 31, 2016 would have been $141,241, a decline of $31,047 when compared to the same period last year. Bloxiverz's revenue declined $67,187 when compared to the same period last year, primarily due to a $72,726 loss of market share and net selling price driven largely by two factors: a) lost business as a result of a new competitor in the neostigmine market who entered the market in the first quarter of 2016 and b) a new molecule approved by the FDA in late 2015 and launched in 2016 with a similar indicated use as Bloxiverz. The decline in Bloxiverz revenue was partially offset by an increase of $4,597 related to the change in the revenue estimate noted above. Vazculep's revenue increased $19,645 when compared to the same period last year due primarily to higher market share and a full year run rate in 2016 when compared to 2015 resulting from its launch in late 2014. Vazculep's sales were further increased by $1,384 related to the change in revenue estimate noted above. The launch of Akovaz in August 2016 contributed $16,831 to product sales for the year ended December 31, 2016. The increase in sales in Other was primarily driven from the February 2016 acquisition of FSC which contributed $5,985 in revenues.

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

2015 Compared to 2014

Product sales and services revenues were $172,288 for the year ended December 31, 2015, compared to $12,193 for the prior year. This represents a $160,095 increase in 2015 from 2014. The primary driver of growth was additional sales volume of $139,672 from Bloxiverz® which enjoyed a full year's run rate from its launch in late 2013 and the launch of Vazculep® in 2015 generating additional sales volume of $20,151.

				Increase / (Decrease)			
	Years Ended December 31,			2016 vs. 2015		2015 vs. 2014	
Cost of Products and Services Sold:	**2016**	**2015**	**2014**	**$**	**%**	**$**	**%**
Cost of products and services sold	$ 13,248	$ 11,410	$ 3,383	$ 1,838	16.1%	$ 8,027	237.3%
Percentage of sales	8.8%	6.6%	22.6%				

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

Cost of products and services sold increased $8,027 during the year ended December 31, 2015 as compared to the same period in 2014 primarily due to increases in respective product sales and services. As a percentage of sales, cost of products sold decreased to 6.6% in 2015 compared to 22.6% in 2014 due primarily to higher sales volumes and a favorable change in product mix.

Research and Development Expenses:	Years Ended December 31, 2016	2015	2014	Increase / (Decrease) 2016 vs. 2015 $	%	2015 vs. 2014 $	%
Research and development	$ 34,611	$ 25,608	$ 17,298	$ 9,003	35.2%	$ 8,310	48.0%
Percentage of sales	23.0%	14.8%	115.5%				

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

Research and development expenses increased $8,310 or 48.0% during the year ended December 31, 2015 as compared to the same period in 2014 primarily due to higher clinical studies and outside services costs including a $2,300 FDA filing fee for Akovaz and the Company's overall continued investment in its pipeline products. These costs were partially offset by a decrease in salaries and employee benefits which were driven largely by changes in foreign exchange rates and a decrease in certain employee benefits in 2015 relative to 2014.

Selling, General and Administrative Expenses:	Years Ended December 31, 2016	2015	2014	Increase / (Decrease) 2016 vs. 2015 $	%	2015 vs. 2014 $	%
Selling, general and administrative	$ 44,179	$ 21,712	$ 15,698	$ 22,467	103.5%	$ 6,014	38.3%
Percentage of sales	29.4%	12.5%	104.8%				

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

Selling, general and administrative expenses increased $6,014 or 38.3% during the year ended December 31, 2015 as compared to the same period in 2014 primarily due to higher stock-based compensation expenses of $5,051 and additional employee recruitment costs associated with the Company's efforts to reinforce its management team.

Intangibles Asset Amortization:	Years Ended December 31, 2016	2015	2014	Increase / (Decrease) 2016 vs. 2015 $	%	2015 vs. 2014 $	%
Intangible asset amortization	$ 13,888	$ 12,564	$ 11,749	$ 1,324	10.5%	$ 815	6.9%
Percentage of sales	9.2%	7.3%	78.5%				

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

Intangible asset amortization expense increased $815 or 6.9% during the year ended December 31, 2015 as compared to the same period in 2014 due to the commencement of amortization related to the acquired In-Process R&D ("IPR&D") Vazculep intangible asset upon the product's launch in 2015.

Changes in Fair Value of Related Party Contingent Consideration:	Years Ended December 31, 2016	2015	2014	Increase / (Decrease) 2016 vs. 2015 $	%	2015 vs. 2014 $	%
Changes in fair value of related party contingent consideration	$ 49,285	$ 30,957	$ 57,491	$ 18,328	59.2%	$ (26,534)	(46.2)%
Percentage of sales	32.8%	17.9%	383.9%				

Changes in fair value of related party contingent consideration increased $18,328 or 59.2% during the year ended December 31, 2016 as compared to the same period in 2015 primarily due to changes in the estimates of the underlying assumptions used to determine the fair values of a:) our acquisition-related contingent consideration earn out payments - Éclat, b:) acquisition related warrants and c:) acquisition related FSC royalty liabilities. As noted in our critical accounting estimates, there are a number of estimates we use when determining the fair value of the acquisition-related earn-out payments - Éclat. These estimates include the long-term pricing environment, market size, the market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows. As a result of changes to these estimates when compared to the same estimates at December 31, 2015, we incurred a charge of $57,609 to increase the fair value of acquisition related liabilities for Éclat primarily as a result of changes in market assumptions around our Akovaz product and a slightly better long term sales and gross profit outlook for Bloxiverz. Additionally, we reduced the fair value of the acquisition related warrants which resulted in a gain of $9,400, primarily due to a lower AVDL stock price at December 31, 2016 compared to December 31, 2015, changes in the volatility of AVDL stock during 2016 and a shorter remaining term. Further, we incurred a charge of $1,076 to increase the fair value of acquisition related FSC royalty liabilities. Each of the underlying assumptions used to determine the fair values of these contingent liabilities can, and often do, change based on adjustments in current market conditions, competition and other factors. These changes can have a material impact on our consolidated statements of income (loss), balance sheet and cash flows.

Changes in fair value of related party contingent consideration decreased $26,534 or 46.2% during the year ended December 31, 2015 as compared to the same period in 2014 primarily due to decreases in the changes in fair value of warrants of $37,970 driven by a reduction in the Company's stock price, which were partially offset by increases in the changes in fair value of the earn-out payments liability of $11,436 due to changes in the associated long-term Éclat product sales forecasts.

				Increase / (Decrease)			
	Years Ended December 31,			**2016 vs. 2015**		**2015 vs. 2014**	
Interest Expense:	**2016**	**2015**	**2014**	**$**	**%**	**$**	**%**
Interest expense	$ 963	$ —	$ 5,747	$ 963	*n/a*	$ (5,747)	(100.0)%
Percentage of sales	(0.6)%	—%	(38.4)%				

Interest expense increased $963 for the year ended December 31, 2016 when compared to the year ended December 31, 2015 as a result of interest on the long term related party note associated with the FSC acquisition. Interest expense decreased $5,747 for the year ended December 31, 2015 when compared to the year ended December 31, 2014 as a result of not incurring interest in 2015 due to extinguishing certain related party debt in 2014.

				Increase / (Decrease)			
	Years Ended December 31,			**2016 vs. 2015**		**2015 vs. 2014**	
Other Expense - Changes in Fair Value of Related Party Payable:	**2016**	**2015**	**2014**	**$**	**%**	**$**	**%**
Other expense - changes in fair value of related party payable	$ 6,548	$ 4,883	$ 3,525	$ 1,665	34.1%	$ 1,358	38.5%
Percentage of sales	(4.4)%	(2.8)%	(23.5)%				

Other expense - changes in fair value of related party payable increased $1,665 or 34.1% during the year ended December 31, 2016 as compared to the same period last year primarily due to changes in the underlying assumptions of the long-term Éclat product sales forecasts as described in the section *Changes in fair value of related party contingent consideration*. As noted in our critical accounting estimates, there are a number of estimates we use when determining the fair value of the related party payable payments. These estimates include the long-term pricing environment, market size, the market share the related products are forecast to achieve and an appropriate discount rate to use when present valuing the related cash flows. These estimates can and often do change based on changes in current market conditions, competition and other factors. As a result of changes to these estimates when compared to the same estimates at December 31, 2015, we incurred a charge of $6,548 to increase the fair value of these liabilities primarily as a result of changes in the market outlook for Akovaz and a slightly better long term sales outlook for Bloxiverz.

Other expense - changes in fair value of related party payable increased $1,358 or 38.5% during the year ended December 31, 2015 as compared to the same period last year primarily due to changes in the underlying assumptions of the long-term Éclat product sales forecasts as described in the section *Changes in fair value of related party contingent consideration*. As a result of changes to these estimates when compared to the same estimates at December 31, 2014, we incurred a charge of $4,883 to increase

the fair value of these liabilities primarily as a result of changes in market assumptions around the long-term sales outlook for Bloxiverz.

				Increase / (Decrease)			
	Years Ended December 31,			**2016 vs. 2015**		**2015 vs. 2014**	
Foreign Exchange Gains:	**2016**	**2015**	**2014**	**$**	**%**	**$**	**%**
Foreign exchange gain	$ 1,123	$ 10,594	$ 11,871	$ (9,471)	(89.4)%	$ (1,277)	(10.8)%
Percentage of sales	0.7%	6.1%	79.3%				

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

Foreign exchange gains declined $1,277 or 10.8% for the year ended December 31, 2015 when compared to the year ended December 31, 2014 primarily due to lower foreign currency exchange gains on assets and liabilities held in currencies other than the functional currency in which it was recorded.

Income Taxes:	Years Ended December 31, 2016	2015	2014	Increase / (Decrease) 2016 vs. 2015 $	2016 vs. 2015 %	2015 vs. 2014 $	2015 vs. 2014 %
Income tax provision (benefit)	$ 31,558	$ 35,907	$ (644)	$ (4,349)	(12.1)%	$ 36,551	(5,675.6)%
Percentage of income (loss) before income taxes	(324.7)%	46.2%	0.7%				

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

Reconciliation to Effective Income Tax Rate:	2016	2015	2014
Statutory tax rate [1]	12.5 %	33.3 %	33.3 %
Non-deductible changes in fair value of contingent consideration	(165.0)%	11.9 %	(24.8)%
Change in valuation allowance	11.8 %	(9.6)%	5.3 %
Income tax deferred charge	(9.7)%	1.3 %	(16.9)%
International tax rates differential	(31.9)%	11.0 %	6.7 %
Nondeductible stock based compensation	(14.8)%	1.3 %	(0.8)%
Cross-border merger	(100.6)%	— %	— %
Unrecognized tax benefit	(15.2)%	0.4 %	— %
State and local taxes (net of federal)	(9.6)%	1.5 %	0.3 %
Other	(2.3)%	(4.9)%	(2.3)%
Effective income tax rate	(324.8)%	46.2 %	0.8 %

Income tax provision (benefit) - at statutory tax rate	$ (1,215)	$ 25,876	$ (30,013)
Non-deductible changes in fair value of contingent consideration	16,036	9,249	22,326
Change in valuation allowance	(1,143)	(7,425)	(4,732)
Income tax deferred charge	938	980	15,273
International tax rates differential	3,097	8,547	(6,023)
Nondeductible stock based compensation	1,436	1,004	693
Cross-border merger	9,773	—	—
Unrecognized tax benefit	1,475	290	—
State and local taxes (net of federal)	934	1,170	(228)
Other	227	(3,784)	2,060
Income tax provision (benefit) - at effective income tax rate	$ 31,558	$ 35,907	$ (644)

[1] The statutory rate reflects the Irish statutory tax rate of 12.5% for fiscal 2016, and the French statutory tax rate of 33.3% for fiscal 2015 and 2014.

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

In 2015, the income tax provision increased by $36,551 when compared to the same period in 2014. The primary reason for the large increase in the income tax provision was a substantial increase in the level of pre-tax book income in the United States and France. Decreases in the amount of nondeductible expenses due to changes in the fair value of contingent consideration and an increase in the benefit from the release of valuation allowances partially offset the income tax provision from the increased amount of pre-tax book income in 2015, when compared to 2014. In 2014, the Company recorded $15,273 of income tax provision related to the transfer of intellectual property from France to Ireland, which did not reoccur in 2015.

Net Income from Discontinued Operations	Years Ended December 31, 2016	2015	2014	Increase / (Decrease) 2016 vs. 2015 $	%	2015 vs. 2014 $	%
Net income from discontinued operations	$ —	$ —	$ 4,018	$ —	*n/a*	$ (4,018)	(100.0)%

On December 1, 2014, Avadel divested its Pessac Facility to Recipharm AB ("Recipharm"). Under the divestiture agreement, Recipharm paid the Company $13,242. This divestiture agreement allowed Avadel to use the development and manufacturing capabilities of the acquired Pessac Facility and to use Recipharm's other facilities for the development or manufacture of its proprietary pipeline if needed. As part of the divestiture agreement, as of December 1, 2014 the Company transferred to Recipharm the Supply Agreement and the associated royalties pertaining to Coreg CR® under the License agreement with GSK to Recipharm. The divestiture of the Pessac Facility has been classified as Discontinued Operations for the twelve-month period ended December 31, 2014 (see *Note 19: Discontinued Operations* to the consolidated financial statements in "Item 8. Financial Statements") with net income attributable to such Discontinued Operations of $4,018. There was no net income attributable to such Discontinued Operations in 2016 or 2015, respectively. The gain on sale of the Pessac Facility in 2014 amounted to $5,007.

The summary statement of operations of the Discontinued Operations for each of the last three years is as follows:

Net Income from Discontinued Operations	2016	2015	2014
Revenues	$ —	$ —	$ 14,967
Operating income (loss)	—	—	(875)
Gain on disposal	—	—	5,007
Interest expense	—	—	(4)
Income tax provision	—	—	(110)
Net income from discontinued operations	$ —	$ —	$ 4,018

Liquidity and Capital Resources

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

Net Cash Provided By (Used In):	Years Ended December 31, 2016	2015	2014	Increase / (Decrease) 2016 vs. 2015 $	%	2015 vs. 2014 $	%
Operating activities	$ 18,901	$ 84,293	$ (10,617)	$ (65,392)	(77.6)%	$ 94,910	(893.9)%
Investing activities	(36,630)	(31,730)	(43,083)	(4,900)	15.4 %	11,353	(26.4)%
Financing activities	(7,954)	(23,751)	95,995	15,797	(66.5)%	(119,746)	(124.7)%

Operating Activities

Net cash provided by operating activities of $18,901 for the twelve months ended December 31, 2016 decreased $65,392 compared to the same prior year period. This decline in operating cash flow is primarily due to lower cash earnings (net loss adjusted for non-cash credits and charges) when compared to the same period last year, largely driven from lower revenues. Additionally, contributing to the lower operating cash flows was a shift in the classification of earn-out payments for related party contingent consideration and royalty payments for related party payables from financing activities to operating activities. During 2016, the

cumulative life-to-date payments of such related party payables reached and exceeded the original fair value of the related liabilities established as part of the purchase price allocation of the Éclat acquisition and as such the Company began classifying all payments in excess of these original fair values within operating activities. Payments in excess of the original fair value totaling $22,721 were classified within operating activities for the twelve months ended December 31, 2016, compared to the same period in 2015 during which all such cash payments were classified as financing activities.

Net cash provided by operating activities of $84,293 for the year ended December 31, 2015 increased $94,910 from the same prior year period. The primary driver of this growth was an increase in cash earnings (net income adjusted for non-cash credits and charges), largely driven by higher revenues.

Investing Activities

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

Cash used in investing activities of $31,730 for the year ended December 31, 2015 decreased $11,353 compared to the same prior year period. This decline in the use of cash was primarily driven by higher proceeds from sales of marketable securities of $23,315 offset partially by lower proceeds from the sales of its Pessac facility of $13,242, which did not repeat in 2015.

Financing Activities

Cash used in financing activities of $7,954 for the twelve months ended December 31, 2016 decreased $15,797 compared to the same prior year period. The decrease in the usage of cash for financing activities was primarily related to lower earn out payments for related party contingent consideration. As noted in the discussion of cash flows from operating activities, contributing to the lower uses of cash for financing activities was a shift in the classification of earn-out payments for related party contingent consideration and royalty payments for related party payables from financing activities to operating activities. During 2016, the cumulative life-to-date payments of such related party payables reached and exceeded the original fair value of the related liabilities established as part of the purchase price allocation of the Éclat acquisition and as such the Company began classifying all payments in excess of these original fair values within operating activities. Payments made before the Company exceeded the original fair value of the related liabilities are classified as financing activities and amounted to $8,117 for the twelve months ended December 31, 2016 compared to $27,897 in the same period last year, during which all such cash payments were classified as financing activities. Additionally, the Company made $4,911 in debt repayments during the twelve months ended December 31, 2015. No such payments were made in 2016 as the related debt was repaid in full in 2015. Cash proceeds from the issuance of ordinary shares and warrants were $6,990 during the twelve months ended December 31, 2015, compared to $440 during the twelve months ended December 31, 2016.

Cash used in financing activities was $23,751 for the year ended December 31, 2015 compared to cash provided by financing activities of $95,995 for the year ended December 31, 2014. The primary reason for the decline in cash flow from financing activities was due to $132,260 of proceeds received in 2014 from an equity capital raise that did not repeat in 2015. Further, the Company used $4,911 in cash for the reimbursement of a loan in 2015 compared to $34,186 in 2014. This decline was a result of the repayment of such loan in 2015 using the proceeds from the 2014 equity capital raise. Additionally, earn out and royalty payments to related parties increased by $26,334 in 2015 compared to 2014, due to higher gross profits in 2015 upon which the royalty applies.

Share Repurchase Program

In March 2017, the Board of Directors approved an authorization to repurchase up to $25,000 of Avadel ordinary shares represented by American Depository Receipts in the open market with an indefinite duration. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our shares, cash resources, alternative investment opportunities, corporate and regulatory requirements and market conditions. This share repurchase program may be modified, suspended or discontinued at any time without prior notice. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program.

Liquidity and Risk Management

We believe that our existing cash and marketable securities balances and cash we expect to generate from operations will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product revenues and expenses, as well as the other factors set forth in “Risk Factors.” To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business. Our assumptions may

prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash and marketable securities balances which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

To continue to grow our business over the longer term, we plan to commit substantial resources to product development and clinical trials of product candidates. In this regard, we have evaluated and expect to continue to evaluate a variety of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur indebtedness, seek equity capital or both. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders.

Other Matters

Litigation

The Company is subject to potential liabilities generally incidental to its business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At December 31, 2016 and 2015, there were no contingent liabilities with respect to any threat of litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Company's consolidated balance sheet, results of operations, cash flows or liquidity.

Material Commitments

The Company has commitments to purchase services from Recipharm Pessac for a total of $22,500 for a five-year period commencing January 1, 2015 (disclosed in *Note 19: Discontinued Operations*).

The Company has a commitment to purchase finished product from a contract manufacturer for a total of $7,238,000 during the one-year period commencing January 1, 2017.

The Company has a commitment to purchase finished product from a contract manufacturer for a twenty-year period commencing August 1, 2015 and ending July 31, 2035. The commitment for any individual year is contractually waived if the Company's net customer sales for that product exceed certain amounts in that same year. Maximum commitments for this arrangement, at 2016 pricing levels and excluding any waived commitments, are as follows for the years ended December 31:

Purchase Commitment:	Balance
2017	$ 778
2018	1,032
2019	1,126
2020	1,126
2021	1,126
Thereafter	15,295
Total	$ 20,483

The Company and its subsidiaries lease office facilities under noncancelable operating leases expiring at various dates. Rent expense, net of rental income, was $970, $752 and $844 in 2016, 2015, and 2014, respectively. Minimum rental commitments for non-cancelable leases in effect at December 31, 2016 are as follows:

Lease Commitment:	Balance
2017	$ 1,117
2018	783
2019	717
2020	699
2021	441
Thereafter	600
Total	$ 4,357

Other than the above commitments, there were no other material commitments outside of the normal course of business. Material commitments in the normal course of business include long-term debt, long-term related party payable, and post-retirement benefit plan obligations which are disclosed in *Note 9: Long-Term Debt, Note 10: Long-Term Related Party Payable,* and *Note 12: Post-Retirement Benefit Plans*, respectively.

Aggregate Contractual Obligations

The following table presents contractual obligations of the Company at December 31, 2016:

	Payments Due by Period				
Contractual Obligations:	**Total**	**Less than 1 Year**	**1 to 3 Years**	**3 to 5 Years**	**More than 5 Years**
Long-term debt	$ 815	$ 268	$ 547	$ —	$ —
Long-term related party payable (undiscounted)	278,236	35,226	57,466	60,587	124,957
Purchase commitments	41,721	12,266	11,908	2,252	15,295
Operating leases	4,982	1,390	1,837	1,155	600
Total contractual cash obligations	$ 325,754	$ 49,150	$ 71,758	$ 63,994	$ 140,852

See *Note 9: Long-Term Debt and Note 10: Long-Term Related Party Payable* to the Company's consolidated financial statements contained in Item 8 – Financial Statements for obligations with respect to the respective items within the above table. Obligations relative to the Deerfield warrant-based contingent consideration of $11,217 are not included within the above table. The Company’s long-term debt does not bear interest and therefore no interest is included in the above table.

See *Note 19: Discontinued Operations* to the Company's consolidated financial statements contained in Item 8 – Financial Statements for obligations with respect to the Company's Recipharm obligation.

See *Note 12: Post-Retirement Benefit Plans* to the Company's consolidated financial statements contained in Item 8 – Financial Statements for obligations with respect to the Company's post-retirement benefit plans. Obligations of $2,431 related to the post-retirement benefit plans are not included within the above table.

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

Interest Rate Risk

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

Foreign Exchange Risk

We have significant operations in Europe as well as in the U.S. Prior to December 31, 2016 each of the Company's non-U.S. subsidiaries and the parent entity, Flamel Technologies S.A., used the Euro as its functional currency. At December 31, 2016, in conjunction with the cross-border merger, the surviving entity in the merger and our new public holding company, Avadel Pharmaceuticals plc or the "Company," chose the U.S. dollar as its functional currency. The functional currency of certain foreign subsidiaries is the local currency. We are exposed to foreign currency exchange risk as the functional currency financial statements of foreign subsidiaries are translated to U.S. dollars. The assets and liabilities of our foreign subsidiaries having a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders' equity. The reported results of our foreign subsidiaries will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposure is related to our subsidiaries that have functional currencies denominated in Euro. A 10% strengthening/(weakening) in the rates used to translate the results of our foreign subsidiaries that have functional currencies denominated in the euro as of December 31, 2016 would have increased/(decreased) net income for the year ended December 31, 2016 by approximately $2,000.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in foreign exchange gain (loss) in the consolidated statements of income (loss). As of December 31, 2016, our primary exposure to transaction risk related to USD net monetary assets and liabilities held by subsidiaries with a Euro functional currency. Realized and unrealized foreign exchange gains resulting from transactional exposure were $1,123 for the year ended December 31, 2016.

Item 8. Financial Statements and Supplementary Data.

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

	Years ended December 31,		
	2016	**2015**	**2014**
Revenues:			
Product sales and services	$ 147,222	$ 172,288	$ 12,193
License and research revenue	3,024	721	2,782
Total	150,246	173,009	14,975
Operating expenses:			
Cost of products and services sold	13,248	11,410	3,383
Research and development	34,611	25,608	17,298
Selling, general and administrative	44,179	21,712	15,698
Intangible asset amortization	13,888	12,564	11,749
Changes in fair value of related party contingent consideration	49,285	30,957	57,491
Loss on early repayment of related party acquisition-related note	—	—	3,013
Total	155,211	102,251	108,632
Operating income (loss)	(4,965)	70,758	(93,657)
Investment and other income	1,635	1,236	927
Interest expense	(963)	—	(5,747)
Other expense - changes in fair value of related party payable	(6,548)	(4,883)	(3,525)
Foreign exchange gain	1,123	10,594	11,871
Income (loss) before income taxes	(9,718)	77,705	(90,131)
Income tax provision (benefit)	31,558	35,907	(644)
Net income (loss) from continuing operations	(41,276)	41,798	(89,487)
Net income from discontinued operations	—	—	4,018
Net income (loss)	$ (41,276)	$ 41,798	$ (85,469)
Earnings (loss) per share - basic:			
Continuing operations	$ (1.00)	$ 1.03	$ (2.47)
Discontinued operations	—	—	0.11
Net income (loss)	$ (1.00)	$ 1.03	$ (2.36)
Earnings (loss) per share - diluted:			
Continuing operations	$ (1.00)	$ 0.96	$ (2.47)
Discontinued operations	—	—	0.11
Net income (loss)	$ (1.00)	$ 0.96	$ (2.36)
Weighted average number of shares outstanding - basic	41,248	40,580	36,214
Weighted average number of shares outstanding - diluted	41,248	43,619	36,214

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2016	**2015**	**2014**
Net income (loss)	$ (41,276)	$ 41,798	$ (85,469)
Other comprehensive income (loss), net of tax:			
Foreign currency translation loss	(1,024)	(15,087)	(18,040)
Net other comprehensive income (loss) on marketable securities, net of $16, ($20), ($0) tax, respectively	116	(147)	(198)
Total other comprehensive loss, net of tax	(908)	(15,234)	(18,238)
Total comprehensive (loss) income	$ (42,184)	$ 26,564	$ (103,707)

See accompanying notes to consolidated financial statements.

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

	December 31,	
	2016	**2015**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,215	$ 65,064
Marketable securities	114,980	79,738
Accounts receivable	17,839	7,487
Inventories	3,258	3,666
Research and development tax credit receivable	—	2,382
Prepaid expenses and other current assets	5,894	8,064
Total current assets	181,186	166,401
Property and equipment, net	3,320	2,616
Goodwill	18,491	18,491
Intangible assets, net	22,837	15,825
Research and development tax credit receivable	1,775	—
Income tax deferred charge	10,342	11,581
Other	7,531	167
Total assets	$ 245,482	$ 215,081
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 268	$ 434
Current portion of long-term related party payable	34,177	25,204
Accounts payable	7,105	5,048
Deferred revenue	2,223	5,121
Accrued expenses	17,222	9,308
Income taxes	1,200	—
Other	226	133
Total current liabilities	62,421	45,248
Long-term debt	547	684
Long-term related party payable	135,170	97,489
Other	5,275	2,526
Total liabilities	203,413	145,947
Shareholders' equity:		
Preferred shares, $0.01 nominal value; 50,000 shares authorized at December 31, 2016, none authorized at December 31, 2015; none issued or outstanding at December 31, 2016 and December 31, 2015, respectively	—	—
Ordinary shares, nominal value of $0.01 and €0.122; 500,000 and 53,178 shares authorized; 41,371 and 41,241 issued and outstanding at December 31, 2016 and 2015, respectively	414	6,331
Additional paid-in capital	385,020	363,984
Accumulated deficit	(319,800)	(278,524)
Accumulated other comprehensive loss	(23,565)	(22,657)
Total shareholders' equity	42,069	69,134
Total liabilities and shareholders' equity	$ 245,482	$ 215,081

See accompanying notes to consolidated financial statements.

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

	Ordinary shares		Additional	Accumulated	Accumulated other comprehensive	Total shareholders'
	Shares	Amount	paid-in capital	deficit	loss	equity
Balance, December 31, 2013	25,613	$ 3,746	$ 211,473	$ (234,853)	$ 10,815	$ (8,819)
Net loss	—	—	—	(85,469)	—	(85,469)
Other comprehensive loss	—	—	—	—	(18,238)	(18,238)
Subscription of warrants	—	—	351	—	—	351
Exercise of stock options or warrants	1,001	164	5,861	—	—	6,025
Vesting of free shares	151	24	(24)	—	—	—
Stock-based compensation expense	—	—	2,894	—	—	2,894
Public offering	12,400	2,099	113,133	—	—	115,232
Shares granted to Recipharm AB	1,026	155	12,894	—	—	13,049
Balance, December 31, 2014	40,191	6,188	346,582	(320,322)	(7,423)	25,025
Net income	—	—	—	41,798	—	41,798
Other comprehensive loss	—	—	—	—	(15,234)	(15,234)
Subscription of warrants	—	—	601	—	—	601
Exercise of stock options or warrants	899	123	6,266	—	—	6,389
Vesting of free shares	151	20	(20)	—	—	—
Stock-based compensation expense	—	—	7,741	—	—	7,741
Excess tax benefit from stock-based compensation	—	—	2,814	—	—	2,814
Balance, December 31, 2015	41,241	6,331	363,984	(278,524)	(22,657)	69,134
Net loss	—	—	—	(41,276)	—	(41,276)
Other comprehensive loss	—	—	—	—	(908)	(908)
Subscription of warrants	—	—	326	—	—	326
Exercise of stock options	15	2	112	—	—	114
Vesting of free shares	115	18	(18)	—	—	—
Stock-based compensation expense	—	—	14,679	—	—	14,679
Cross-border merger nominal value adjustment	—	(5,937)	5,937	—	—	—
Balance, December 31, 2016	41,371	$ 414	$ 385,020	$ (319,800)	$ (23,565)	$ 42,069

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2016	**2015**	**2014**
Cash flows from operating activities:			
Net income (loss)	$ (41,276)	$ 41,798	$ (85,469)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	14,489	13,132	14,141
Loss (gain) on disposal of property and equipment	110	—	(4,952)
Loss on sale of marketable securities	826	779	—
Unrealized foreign currency exchange gain	(349)	(8,969)	(6,252)
Gains on waiver of research and development grants and other	—	(1,498)	(589)
Remeasurement of related party acquisition-related contingent consideration	49,285	30,957	60,503
Remeasurement of related party financing-related royalty agreements	6,548	4,883	3,319
Change in deferred tax and income tax deferred charge	(4,000)	69	(2,113)
Stock-based compensation expense	14,679	7,741	2,690
Increase (decrease) in cash from:			
Accounts receivable	(10,050)	(8,440)	3,249
Inventories	1,831	3,036	(3,112)
Prepaid expenses and other current assets	3,412	(684)	(2,329)
Research and development tax credit receivable	397	2,975	13,210
Accounts payable & other current liabilities	(434)	(8,533)	7,219
Deferred revenue	(2,923)	3,815	(55)
Accrued expenses	6,764	3,376	452
Accrued income taxes	1,778	(393)	70
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(20,252)	—	—
Royalty payments for related party payable in excess of original fair value	(2,469)	—	—
Other long-term assets and liabilities	535	249	(10,599)
Net cash provided by (used in) operating activities	18,901	84,293	(10,617)
Cash flows from investing activities:			
Purchases of property and equipment	(1,201)	(1,629)	(1,728)
Proceeds from disposal of property and equipment	—	—	13,242
Acquisitions of businesses, including cash acquired and other adjustments	628	—	—
Proceeds from sales of marketable securities	71,546	48,308	24,993
Purchases of marketable securities	(107,603)	(78,409)	(79,590)
Net cash used in investing activities	(36,630)	(31,730)	(43,083)
Cash flows from financing activities:			
Reimbursement of loans	—	(4,911)	(34,186)
Reimbursement of conditional R&D grants	(277)	(747)	(355)
Principal payments on capital lease obligations	—	—	(161)
Earn-out payments for related party contingent consideration	(6,892)	(24,526)	(1,357)
Royalty payments for related party payable	(1,225)	(3,371)	(206)
Excess tax benefit from stock-based compensation	—	2,814	—
Cash proceeds from issuance of ordinary shares and warrants	440	6,990	132,260
Net cash provided by (used in) financing activities	(7,954)	(23,751)	95,995
Effect of exchange rate changes on cash and cash equivalents	(166)	(3,508)	(9,171)
Net increase (decrease) in cash and cash equivalents	(25,849)	25,304	33,124
Cash and cash equivalents at January 1	65,064	39,760	6,636
Cash and cash equivalents at December 31	$ 39,215	$ 65,064	$ 39,760
Supplemental disclosures of cash flow information:			
Income tax paid	$ 27,180	$ 42,121	$ 403
Interest paid	788	4,738	4,431

See accompanying notes to consolidated financial statements.

NOTE 1 : Summary of Significant Accounting Policies

Nature of Operations. Avadel Pharmaceuticals PLC ("Avadel," the "Company," "we," "our," or "us") is a specialty pharmaceutical company engaged in identifying, developing, and commercializing niche branded pharmaceutical products mainly in the U.S. Our business model consists of three distinct strategies:

- the development of differentiated, patent protected products through application of the Company's proprietary patented drug delivery platforms, Micropump® and LiquiTime®, that target high-value solid and liquid oral and alternative dosages forms through the U.S. Food and Drug Administration (FDA) 505(b)(2) approval process, which allows a sponsor to submit an application that doesn't depend on efficacy, safety, and toxicity data created by the sponsor. In addition to Micropump® and LiquiTime®, the Company has two other proprietary drug delivery platforms, Medusa™ (hydrogel depot technology for use with large molecules and peptides) and Trigger Lock™ (controlled release of opioid analgesics with potential abuse deterrent properties).

- the identification of Unapproved Marketed Drugs ("UMDs"), which are currently sold in the U.S., but unapproved by the FDA, and the pursuit of approval for these products via a 505(b)(2) New Drug Application (NDA). To date, the Company has received approvals through this "unapproved-to-approved" avenue for three products: Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection) and Akovaz® (ephedrine sulfate injection). As a potential source of near-term revenue growth, Avadel is working on the development of a fourth product for potential NDA submission by year-end 2017, and seeks to identify additional product candidates for development with this strategy.

- the acquisition of commercial and or late-stage products or businesses. The Company markets three branded pediatric-focused pharmaceutical products in the primary care space, and a 510(k) approved device that will launch in the second quarter of 2017, all of which were purchased through the acquisition of FSC Laboratories and FSC Pediatrics on February 5, 2016. We will consider further acquisitions, and the Company continues to look for assets that could fit strategically into its current or potential future commercial sales force.

The Company was incorporated in Ireland on December 1, 2015 as a private limited company, and re-registered as an Irish public limited company on November 21, 2016. Its headquarters are in Dublin, Ireland and it has operations in St. Louis, Missouri, United States, and Lyon, France.

The Company is an Irish public limited company, or plc, and is the successor to Flamel Technologies S.A., a French *société anonyme* ("Flamel"), as the result of the merger of Flamel with and into the Company which was completed at 11:59:59 p.m., Central Europe Time, on December 31, 2016 (the "Merger") pursuant to the agreement between Flamel and Avadel entitled Common Draft Terms of Cross-Border Merger dated as of June 29, 2016 (the "Merger Agreement"). Immediately prior to the Merger, the Company was a wholly owned subsidiary of Flamel. As a result of the Merger Agreement:

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

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

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

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

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

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

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

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

Further details about the reincorporation, the Merger and the Merger Agreement are contained in our definitive proxy statement filed with the Securities and Exchange Commission on July 5, 2016, and within the Annual Report on Form 10-K of which these financial statements are a part in Item 1 thereof under the caption “Business - The Flamel Merger.”

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

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

Reclassifications and Immaterial Corrections of Prior Period Amounts. The consolidated financial statements for prior periods contain certain reclassifications to conform to the presentation used in 2016. Additionally, the Company has identified certain immaterial errors related to prior reporting periods. The Company has assessed the impact of the errors on its prior period financial statements and concluded that the errors were not material to those financial statements. Although the effect of the errors was not material to any previously issued financial statements, the cumulative effect of correcting the errors would have been material for the period ended December 31, 2016. Consequently, the Company has presented the effects of these errors and reclassifications on its prior period financial statements in the tables below. In future filings, the financial statements for comparative periods affected by these errors and reclassifications will be revised.

The impact of the above errors and reclassifications on previously presented line items for each comparative period presented is as follows:

	Twelve Months Ended December 31, 2014			
		Correction of Immaterial Errors		
Consolidated Statement of Loss:	**As filed**	**(b)**	**(f)**	**As revised**
Product sales and services	$ 11,993	$ 200	$ —	$ 12,193
Total revenue	14,775	200	—	14,975
Operating income (loss)	(93,857)	200	—	(93,657)
Income (loss) before income taxes	(90,331)	200	—	(90,131)
Income tax provision (benefit)	(1,407)	70	693	(644)
Net income (loss) from continuing operations	(88,924)	130	(693)	(89,487)
Net income (loss)	(84,906)	130	(693)	(85,469)
Net loss per share - basic	$ (2.34)	$ —	$ (0.02)	$ (2.36)
Net loss per share - diluted	$ (2.34)	$ —	$ (0.02)	$ (2.36)

Consolidated Statement of Income:	Twelve Months Ended December 31, 2015				
		Correction of Immaterial Errors			
	As filed	(a)	(b)	(c)	As revised
Product sales and services	$ 172,488	$ —	$ (200)	$ —	$ 172,288
Total revenue	173,209	—	(200)	—	173,009
Cost of products and services sold	10,921	—	—	489	11,410
Total operating expenses	101,762	—	—	489	102,251
Operating income (loss)	71,447	—	(200)	(489)	70,758
Income (loss) before income taxes	78,394	—	(200)	(489)	77,705
Income tax provision (benefit)	37,735	(1,587)	(70)	(171)	35,907
Net income (loss) from continuing operations	40,659	1,587	(130)	(318)	41,798
Net income (loss)	40,659	1,587	(130)	(318)	41,798
Net income (loss) per share - basic	$ 1.00	$ 0.04	$ —	$ (0.01)	1.03
Net income (loss) per share - diluted	$ 0.93	$ 0.04	$ —	$ (0.01)	$ 0.96

Consolidated Balance Sheet:	December 31, 2015						
		Correction of Immaterial Errors			*Reclassifications*		
	As filed	(a)	(c)	(d)	(e)	(g)	As revised
Accounts receivable	$ 6,978	$ —	$ —	$ —	$ 509	$ —	$ 7,487
Inventories	4,155	—	(489)	—	—	—	3,666
Prepaid expenses and other current assets	7,989	—	—	—	—	75	8,064
Total current assets	166,306	—	(489)	—	509	75	166,401
Other	158	—	—	—	—	9	167
Total assets	214,977	—	(489)	—	509	84	215,081
Current portion of long-term related party payable	28,614	—	—	(3,410)	—	—	25,204
Accounts payable	10,565	—	—	—	(5,517)	—	5,048
Accrued expenses	3,598	—	—	—	5,710	—	9,308
Income taxes	323	(228)	(171)	—	—	76	—
Total current liabilities	48,788	(228)	(171)	(3,410)	193	76	45,248
Long-term related party payable	94,079	—	—	3,410	—	—	97,489
Deferred taxes	1,351	(1,359)	—	—	—	8	—
Other	2,210	—	—	—	316	—	2,526
Total liabilities	147,112	(1,587)	(171)	—	509	84	145,947
Accumulated deficit	(279,793)	1,587	(318)	—	—	—	(278,524)
Total shareholders' equity	67,865	1,587	(318)	—	—	—	69,134
Total liabilities and shareholders' equity	214,977	—	(489)	—	509	84	215,081

(a) Reflects the cumulative 2015 correction of $1,587 of income tax benefits related to the deductibility of the U.S. Internal Revenue Code Section 483 imputed interest on contingent consideration liabilities which should have been recorded in prior periods ($866, $292, $863 and ($434) in the first, second, third and fourth quarters of 2015, respectively).

(b) Reflects the correction of a $200 overstatement of revenue in the first quarter of 2015 resulting from errors in certain estimates of ending inventory amounts at our wholesalers which were originally corrected in the first quarter of 2015 but should have been recorded in the fourth quarter of 2014. As this item was originally corrected in the first quarter of 2015, no adjustment was required to correct the consolidated balance sheet at December 31, 2015.

(c) Reflects the correction of a $489 error in the Company’s inventory obsolescence reserve accrual and expense which was originally recorded in the first quarter of 2016 but should have been recorded in the fourth quarter of 2015.

(d) Reflects the correction of a balance sheet classification error which overstated the current portion of the long-term related party payable by $3,410.

(e) Reflects revisions to the presentation of certain gross to net revenue reserves which were previously included in accounts payable and are now included in accrued expenses.

(f) Reflects the correction of $2,606 of income tax benefits from stock-based compensation and certain other items which were originally recorded in the fourth quarter of 2015 but should have been recorded in prior periods ($360 in 2012, $333 in 2013, $(693) in 2014, and $830, $1,026 and $750 in the first, second and third quarters of 2015, respectively). As these items were originally corrected in the fourth quarter of 2015, no adjustment was required to correct the consolidated balance sheet at December 31, 2015.

(g) Reflects balance sheet reclassifications required to properly net the accrued income tax and deferred income tax amounts within the balance sheet as a result of the adjustments made in items (a) through (f) above.

In addition to the specific amounts identified within the tables above, the Company also changed the names of the previously-reported "Interest expense – changes in fair value of related party financing related contingent consideration" line on the consolidated statement of income (loss) to "Other expense – changes in fair value of related party payable", and the previously-reported "Long-term related party contingent consideration payable" line on the consolidated balance sheet to "Long-term related party payable" to better reflect the underlying nature of certain royalty agreements.

While the balance sheet revisions and reclassifications noted in the tables above impact their corresponding captions within the cash flows provided by (used in) operating activities section of the Company's consolidated statements of cash flows in each quarterly period of 2015, there was no impact to the total net cash provided by (used in) operating activities in any of these periods.

Additionally, $76,213 of marketable securities as of December 31, 2015 were reclassified from a Level 1 fair value hierarchy classification, as reported in prior filings, to a Level 2 classification based on the criteria set forth in *Note 3: Fair Value Measurement*.

Revenue

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

Product Sales and Services

Revenue is generally realized or realizable and earned when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the seller's price to the buyer is fixed or determinable, and collectability is reasonably assured. The Company records revenue from product sales when title and risk of ownership have been transferred to the customer, which is typically upon delivery to the customer and when the selling price is determinable. As is customary in the pharmaceutical industry, the Company's gross product sales are subject to a variety of deductions in arriving at reported net product sales. These adjustments include estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

For generic and branded products sold in mature markets where the ultimate net selling price to the customer is estimable, the Company recognizes revenues upon shipment to the wholesaler. For new product launches, we recognize revenue once sufficient data is available to determine product acceptance in the marketplace such that product returns and other deductions may be estimated based on historical data and there is evidence of reorders and consideration is made of wholesaler inventory levels. In connection with the third quarter 2016 launch of Akovaz, we determined that sufficient data was available to determine the ultimate net selling price to the customer, and therefore, we began to recognize revenue upon shipment to our wholesaler customers.

Prior to the second quarter 2016, we did not have sufficient historical data to estimate certain revenue deductions. As such, we could not accurately estimate the ultimate net selling price of our Avadel Legacy Pharmaceuticals (formerly Éclat) portfolio of products. As a result, we delayed revenue recognition on these products until the wholesaler sold the product through to its customers.

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

License and Research Revenue

Our license and research revenues consist of fees and milestone payments. Non-refundable fees where we have continuing performance obligations are deferred and are recognized ratably over the projected performance period. We recognize milestone payments, which are typically related to regulatory, commercial or other achievements by us or our licensees and distributors, as revenues when the milestone is accomplished and collection is reasonably assured. For the year ended December 31, 2016, we recognized $3,024 of revenue from license agreements.

Government Grants

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

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

Research and Development

Research and development expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, and other research and development expenses. Clinical studies and outside services costs relate primarily to services performed by clinical research organizations and related clinical or development manufacturing costs, materials and supplies, filing fees, regulatory support, and other third party fees. Personnel expenses relate primarily to salaries, benefits and stock-based compensation. Other research and development expenses primarily include overhead allocations consisting of various support and facilities-related costs. R&D expenditures are charged to operations as incurred.

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

Stock-based Compensation

The Company accounts for stock-based compensation based on grant-date fair value estimated in accordance with ASC 718. The fair value of stock options and warrants is estimated using Black-Scholes option-pricing valuation models (“Black-Scholes model”). As required by the Black-Sholes model, estimates are made of the underlying volatility of AVDL stock, a risk-free rate and an expected term of the option or warrant. We estimated the expected term using a simplified method, as we do not have enough historical exercise data for a majority of such options and warrants upon which to estimate an expected term. The Company recognizes compensation cost, net of an estimated forfeiture rate, using the accelerated method over the requisite service period of the award.

Income Taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, we determine deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

We recognize deferred tax assets to the extent that we believe that these assets are more likely than not to be realized. In making such a determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If we determine that we would be able to realize our deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

We record uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

We recognize interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheet.

Discontinued Operations

The Company followed the guidance in Financial Accounting Standards Board Accounting Standards Codification (ASC) Topic 205 *Presentation of Financial Statements* (ASC 205), Topic 360 *Property, Plant and Equipment* (ASC 360) and Accounting Standards Update (ASU 2014-8), *Reporting of Discontinued Operations and Disclosures of Disposals of Components of an Entity* in determining the accounting for the divestiture of the Company's Pessac, France facility and the related business to Recipharm in December 2014. In 2014, the Company opted to early adopt the provisions of ASU 2014-8 as management believed that all criteria for presenting the disposal of Pessac facility and its business as a discontinued operation were met, and that presenting the disposal as a discontinued operation would better reflect the Company's ongoing operations.

The divestiture of the Pessac facility was part of a strategic shift that had and will have a major effect on the Company's operations and financial results. Prior to the acquisition of the Avadel Legacy Pharmaceutical (formerly Éclat) products in March 2012, the Company's primary focus was to develop and license its proprietary drug delivery platforms (Micropump®, LiquiTime®, Trigger Lock™ and Medusa™) with pharmaceutical companies and biotechnology partners (e.g. the licensing of Micropump® to GSK to develop Coreg CR® with GSK bringing and commercializing the product to market). With the acquisition of the Avadel Legacy Pharmaceutical (formerly Éclat) products, the Company shifted its focus to combining novel, high-value internally developed products with its leading drug delivery platforms -- reducing its reliance on products developed with partners -- and commercializing niche branded and generic pharmaceutical products. The divestiture of the Pessac facility to Recipharm and the transfer to Recipharm of the GSK's Supply Agreement and royalty income relating to Coreg CR ® was an implementation of this strategic shift. Avadel sold over 50% of its historical revenues as a result of the divestiture of the Pessac facility, which has a major impact on the Company's operations and results.

The divestiture of the Pessac facility was accomplished in a single transaction and the assets, contracts and liabilities referred to in the Asset Purchase Agreement signed between Avadel and Recipharm were determined to represent a disposal group. This disposal group was considered to be a component of the Company. While the Pessac facility and its related business were not identified as reportable segment or operating segment, as the Company operates in only one segment, the Pessac facility and its related business is considered to be an asset group as the transferred assets, liabilities and contracts represent the lowest level for which identifiable cash flows are largely independent of the cash flows of other groups of assets and liabilities. The Company transferred all future cash outflows and inflows relating to the Pessac Facility that can be clearly distinguished operationally and for financial reporting purposes.

The results of discontinued operations, less income taxes, have been reported as a separate component of income in the consolidated statements of income (loss). The assets and liabilities of the discontinued operation have been reported separately in the asset and liability sections of the consolidated balance sheets for the periods presented therein. *Note 19: Discontinued Operations* contains a description of the facts and circumstances related to the disposal, the gain and loss on disposal and the specific line items included in the consolidated statements of income (loss), consolidated balance sheets and consolidated statements of cash flows relative to the disposal group.

Cash and Cash Equivalents

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

Marketable Securities

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

Accounts Receivable

Accounts receivable are stated at amounts invoiced net of allowances for doubtful accounts and certain other gross to net deductions. The Company makes judgments as to its ability to collect outstanding receivables and provides allowances for the portion of receivables deemed uncollectible. Provision is made based upon a specific review of all significant outstanding invoices. A majority of accounts receivable is due from three significant customers. See *Note 18: Company Operations by Product, Customer and Geographic Area.*

Inventories

Inventories consist of raw materials and finished products, which are stated at lower of cost or market determined under the first-in, first-out ("FIFO") method. Raw materials used in the production of pre-clinical and clinical products are expensed as R&D costs when consumed. The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow-moving on a case by case basis.

Property and Equipment

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

Laboratory equipment	4-8 years
Office and computer equipment	3 years
Leasehold improvements, furniture, fixtures and fittings	5-10 years

Goodwill

Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. The Company has determined that it operates in a single segment and has a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then, in the second step, the loss is measured as the excess of recorded goodwill over the implied fair value of the goodwill. Implied fair value of goodwill is the excess of the fair value of the reporting unit as a whole over the fair value of all separately identified assets and liabilities within the reporting unit. The Company tests goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. The Company uses projections of future discounted cash flows and takes into account assumptions regarding the evolution of the market and the Company's ability to successfully develop and commercialize its products. Changes in market conditions could have a major impact on the valuation of these assets and could result in potential associated impairment. During the fourth quarter of 2016, we performed our required annual impairment test of goodwill and have determined that no impairment of goodwill existed at December 31, 2016 or 2015.

Long-Lived Assets

Long-lived assets include fixed assets and intangible assets. Intangible assets consist primarily of purchased licenses, in-process R&D and intangible assets recognized as part of the Éclat and FSC acquisitions. Acquired IPR&D has an indefinite life and is not amortized until completion and development of the project, at which time the IPR&D becomes an amortizable asset. Amortization of acquired IPR&D is computed using the straight-line method over the estimated useful life of the assets.

Long-lived assets are reviewed for impairment whenever conditions indicate that the carrying value of the assets may not be fully recoverable. Such impairment tests are based on a comparison of the pretax undiscounted cash flows expected to be generated by the asset to the recorded value of the asset. If impairment is indicated, the asset value is written down to its market value if readily determinable or its estimated fair value based on discounted cash flows. Any significant changes in business or market conditions that vary from current expectations could have an impact on the fair value of these assets and any potential associated impairment. The Company has determined that no indications of impairment existed at December 31, 2016 or 2015.

Acquisition-related Contingent Consideration

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

Financing-related Royalty Agreements

We also entered into two royalty agreements with related parties in connection with certain financing arrangements. We elected the fair value option for the measurement of the financing-related contingent consideration payable associated with the royalty agreements with certain Deerfield and Broadfin entities, both of whom are related parties (see *Note 10: Long-Term Related Party Payable*). The fair value of financing-related royalty agreements is estimated using many of the components used to determine the fair value of the acquisition-related contingent consideration noted above. Changes to these components can also have a material impact on our consolidated statements of income (loss), balance sheets and statements of cash flows. Changes in the fair value of this liability are recorded in the consolidated statements of income (loss) as other expense - changes in fair value of related party payable.

Foreign Currency Translation

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

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, including marketable securities and contingent liabilities at the date of the consolidated financial statements and the reported amounts of sales and expenses during the periods presented. Actual results could differ from those estimates under different assumptions or conditions.

NOTE 2 : Effect of New Accounting Standards

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2017-04, "*Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment."* This update eliminates step 2 from the goodwill impairment test, and requires the goodwill impairment test to be performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. This guidance is effective for the Company in the first quarter of fiscal 2020. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company will assess the timing of adoption and impact of this guidance to future impairment considerations.

In January, 2017, the FASB issued ASU 2017-01, "*Business Combinations (Topic 805): Clarifying the Definition of a Business*." This update provides a screen to determine whether or not a set of assets is a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set of assets is not a business. If the screen is not met, the amendments in this update (1) require that to be considered a business, a set of assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. This guidance is effective for the Company in the first quarter of fiscal 2018. Early adoption is permitted for transactions not previously reported in the Company's consolidated financial statements. The Company will assess the timing of adoption and impact of this guidance on further transactions.

In October 2016, the FASB issued ASU 2016-16, "*Income Taxes (Topic 740), Intra-Entity Transfers of Assets Other Than Inventory*," which requires companies to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. ASU 2016-16 is effective for annual reporting periods, and interim periods therein, beginning after December 15, 2017. The Company is currently in the process of evaluating the impact of ASU 2016-16 on its consolidated financial statements. In 2017, the Company plans to adopt the provisions of ASU 2016-16, related to Intra-Entity Transfers of Assets Other Than Inventory. Adoption of ASU 2016-16 will eliminate the $10,342 income tax deferred charge recorded within the consolidated balance sheet as of December 31, 2016.

In August 2016, the FASB issued ASU 2016-15, *"Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*." ASU 2016-15 identifies how certain cash receipts and cash payments are presented and classified in the Statement of Cash Flows under Topic 230. ASU 2016-15 is effective for the Company for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. ASU 2016-15 should be applied retrospectively and early adoption is permitted, including adoption in an interim period. The Company does not believe this standard will materially impact its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09 "*Revenue from Contracts with Customers"* which supersedes the most current revenue recognition requirements. This ASU requires entities to recognize revenue in a way that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services. Through May 2016, the FASB issued ASU 2016-08 "*Principal versus Agent Considerations (Reporting Revenue Gross versus Net),"* ASU 2016-10 "*Identifying Performance Obligations and Licensing,"* and ASU 2016-12, "*Narrow-Scope Improvements and Practical Expedients,"* which provide supplemental adoption guidance and clarification to ASU 2014-09, respectively. These ASUs will be effective for annual and interim periods beginning after December 15, 2017 with early adoption for annual and interim periods beginning after December 15, 2016 permitted and should be applied retrospectively to each prior reporting period presented or as a cumulative effect adjustment as of the date of adoption. The Company is currently evaluating this pronouncement to determine the impact of its adoption on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, "*Improvements to Employee Share-Based Payment Accounting"* which amends Accounting Standards Codification ("ASC") Topic 718 "*Compensation – Stock Compensation"*. This update simplifies several aspects of accounting for share-based payment awards to employees, including the accounting for income taxes, classification of awards as either equity or liabilities and classification in the statement of cash flows. The standard is effective for annual reporting periods beginning after December 15, 2016. The Company does not believe this standard will materially impact its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, "*Leases*" which supersedes ASC 840 "*Leases*" and creates a new topic, ASC 842 "*Leases*." This update requires lessees to recognize on their balance sheet a lease liability and a lease asset for all leases, including operating leases, with a term greater than 12 months. The update also expands the required quantitative and qualitative disclosures surrounding leases. This update is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years, with earlier application permitted. This update will be applied using a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company is currently evaluating the effect of this update on its consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, *"Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*." The amendments in this update address certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2017, and requires a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. Early adoption is not permitted. The new guidance will require the change in fair value of equity investments with readily determinable fair values to be recognized through the income statements. We are currently evaluating the full impact of the standard; however, upon adoption, the change in the fair value of our available-for-sale equity investments will be recognized in our consolidated statement of income (loss) rather than our consolidated statement of comprehensive income (loss).

In July 2015, the FASB issued ASU 2015-11, "*Simplifying the Measurement of Inventory"* which requires an entity to measure inventory within the scope of this ASU at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The effective date for the standard is for fiscal years beginning after December 15, 2016. The new standard is to be applied prospectively and early adoption is permitted. The Company does not expect ASU 2015-11 to have a material impact on its consolidated financial statements.

NOTE 3 : FAIR VALUE MEASUREMENTS

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

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

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

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

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

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

	As of December 31, 2016			As of December 31, 2015		
Fair Value Measurements:	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Marketable securities (see Note 4)						
Equity securities	$ 4,033	$ —	$ —	$ 3,525	$ —	$ —
Time deposits	—	—	—	—	13,641	—
Corporate bonds	—	57,348	—	—	42,139	—
Government securities - U.S.	—	42,814	—	—	13,738	—
Government securities - Non-U.S.	—	233	—	—	1,063	—
Other fixed-income securities	—	10,471	—	—	3,992	—
Other securities	—	81	—	—	1,640	—
Total assets	$ 4,033	$ 110,947	$ —	$ 3,525	$ 76,213	$ —
Related party payable (see Note 10)	—	—	169,347	—	—	122,693
Total liabilities	$ —	$ —	$ 169,347	$ —	$ —	$ 122,693

A review of fair value hierarchy classifications is conducted on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification for certain financial assets or liabilities. During the fiscal year ended December 31, 2016 and December 31, 2015, there were no transfers in and out of Level 1, 2, or 3. During the twelve months ended December 31, 2016, 2015 and 2014, we did not recognize any other-than-temporary impairment loss.

In 2016, as part of management's review of the consolidated financial statements, we reassessed the fair value level of certain investment grade marketable securities and as a result moved all corporate bonds, government securities, other fixed income securities, and certain other securities from Level 1 to Level 2 assets.

Some of the Company's financial instruments, such as cash and cash equivalents, accounts receivable and accounts payable, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature. Additionally, the Company's long-term debt is reflected in the balance sheet at carrying value, which approximates fair value, as these represent non-interest bearing grants from the French government and are repayable only if the research project is technically or commercially successful.

NOTE 4 : Marketable Securities

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

The following tables show the Company's available-for-sale securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category as of December 31, 2016 and 2015, respectively:

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

	2015			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Equity securities	$ 3,510	$ 29	$ (14)	$ 3,525
Time deposits	13,641	—	—	13,641
Corporate bonds	42,129	1,520	(1,510)	42,139
Government securities - U.S.	13,822	4	(88)	13,738
Government securities - Non-U.S.	1,112	8	(57)	1,063
Other fixed-income securities	4,008	—	(16)	3,992
Other securities	1,663	—	(23)	1,640
Total	$ 79,885	$ 1,561	$ (1,708)	$ 79,738

We determine realized gains or losses on the sale of marketable securities on a specific identification method. We recognized gross realized gains of $1,265, $241, and $24 for the twelve months ended December 31, 2016, 2015, and 2014, respectively. These realized gains were offset by realized losses of $586, $677, and $81 for the twelve-months ended December 31, 2016, 2015, and 2014, respectively. We reflect these gains and losses as a component of investment and other income in the accompanying consolidated statements of income (loss).

The following table summarizes the estimated fair value of our investments in marketable debt securities, accounted for as available-for-sale securities and classified by the contractual maturity date of the securities as of December 31, 2016:

	Maturities				
Marketable Securities:	**Less than 1 Year**	**1-5 Years**	**5-10 Years**	**Greater than 10 Years**	**Total**
Equity securities	$ 4,033	$ —	$ —	$ —	$ 4,033
Corporate bonds	11,933	39,325	5,655	435	57,348
Government securities - U.S.	2,258	33,270	1,530	5,756	42,814
Government securities - Non-U.S.	—	—	233	—	233
Other fixed-income securities	—	8,199	1,996	276	10,471
Other securities	81	—	—	—	81
Total	$ 18,305	$ 80,794	$ 9,414	$ 6,467	$ 114,980

The Company has classified our investment in available-for-sale marketable securities as current assets in the consolidated balance sheets at December 31, 2016 and 2015, respectively, as the securities need to be available for use, if required, to fund current operations. There are no restrictions placed around the sale of any securities in our investment portfolio.

NOTE 5 : Inventory

The principal categories of inventories, net reserves of $3,223 and $806 in 2016 and 2015, respectively, are comprised of the following as of December 31:

Inventory:	**2016**	**2015**
Finished goods	$ 2,429	$ 2,545
Raw materials	829	1,121
Total	$ 3,258	$ 3,666

NOTE 6 : Property and Equipment, net

The principal categories of property and equipment, net at December 31, 2016 and 2015, respectively, are as follows:

Property and Equipment, net:	2016	2015
Laboratory equipment	$ 9,019	$ 9,963
Office and computer equipment	2,519	2,968
Furniture, fixtures and fittings	4,239	4,315
Less - accumulated depreciation	(12,457)	(14,630)
Total	$ 3,320	$ 2,616

Depreciation expense for the years ended December 31, 2016, 2015 and 2014 was $601, $568 and $681, respectively.

NOTE 7 : Acquisitions

On February 5, 2016, the Company completed its acquisition of FSC, previously a Charlotte, North Carolina-based specialty pharmaceutical company dedicated to providing innovative solutions to unmet medical needs for pediatric patients, from Deerfield CSF, LLC, a Deerfield Management company ("Deerfield"), a related party.

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

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

These items are reported in related party payable within the Company's consolidated balance sheet, and is further disclosed in *Note 10: Long-Term Related Party Payable*.

The Company finalized its purchase price allocation as noted in the following table. The fair values assigned to the acquired assets and liabilities have been recognized as follows:

Assigned Fair Value:	2016 Final
Accounts receivable	$ 142
Inventories	1,135
Prepaid expenses and other current assets	1,712
Intangible assets:	
Acquired product marketing rights	16,600
Acquired developed technology	4,300
Deferred tax assets	853
Other assets	277
Accounts payable and other liabilities	(3,827)
Total	$ 21,192

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

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

Had the FSC acquisition been completed as of the beginning of 2015, the Company's unaudited pro forma net sales and net loss for the twelve months ended December 31, 2016 and 2015 would have been as follows:

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

NOTE 8 : Goodwill and Intangible Assets

The Company's amortizable and unamortizable intangible assets at December 31, 2016 and 2015, respectively, are as follows:

	2016			2015		
Goodwill and Intangible Assets:	Gross Value	Accumulated Amortization	Net Book Value	Gross Value	Accumulated Amortization	Net Book Value
Amortizable intangible assets:						
Acquired IPR&D - Bloxiverz	$ 35,248	$ (35,248)	$ —	$ 35,248	$ (23,498)	$ 11,750
Acquired IPR&D - Vazculep	12,061	(8,801)	3,260	12,061	(7,986)	4,075
Acquired product marketing rights	16,600	(1,019)	15,581	—	—	—
Acquired developed technology	4,300	(304)	3,996	—	—	—
Total amortizable intangible assets	$ 68,209	$ (45,372)	$ 22,837	$ 47,309	$ (31,484)	$ 15,825
Unamortizable intangible assets:						
Goodwill	$ 18,491	$ —	$ 18,491	$ 18,491	$ —	$ 18,491
Total unamortizable intangible assets	$ 18,491	$ —	$ 18,491	$ 18,491	$ —	$ 18,491

The Company recorded amortization expense related to amortizable intangible assets of $13,888, $12,564 and $11,749 for the years ended December 31, 2016, 2015 and 2014, respectively.

Amortizable intangible assets are amortized over their estimated useful lives, which range from three to fifteen years, using the straight-line method. Total future amortization of intangible assets for the next five years is as follows:

Estimated Amortization Expense:	Balance
2017	$ 2,258
2018	2,258
2019	2,258
2020	2,258
2021	1,443

NOTE 9 : Long-Term Debt

French government agencies provide financing to French companies for research and development. At December 31, 2016 and 2015, the Company had outstanding loans of $815 and $1,118, respectively for various programs. These loans do not bear interest and are repayable only in the event the research project is technically or commercially successful. Potential repayment is scheduled to occur through 2019.

During the years ended December 31, 2016, 2015 and 2014, the Company repaid $277, $747 and $355, of loans associated with specific research projects, respectively. In addition, during 2015 the Company received waivers of repayment for the remaining portion of certain loans of $1,498 on the basis of limited commercial and technical success. Amounts waived are reported as reductions to R&D expenses in the Company's consolidated statements of income (loss). No such waivers were received during 2016 or 2014.

NOTE 10 : Long-Term Related Party Payable

Long-term related party payable and related activity are reported at fair value and consist of the following at December 31, 2016 and 2015, respectively:

		Activity during the Twelve Months Ended December 31, 2016				
				Changes in Fair Value of Related Party Payable		
	Balance, December 31, 2015	Additions	Payments to Related Parties	Operating Expense	Other Expense	Balance, December 31, 2016
Acquisition-related:						
Warrants - Éclat Pharmaceuticals [(a)]	$ 20,617	$ —	$ —	$ (9,400)	$ —	$ 11,217
Earn-out payments - Éclat Pharmaceuticals [(b)]	90,468	—	(26,700)	57,609	—	121,377
Royalty agreement - FSC [(c)]	—	6,659	(444)	1,076	—	7,291
Financing-related:						—
Royalty agreement - Deerfield [(d)]	7,862	—	(2,501)	—	4,433	9,794
Royalty agreement - Broadfin [(e)]	3,746	—	(1,193)	—	2,115	4,668
Long-term liability - FSC [(f)]	—	15,000	—	—	—	15,000
Total related party payable	122,693	$ 21,659	$ (30,838)	$ 49,285	$ 6,548	169,347
Less: current portion	(25,204)					(34,177)
Total long-term related party payable	$ 97,489					$ 135,170

Each of the above items is associated with related parties as further described in *Note 20: Related Party Transactions.*

(a) As part of the consideration for the Company's acquisition of Éclat Pharmaceuticals, LLC on March 13, 2012, the Company issued two warrants with a six-year term which allow for the purchase of a combined total of 3,300 ordinary shares of Avadel. One warrant is exercisable for 2,200 ordinary shares at an exercise price of $7.44 per share, and the other warrant is exercisable for 1,100 ordinary shares at an exercise price of $11.00 per share.

The fair value of the warrants is estimated on a quarterly basis using a Black-Scholes option pricing model with the following assumptions as of December 31, 2016 and 2015:

Warrant Assumptions:	2016	2015
Weighted average exercise price per share	$ 8.63	$ 8.63
Expected term (years)	1.25	2.25
Expected volatility	54.20%	64.54%
Risk-free interest rate	0.94%	0.93%
Expected dividend yield	—	—

These Black-Scholes fair value measurements are based on significant inputs not observable in the market and thus represent a level 3 measurement as defined in ASC 820. The fair value of the warrant consideration is most sensitive to movement in the Company's share price and expected volatility at the balance sheet date.

Expected term: The expected term of the options or warrants represents the period of time between the grant date and the time the options or warrants are either exercised or forfeited, including an estimate of future forfeitures for outstanding options or warrants. Given the limited historical data and the grant of stock options and warrants to a limited population, the simplified method has been used to calculate the expected life.

Expected volatility: The expected volatility is calculated based on an average of the historical volatility of the Company's stock price for a period approximating the expected term.

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

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

At the closing date of the 2012 Éclat acquisition and at December 31, 2016, it was uncertain as to whether the Company would ultimately fulfill its obligation under these warrants using Company shares or cash. Accordingly, pursuant to the guidance of ASC 480, the Company determined that these warrants should be classified as a long-term liability. This classification as a long-term liability was further supported by the Company's determination, pursuant to the guidance of ASC 815-40-15-7(i), that these warrants could also not be considered as being indexed to the Company's own stock, on the basis that the exercise price for the warrants is determined in U.S. dollars, although the functional currency of the Company at the closing date of the Éclat acquisition was the Euro.

(b) In March 2012, the Company acquired all of the membership interests of Éclat from Breaking Stick Holdings, L.L.C. ("Breaking Stick", formerly Éclat Holdings), an affiliate of Deerfield. Breaking Stick is majority owned by Deerfield, with a minority interest owned by Mr. Michael Anderson, the Company's CEO, and certain other current and former employees. As part of the consideration, the Company committed to provide quarterly earn-out payments equal to 20% of any gross profit generated by certain Éclat products. These payments will continue in perpetuity, to the extent gross profit of the related products also continue in perpetuity.

(c) In February 2016, the Company acquired all of the membership interests of FSC from Deerfield. The consideration for this transaction in part included a commitment to pay quarterly a 15% royalty on the net sales of certain FSC products, up to $12,500 for a period not exceeding ten years.

(d) As part of a February 2013 debt financing transaction conducted with Deerfield, the Company received cash of $2,600 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 1.75% royalty on the net sales of certain Éclat products until December 31, 2024.

(e) As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund, a related party and current shareholder, the Company received cash of $2,200 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 0.834% royalty on the net sales of certain Éclat products until December 31, 2024.

(f) In February 2016, the Company acquired all of the membership interests of FSC from Deerfield. The consideration for this transaction in part consists of payments totaling $1,050 annually for five years with a final payment in January 2021 of $15,000. Substantially all of FSC's, and its subsidiaries, assets are pledged as collateral under this agreement.

At December 31, 2016, the fair value of each related party payable listed in (b) through (e) above was estimated using a discounted cash flow model based on probability-adjusted annual net revenues or gross profit, as appropriate, of each of the specified Éclat and FSC products using an appropriate risk-adjusted discount rate ranging from 15% to 22%. These fair value measurements are based on significant inputs not observable in the market and thus represent a level 3 measurement as defined in ASC 820. Subsequent

changes in the fair value of the acquisition-related related party payables, resulting primarily from management's revision of key assumptions, will be recorded in the Consolidated Statements of Income (Loss) in the line items entitled *"Changes in fair value of related party contingent consideration"* for items noted in (b) and (c) above and in *"Other expense - changes in fair value of related party payable"* for items (d) and (e) above. See *Note 1: Summary of Significant Accounting Policies* under the caption Acquisition-related Contingent Consideration and Financing-related Royalty Agreements for more information on key assumptions used to determine the fair value of these liabilities.

The Company has chosen to make a fair value election pursuant to ASC 825, "*Financial Instruments*" for its royalty agreements detailed in items (d) and (e) above. These financing-related liabilities are recorded at fair market value on the consolidated balance sheets and the periodic change in fair market value is recorded as a component of "Other expense – change in fair value of related party payable" on the consolidated statements of income (loss).

The following table summarizes changes to the related party payables, a recurring Level 3 measurement, for the twelve-month periods ended December 31, 2016, 2015 and 2014:

Related Party Payable:	**Balance**
Balance at December 31, 2013	65,670
Payment of related party payable	(11,936)
Fair value adjustments [(1)]	61,016
Balance at December 31, 2014	114,750
Payment of related party payable	(27,897)
Fair value adjustments [(1)]	35,840
Balance at December 31, 2015	122,693
Additions [(2)]	21,659
Payment of related party payable	(30,838)
Fair value adjustments [(1)]	55,833
Balance at December 31, 2016	169,347

[(1)] Fair value adjustments are reported as Changes in fair value of related party contingent consideration and Other expense - changes in fair value of related party payable in the Consolidated Statements of Income (Loss).

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

NOTE 11 : Income Taxes

In 2016, we changed our jurisdiction of incorporation from France to Ireland by merging with and into our wholly owned Irish subsidiary. Information about the reincorporation was included in the definitive proxy statement filed with the Securities and Exchange Commission on July 5, 2016. Accordingly, beginning in 2016, the Company reports the Irish tax jurisdiction as its Domestic jurisdiction. For periods prior to 2016, the French tax jurisdiction was the Domestic jurisdiction.

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

Income (Loss) Before Income Taxes:	**2016**	**2015**	**2014**
Ireland	$ (22,866)	$ (29,469)	$ —
United States	32,786	100,552	(89,739)
France	(19,638)	6,622	(392)
Total income (loss) before income taxes	$ (9,718)	$ 77,705	$ (90,131)

The income tax provision (benefit) for the years ended December 31, is as follows:

Income Tax Provision (Benefit):	2016	2015	2014
Current:			
United States - Federal	$ 30,738	$ 33,289	$ —
United States - State	1,081	970	—
France	5,267	1,657	1,400
Total current	37,086	35,916	1,400
Deferred:			
United States - Federal	(6,443)	504	(1,713)
United States - State	(23)	1,234	(331)
France	938	(1,747)	—
Total deferred	(5,528)	(9)	(2,044)
Income tax provision (benefit)	$ 31,558	$ 35,907	$ (644)

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

Reconciliation to Effective Income Tax Rate:	2016	2015	2014
Statutory tax rate [1]	12.5 %	33.3 %	33.3 %
Non-deductible changes in fair value of contingent consideration	(165.0)%	11.9 %	(24.8)%
Change in valuation allowance	11.8 %	(9.6)%	5.3 %
Income tax deferred charge	(9.7)%	1.3 %	(16.9)%
International tax rates differential	(31.9)%	11.0 %	6.7 %
Nondeductible stock based compensation	(14.8)%	1.3 %	(0.8)%
Cross-border merger	(100.6)%	— %	— %
Unrecognized tax benefit	(15.2)%	0.4 %	— %
State and local taxes (net of federal)	(9.6)%	1.5 %	0.3 %
Other	(2.3)%	(4.9)%	(2.3)%
Effective income tax rate	(324.8)%	46.2 %	0.8 %

Income tax provision (benefit) - at statutory tax rate	$ (1,215)	$ 25,876	$ (30,013)
Non-deductible changes in fair value of contingent consideration	16,036	9,249	22,326
Change in valuation allowance	(1,143)	(7,425)	(4,732)
Income tax deferred charge	938	980	15,273
International tax rates differential	3,097	8,547	(6,023)
Nondeductible stock based compensation	1,436	1,004	693
Cross-border merger	9,773	—	—
Unrecognized tax benefit	1,475	290	—
State and local taxes (net of federal)	934	1,170	(228)
Other	227	(3,784)	2,060
Income tax provision (benefit) - at effective income tax rate	$ 31,558	$ 35,907	$ (644)

[1] The statutory rate reflects the Irish statutory tax rate of 12.5% for fiscal 2016, and the French statutory tax rate of 33.3% for fiscal 2015 and 2014.

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

In 2015, the income tax provision increased by $36,551 when compared to the same period in 2014. The primary reason for the large increase in the income tax provision was a substantial increase in the level of pre-tax book income in the United States and France. Decreases in the amount of nondeductible expenses due to changes in the fair value of contingent consideration and an increase in the benefit from the release of valuation allowances partially offset the income tax provision from the increased amount of pre-tax book income in 2015, when compared to 2014. In 2014, the Company recorded $15,273 of income tax provision related to the transfer of intellectual property from France to Ireland, which did not reoccur in 2015.

Unrecognized Tax Benefits

The Company or one of its subsidiaries files income tax returns in Ireland, France, United States and various states. With few exceptions, the Company is no longer subject to Irish, French, US Federal, and state and local examinations for years before 2012. The Internal Revenue Service (IRS) commenced an examination of the Company's US income tax return for 2015 in the 4th quarter of 2016 that is anticipated to be completed by the end of 2017.

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

Unrecognized Tax Benefit Activity	2016	2015	2014
Balance at January 1:	$ 448	$ —	$ —
Additions based on tax positions related to the current year	1,578	448	—
Additions (reductions) for tax positions of prior years	(340)	—	—
Statute of limitations expiration	—	—	—
Settlements	—	—	—
Balance at December 31:	$ 1,686	$ 448	$ —

It is reasonably possible that within the next twelve months, as a result of activities performed in various jurisdictions, that the unrecognized tax benefits could change by up to $250. Interest and penalties could change by up to $50.

At December 31, 2016, 2015, and 2014, there are $1,565, $291, and $0 of unrecognized tax benefits that if recognized would affect the annual effective tax rate.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2016, 2015, and 2014, the Company recognized approximately $26, $0, and $0 in interest and penalties. The Company had approximately $27, and $0 for the payment of interest and penalties accrued at December 31, 2016, and 2015 respectively.

Deferred Tax Assets (Liabilities)

Deferred income tax provisions reflect the effect of temporary differences between consolidated financial statement and tax reporting of income and expense items. The net deferred tax assets/liabilities at December 31, 2016 and 2015 resulted from the following temporary differences:

Net Deferred Tax Assets and Liabilities:	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	$ 11,566	$ 44,587
Stock based compensation	5,012	1,767
Fair value royalty agreements	3,386	2,435
Fair value contingent consideration	2,152	1,348
Other	583	1,037
Total deferred tax assets	22,699	51,174
Valuation allowances	(7,599)	(45,516)
Net deferred tax assets	15,100	5,658
Deferred tax liabilities:		
Amortization	(4,349)	(5,649)
Accounts receivable	(3,319)	—
Total deferred tax liabilities	(7,668)	(5,649)
Net deferred tax assets	$ 7,432	$ 9

At December 31, 2016, the Company had $45,907 of net operating losses in Ireland that do not have an expiration date and $14,920 of net operating losses in the United States that expire 2033 through 2035. The US net operating losses were acquired as part of the acquisition of FSC. A valuation allowance is recorded if, based on the weight of available evidence, it is more likely than not that a deferred tax asset will not be realized. This assessment is based on an evaluation of the level of historical taxable income and projections for future taxable income. For the year ended December 31, 2016, the Company recorded $5,738 of valuation allowances related to Irish net operating losses and $1,272 of valuation allowance on U.S. net operating losses. The U.S. net operating losses are subject to an annual limitation as a result of the acquisition of FSC under internal revenue code section 382 and will not be fully utilized before they expire. In 2016, the Company removed all French net operating losses and the corresponding valuation allowances from the inventory of deferred tax assets as a result of the cross-border merger. For the year ended December

31, 2015, the Company recorded $40,959 and $3,628 of valuation allowances related to French and Irish net operating losses, respectively. The Company believes that it will generate sufficient future taxable income to realize the tax benefits related to the remaining net deferred tax assets.

We recorded a valuation allowance against all of our net operating losses in Ireland as of both December 31, 2016, and December 31, 2015. We intend to continue maintaining a full valuation allowance on the Irish net operating losses until there is sufficient evidence to support the reversal of all or some portion of these allowances. However, given our anticipated future earnings, we believe that there is a reasonable possibility that within the next 12 months, sufficient positive evidence may become available to allow us to reach a conclusion that a significant portion of the valuation allowance on the Irish net operating losses will no longer be needed. Release of the valuation allowance would result in the recognition of deferred tax assets and a decrease to income tax expense for the period the release is recorded. However, the exact timing and amount of the valuation allowance release are subject to change on the basis of the level of profitability that we are able to actually achieve.

At December 31, 2016, the Company has no unremitted earnings outside of Ireland as measured on a US GAAP basis. Whereas the measure of earnings for purposes of taxation of a distribution may differ for tax purposes, these earnings, which are considered to be invested indefinitely, would become subject to income tax if they were remitted as dividends or if the Company were to sell its stock in the subsidiaries. It is not practicable to estimate the amount of deferred tax liability on such earnings, if any.

Research and Development Tax Credits Receivable

The French government provides tax credits to companies for spending on innovative R&D. These credits are recorded as an offset of R&D expenses and are credited against income taxes payable in each of the four years after being incurred or, if not so utilized, are recoverable in cash. As of December 31, 2016, the Company's net Research tax credit receivable amounts to $1,775 and represents a gross research tax credit of $3,376, partially offset by current income tax payable of $1,601. The Company utilized $4,001 of research tax credits in 2016 to offset the tax cost of the cross-border merger. As of December 31, 2015, the Company's net Research tax credit receivable amounts to $2,382 and represents a gross research tax credit of $3,720, partially offset by current income tax payable of $1,338.

Income Tax Deferred Charge

On December 16, 2014, the Company transferred all of its intangible intellectual property from its French entity to its Irish entity as a part of a global reorganization. The intellectual property includes patents on drug delivery platforms, clinical data sets and other intangible assets related to the pipeline of proprietary products in development. This intra-entity transaction resulted in a charge of $14,088 of related taxes to the French government in December 2014. As this represents an intra-entity transaction, no deferred tax asset has been recognized, but rather was originally recorded as $986 of prepaid expenses and $13,102 of a long-term Income tax deferred charge asset in accordance with ASC 740-10-25-3 (e). This income tax deferred charge asset is amortized over the tax life of the asset at a rate of 7% per year and will result in tax relief in Ireland of $8,500 from 2016 to 2029, subject to the ability to realize tax benefits for additional deductions. At December 31, 2016, the balance of these respective accounts was classified as prepaid expenses of $814 and Income tax deferred charge asset of $10,342. At December 31, 2015, the balance of these respective accounts was classified as prepaid expenses of $842 and Income tax deferred charge asset of $11,581. In 2017, the Company plans to adopt the provisions of ASU 2016-16, related to Intra-Entity Transfers of Assets Other Than Inventory. Adoption of ASU 2016-16 will eliminate the $11,156 income tax deferred charge recorded within the consolidated balance sheet as of December 31, 2016.

Cross-Border Merger

In 2016, we changed our jurisdiction of incorporation from France to Ireland by merging with and into our wholly owned Irish subsidiary. Information about the reincorporation was included in the definitive proxy statement filed with the Securities and Exchange Commission on July 5, 2016. Prior to the Merger, the Company submitted a request to the French tax authority seeking to benefit from a special regime for mergers and demergers, conditional upon a formal consent of the French tax authority which would allow for the deferral of a portion of the tax cost of the cross-border merger. However, to date the Company has not received, nor does it expect to receive consent resulting in the taxation of deferred profits and built in gains of the Company upon completion of the cross-border merger. The completion of the cross-border merger resulted in the recognition of a net income tax provision of $4,001, after considering tax benefits from the utilization of current and prior year French net operating losses. The Company was able to utilize $4,001 of French research and development tax credits to offset the remaining cost of the transaction. The Company also removed $111,495 of French net operating losses as the carryforward of the losses was contingent on receiving favorable consent from the French tax authority. The French net operating losses had a full valuation allowance resulting in no impact to the income tax provision.

On March 8, 2017, the European Court of Justice issued a ruling on case C-14/16, related to the treatment of cross-border mergers amongst entities that operate within Member States of the EU. Based on our initial assessment of the ruling, the Company may

not have been required to apply for an advanced ruling from the French Tax Authority in order to defer a portion of the tax cost of the cross-border merger. The impact of this ruling could potentially generate an income tax benefit in 2017 of $3,848 by restoring $2,582 of French research and development tax credits and releasing $1,266 of unrecognized tax benefits originally recognized as part of the cross-border merger. The Company is in the process of assessing the administrative and legal options to potentially secure recovery of these benefits.

NOTE 12 : Post-Retirement Benefit Plans

Post-Retirement Benefit Contributions to French Government Agencies

The Company is required by French law to deduct specific monthly payroll amounts to support post-retirement benefit programs sponsored by the relevant government agencies in France. As the ultimate obligation is maintained by the French government agencies, there is no additional liability recorded by the Company in connection with these plans. Expenses recognized for these plans were $348 in 2016, $573 in 2015, and $719 in 2014.

Retirement Indemnity Obligation – France

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

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

Retirement Benefit Obligation Assumptions:	2016	2015	2014
Compensation rate increase	3.00%	3.00%	3.00%
Discount rate	1.31%	2.03%	1.49%
Employee turn-over	Actuarial standard and average of the last 5 years		
Average age of retirement	60 to 65 years actuarial standard based on age and professional status		

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

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

Retirement Benefit Obligation Activity:	2016	2015
Retirement indemnity benefit obligation, beginning of year	$ 2,170	$ 2,350
Service cost	123	117
Interest cost	29	20
Benefits paid	—	(46)
Actuarial loss (gain)	203	(27)
Exchange rate changes	(94)	(244)
Retirement indemnity benefit obligation, end of year	$ 2,431	$ 2,170

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

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

Future Retirement Indemnity Benefit Obligation:	Balance
2017	$ —
2018	—
2019	11
2020	—
2021	—
Next five years	1,061
Total	1,072

NOTE 13 : Other Assets and Liabilities

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

Prepaid Expenses and Other Current Assets:	2016	2015
Valued-added tax recoverable	$ 736	$ 1,099
Prepaid expenses	3,442	2,921
Advance to suppliers and other current assets	1,265	518
Income tax receivable	451	3,526
Total	$ 5,894	$ 8,064

Other Non-Current Assets:	2016	2015
Deferred tax assets	$ 7,432	$ 9
Other	99	158
Total	$ 7,531	$ 167

Accrued Expenses	2016	2015
Accrued compensation	$ 3,291	$ 1,888
Accrued social charges	794	1,710
Customer allowances	7,981	5,710
Accrued contract research organization	1,764	—
Other	3,392	—
Total	$ 17,222	$ 9,308

Other Non-Current Liabilities	2016	2015
Provision for retirement indemnity	$ 2,431	$ 2,170
Customer allowances	905	—
Unrecognized tax benefits	1,565	291
Other	374	65
Total	$ 5,275	$ 2,526

NOTE 14: Contingent Liabilities and Commitments

Litigation

The Company is subject to potential liabilities generally incidental to its business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At December 31, 2016 and 2015, there were no contingent liabilities with respect to any threat of litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Company's consolidated balance sheet, results of operations, cash flows or liquidity.

Material Commitments

The Company has commitments to purchase services from Recipharm Pessac for a total of $22,500 for a five-year period commencing January 1, 2015 (disclosed in *Note 19: Discontinued Operations*).

The Company has a commitment to purchase finished product from a contract manufacturer for a total of $7,238 during the one-year period commencing January 1, 2017.

The Company has a commitment to purchase finished product from a contract manufacturer for a twenty-year period commencing August 1, 2015 and ending July 31, 2035. The commitment for any individual year is contractually waived if the Company's net customer sales for that product exceed certain amounts in that same year. Maximum commitments for this arrangement, at 2016 pricing levels and excluding any waived commitments, are as follows for the years ended December 31:

Purchase Commitment:	**Balance**
2017	$ 778
2018	1,032
2019	1,126
2020	1,126
2021	1,126
Thereafter	15,295
Total	$ 20,483

The Company and its subsidiaries lease office facilities under noncancelable operating leases expiring at various dates. Rent expense, net of rental income, was $970, $752 and $844 in 2016, 2015, and 2014, respectively. Minimum rental commitments for non-cancelable leases in effect at December 31, 2016 are as follows:

Lease Commitment:	**Balance**
2017	$ 1,117
2018	783
2019	717
2020	699
2021	441
Thereafter	600
Total	$ 4,357

Other than the above commitments, there were no other material commitments outside of the normal course of business. Material commitments in the normal course of business include long-term debt, long-term related party payable, and post-retirement benefit plan obligations which are disclosed in *Note 9: Long-Term Debt, Note 10: Long-Term Related Party Payable,* and *Note 12: Post-Retirement Benefit Plans*, respectively.

The following table presents contractual obligations of the Company at December 31, 2016:

Contractual Obligations:	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
Long-term debt	$ 815	$ 268	$ 547	$ —	$ —
Long-term related party payable (undiscounted)	278,236	35,226	57,466	60,587	124,957
Purchase commitments	41,721	12,266	11,908	2,252	15,295
Operating leases	4,982	1,390	1,837	1,155	600
Total contractual cash obligations	$ 325,754	$ 49,150	$ 71,758	$ 63,994	$ 140,852

NOTE 15 : Equity Instruments and Stock Based Compensation

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

Stock-based Compensation Expense:	2016	2015	2014
Cost of products and services sold	$ —	$ —	$ 38
Research and development	3,523	1,587	1,027
Selling, general and administrative	11,156	6,154	1,829
Total stock-based compensation expense	$ 14,679	$ 7,741	$ 2,894

As of December 31, 2016, the Company expects $12,874 of unrecognized expense related to granted, but non-vested stock-based compensation arrangements to be incurred in future periods. This expense is expected to be recognized over a weighted average period of 3.2 years.

The excess tax benefit related to stock-based compensation recorded by the Company was $65 and $1,767, for the years ended December 31, 2016 and 2015. There was no similar amount for the year ended December 31, 2014.

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

Capital Stock

We have 500,000 shares of authorized ordinary shares with a nominal value of $0.01 per common share. As of December 31, 2016, we had 41,371 shares of ordinary shares issued and outstanding. The Board of Directors is authorized to issue preferred stock in series, and with respect to each series, to fix its designation, relative rights (including voting, dividend, conversion, sinking fund, and redemption rights), preferences (including dividends and liquidation) and limitations. We have 50,000 shares of authorized preferred stock, $0.01 nominal value, none of which is currently outstanding.

Determining the Fair Value of Stock Options and Warrants

The Company measures the total fair value of stock options and warrants on the grant date using the Black-Scholes option-pricing model and recognizes each grant's fair value as compensation expense over the period that the option or warrant vests. Options are granted to employees of the Company and generally become exercisable within four years following the grant date and expire ten years after the grant date. Warrants are typically issued to the Company's Board of Directors as compensation for services rendered and generally become exercisable within one year following the grant date, and expire four years after the grant date.

The weighted-average assumptions under the Black-Scholes option-pricing model for stock option and warrant grants as of December 31, 2016, 2015 and 2014, are as follows:

Stock Option and Warrant Assumptions:	2016	2015	2014
Stock option grants:			
Expected term (years)	6.25	6.25	6.25
Expected volatility	58.39%	58.59%	59.00%
Risk-free interest rate	2.04%	1.89%	1.79%
Expected dividend yield	—	—	—
Warrant grants:			
Expected term (years)	2.50	2.50	2.50
Expected volatility	60.57%	55.00%	58.00%
Risk-free interest rate	0.82%	0.89%	0.75%
Expected dividend yield	—	—	—

Expected term: The expected term of the options or warrants represents the period of time between the grant date and the time the options or warrants are either exercised or forfeited, including an estimate of future forfeitures for outstanding options or warrants. Given the limited historical data and the grant of stock options and warrants to a limited population, the simplified method has been used to calculate the expected life.

Expected volatility: The expected volatility is calculated based on an average of the historical volatility of the Company's stock price for a period approximating the expected term.

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

Expected dividend yield: The expected dividend yield is based on the Company's authorized periodic dividend and the Company's expectation for dividend yields over the expected term. The Company has not distributed any dividends since its inception, and has no plan to distribute dividends in the foreseeable future.

Stock Options

A summary of the combined stock option activity and other data for the Company's stock option plans for the year ended December 31, 2016 is as follows:

Stock Option Activity and Other Data:	Number of Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Stock options outstanding, January 1, 2016	2,326	$ 13.84		
Granted	1,505	10.68		
Exercised	(15)	6.50		
Forfeited	(6)	14.35		
Expired	(78)	31.70		
Stock options outstanding, December 31, 2016	3,732	$ 12.07	8.48 years	$ 3,681
Stock options exercisable, December 31, 2016	1,161	$ 10.49	6.76 years	$ 3,035

The aggregate intrinsic value of options exercised during the years ended December 31, 2016, 2015 and 2014 was $58, $10,063, and $3,789, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2016, 2015 and 2014 was $6.14, $9.38 and $9.19 per share, respectively.

At December 31, 2016, there were 94 shares authorized for stock option grants in subsequent periods.

Warrants

A summary of the combined warrant activity and other data for the year ended December 31, 2016 is as follows:

Warrant Activity and Other Data:	Number of Warrants	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Warrants outstanding, January 1, 2016	668	$ 16.97		
Granted	291	13.59		
Exercised	—	—		
Forfeited	—	—		
Expired	—	—		
Warrants outstanding, December 31, 2016	959	$ 16.05	2.47 years	$ 276
Warrants exercisable, December 31, 2016	668	$ 17.12	1.97 years	$ 276

Each of the above warrants is convertible into one ordinary share. The aggregate intrinsic value of warrants exercised during the years ended December 31, 2016, 2015 and 2014 was $0, $2,698 and $3,107, respectively.

The weighted average grant date fair value of warrants granted during the years ended December 31, 2016, 2015 and 2014 was $2.99, $5.92 and $3.90 per share, respectively.

At December 31, 2016, an additional 3,300 warrants were outstanding and exercisable relative to consideration paid for the Company's acquisition of Éclat Pharmaceuticals, LLC on March 13, 2012. These warrants are not considered stock-based compensation and are therefore excluded from the above tables, and instead are addressed within *Note 10: Long-Term Related Party Payable*.

At December 31, 2016, there were 59 shares authorized for warrant grants in subsequent periods.

Free Share Awards

Free share awards represent Company shares issued free of charge to employees of the Company as compensation for services rendered. The Company measures the total fair value of free share awards on the grant date using the Company's stock price at the time of the grant. Free share awards granted prior to 2016 generally cliff vest at the end of a four-year vesting period, and are expensed over a two or four-year service period. Free share awards granted during 2016 were fully expensed at the date of grant as they contain no service requirement. Employees, however, are not free to trade these awards until the end of a two-year holding period.

A summary of the Company's free share awards as of December 31, 2016, and changes during the year then ended, is reflected in the table below.

Free Share Activity and Other Data:	Number of Free Share Awards	Weighted Average Grant Date Fair Value
Non-vested free share awards outstanding, January 1, 2016	226	$ 13.95
Granted	463	12.11
Vested	(115)	13.44
Forfeited	(1)	16.27
Non-vested free shares awards outstanding, December 31, 2016	573	$ 12.57

The weighted average grant date fair value of free share awards granted during the years ended December 31, 2016 and 2014 was $12.11 and $16.30, respectively. There were no free share awards granted in 2015.

At December 31, 2016, there were 290 shares authorized for free share award grants in subsequent periods.

NOTE 16 : Earnings (Loss) Per Share

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

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

Basic and Diluted Earnings (Loss) Per Share:	2016	2015	2014
Net income (loss)			
Net income (loss) from continuing operations	$ (41,276)	$ 41,798	$ (89,487)
Net income (loss) from discontinued operations	—	—	4,018
Net income (loss)	$ (41,276)	$ 41,798	$ (85,469)
Weighted average shares:			
Basic shares	41,248	40,580	36,214
Effect of dilutive securities—options and warrants outstanding	—	3,039	—
Diluted shares	41,248	43,619	36,214
Earnings (loss) per share - basic:			
Continuing operations	$ (1.00)	$ 1.03	$ (2.47)
Discontinued operations	—	—	0.11
Net income (loss) per share - basic	$ (1.00)	$ 1.03	$ (2.36)
Earnings (loss) per share - diluted:			
Continuing operations	$ (1.00)	$ 0.96	$ (2.47)
Discontinued operations	—	—	0.11
Net income (loss) per share - diluted	$ (1.00)	$ 0.96	$ (2.36)

Potential common shares of 8,564, 635, and 6,753 were excluded from the calculation of weighted average shares for the years ended December 31, 2016, 2015 and 2014, because their effect was considered to be anti-dilutive. For the years ended December 31, 2016 and 2014, the effects of dilutive securities were entirely excluded from the calculation of earnings per share as a net loss was reported in these periods.

NOTE 17 : Comprehensive Income (Loss)

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

Accumulated Other Comprehensive Income (Loss):	2016	2015	2014
Foreign currency translation adjustment:			
Beginning balance	$ (22,312)	$ (7,225)	$ 10,815
Net other comprehensive (loss) income	(1,024)	(15,087)	(18,040)
Balance at December 31,	(23,336)	(22,312)	(7,225)
Unrealized gain (loss) on marketable securities, net			
Beginning balance	(345)	(198)	—
Net other comprehensive (loss) income, net of $16, ($20), ($0), tax, respectively	116	(147)	(198)
Balance at December 31,	(229)	(345)	(198)
Accumulated other comprehensive loss at December 31,	$ (23,565)	$ (22,657)	$ (7,423)

NOTE 18 : Company Operations by Product, Customer and Geographic Area

The Company has determined that it operates in one segment, the development and commercialization of pharmaceutical products, including controlled-release therapeutic products based on its proprietary drug delivery technologies. The Company's Chief Operating Decision Maker is the CEO. The CEO and the Company's Board of Directors review profit and loss information on a consolidated basis to assess performance and make overall operating decisions as well as resource allocations.

The following table presents a summary of total revenues by these products for the twelve months ended December 31, 2016, 2015, and 2014:

Revenue by Product:	**2016**	**2015**	**2014**
Bloxiverz	$ 82,896	$ 150,083	$ 10,411
Vazculep	39,796	20,151	—
Akovaz	16,831	—	—
Other	7,699	2,054	1,782
Total product sales and services	147,222	172,288	12,193
License and research revenue	3,024	721	2,782
Total revenues	$ 150,246	$ 173,009	$ 14,975

Concentration of credit risk with respect to accounts receivable is limited due to the high credit quality comprising the payer base. Management periodically monitors the creditworthiness of its customers and believes that it has adequately provided for any exposure to potential credit loss.

The following table presents a summary of total revenues by significant customer for the twelve months ended December 31, 2016, 2015, and 2014:

Revenue by Significant Customer:	**2016**	**2015**	**2014**
Customer A	$ 51,648	$ 53,988	$ 3,937
Customer B	39,359	60,420	3,859
Customer C	30,916	43,434	3,563
Customer D	17,728	—	—
Other	7,571	14,446	834
Total product sales and services	147,222	172,288	12,193
License and research revenue	3,024	721	2,782
Total revenues	$ 150,246	$ 173,009	$ 14,975

As of December 31, 2016, the Company had three customers each of which accounted for 10% or more of the accounts receivable balance. One customer accounted for 42%, or $7,472, a second customer accounted for 24% or $4,307, and a third customer accounted for 24% or $4,291. As of December 31, 2016, the Company had no significant past due account receivable balances.

The following table summarizes revenues by geographic region for the twelve months ended December 31, 2016, 2015, and 2014:

Revenue by Geographic Region:	**2016**	**2015**	**2014**
United States	$ 147,283	$ 172,179	$ 14,502
France	—	89	473
Ireland	2,963	741	—
Total	$ 150,246	$ 173,009	$ 14,975

Currently we depend on a single contract manufacturing organization for the manufacture of Bloxiverz, Vazculep and Akovaz, and to deliver certain raw materials used in their production, from which we derive a majority of our revenues. Additionally, we purchase certain raw materials used in our products from a limited number of suppliers, including a single supplier for certain key ingredients.

Non-monetary long-lived assets primarily consist of property and equipment, goodwill and intangible assets. The following table summarizes non-monetary long-lived assets by geographic region as of December 31, 2016, 2015, and 2014:

Long-lived Assets by Geographic Region:	2016	2015	2014
United States	$ 42,021	$ 34,515	$ 47,077
France	2,524	2,317	1,704
Ireland	202	258	—
Total	$ 44,747	$ 37,090	$ 48,781

NOTE 19 : Discontinued Operations

On December 1, 2014, the Company signed an Asset Purchase Agreement with Recipharm AB ("Recipharm") to divest its development and manufacturing facility and associated business located in Pessac, France. The assets included in the divestiture were tangible equipment, furniture and fixtures, inventories and all intellectual property rights relating to the operation and technological know-how necessary in manufacturing the products that are produced in the facility, as well as the assignment to Recipharm of all employees, customer contracts and liabilities which primarily relate to agreements of the Company with GlaxoSmithKline ("GSK") for the manufacture and sale of Coreg CR®, which was Avadel's lead product at the time, using its Micropump drug delivery platform and manufactured in the Pessac Facility.

The aggregate consideration received for the divested assets and business was $13,200, plus the value of divested inventory as determined using inventory valuation methodology as defined by the two parties. All cash and receivables pertaining to the Pessac Facility business prior to the sale were retained by the Company. A contribution of $700 was made by the Company to finance potential future retirement indemnities payable on transferred employees. The business was accounted for as a discontinued operation in the fourth quarter of 2014 and, therefore, the operating results of our Pessac Facility business were included in Discontinued Operations in the Company's consolidated financial statements for all applicable years presented. The Company recognized a $5,007 gain on disposal, which was included in our income from Discontinued Operations, in fiscal year 2014. Concurrently with the above, Recipharm made an investment of $13,000 in newly issued Avadel (formerly Flamel) shares, the purchase price of which was based on the average of the trailing 20 days' trading prices of the Company's shares prior to the closing date.

In connection with the Asset Purchase Agreement, the Company also entered into a number of other agreements with Recipharm:

Master Agreement on Supply and Services of Products ("MSA")

Recipharm will provide various services in the domain of R&D and manufacture of pharmaceutical products for an initial non-cancellable period of five years.

Over the initial term, any services to be provided shall include internal and external costs incurred by Recipharm plus 20%, which has been determined to be the fair value for such services. The minimum amount of services per year, for a cumulative total of $22,500 as follows:

Annual Service Minimum:	Amount
Year 1	$ 4,250
Year 2	4,250
Year 3	4,250
Year 4	4,875
Year 5	4,875
Total	$ 22,500

During the year ended December 31, 2016 and December 31, 2015, the Company recorded $4,541 and $4,089 of research and development expenses, and cash outflows of $939 and $5,679, related to this commitment to Recipharm.

Option Agreement

Recipharm has a first option (right of first refusal) to discuss and negotiate licenses of the Company's intellectual property rights for the sale of certain products in Europe. Upon exercise of the option, Recipharm and the Company shall agree in good faith on terms and conditions of the related license agreement within forty-five (45) days from the exercise of the option. The term of the

Option Agreement is from the signing of the agreement through December 31, 2017. The Company received no compensation related to the option agreement.

Summary results of operations for the divested Pessac business were as follows for the years ended December 31:

Net Income from Discontinued Operations:	2016	2015	2014
Revenues	$ —	$ —	$ 14,967
Operating income (loss)	—	—	(875)
Gain on disposal	—	—	5,007
Interest expense	—	—	(4)
Income tax provision	—	—	(110)
Net income from discontinued operations	$ —	$ —	$ 4,018

The major cash flows related to Discontinued Operations as included in the consolidated statements of cash flows are as follows for the years ended December 31:

Cash Flow Related to Discontinued Operation:	2016	2015	2014
Capital expenditures	$ —	$ —	$ 1,271
Depreciation and amortization	—	—	1,709
Operating and investing non-cash elements	—	—	(740)

NOTE 20 : Related Party Transactions

In March 2012, the Company acquired all of the membership interests of Éclat from Breaking Stick Holdings, L.L.C. (“Breaking Stick”, formerly Éclat Holdings), an affiliate of Deerfield Capital L.P (“Deerfield”), a significant shareholder of the Company. As of December 31, 2016 and 2015, the remaining consideration obligations for this transaction consisted of two warrants to purchase a total of 3,300 shares of Avadel and commitments to make earnout payments to Breaking Stick of 20% of any gross profit generated by certain Éclat products (the “Products”). Breaking Stick is majority owned by Deerfield, with a minority interest owned by Mr. Michael Anderson, the Company’s CEO, and certain other current and former employees. The original consideration for the acquisition of Éclat also included a $12 million senior note payable to the majority owners of Breaking Stick, which was fully repaid in March 2014 using the net proceeds from the Company’s public offering of ADS’s.

As part of a February 2013 debt financing transaction conducted with Deerfield Management, Éclat entered into a Royalty Agreement with Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P., both affiliates of the Deerfield Entities (together, “Deerfield PDF/Horizon”). The Royalty Agreement provides for Éclat to pay Deerfield PDF/Horizon 1.75% of the net sales of the Products sold by the Company and any of its affiliates until December 31, 2024, with royalty payments accruing daily and paid in arrears for each calendar quarter during the term of the Royalty Agreement. The Company has also entered into a Security Agreement dated February 4, 2013 with Deerfield PDF/Horizon, whereby Deerfield PDF/Horizon was granted a security interest in the intellectual property and regulatory rights related to the Products to secure the obligations of Éclat and Avadel US Holdings, Inc., including the full and prompt payment of royalties to Deerfield PDF/Horizon under the Royalty Agreement. This original Deerfield debt financing transaction also included a $15 million facility agreement which was repaid in full in March 2014 using the net proceeds from the Company’s public offering of ADS’s.

As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund (“Broadfin”), the Company entered into a Royalty Agreement with Broadfin, a significant shareholder of the Company, dated as of December 3, 2013 (the “Broadfin Royalty Agreement”). Pursuant to the Broadfin Royalty Agreement, the Company is required to pay a royalty of 0.834% on the net sales of certain products sold by the Company and any of its affiliates until December 31, 2024. This original Broadfin debt financing transaction also included a $5 million facility agreement which was repaid in full in March 2014 using the net proceeds from the Company’s public offering of ADS’s.

On February 8, 2016, the Company entered into an agreement to acquire FSC Holdings, LLC (“FSC”), a Charlotte, NC-based specialty pharmaceutical company dedicated to providing innovative solutions to unmet medical needs for pediatric patients, from Deerfield CSF, LLC, a Deerfield Management company (“Deerfield”), a related party. Under the terms of the acquisition, which was completed on February 8, 2016, the Company will pay $1,050 annually for five years with a final payment in January 2021 of $15,000 for a total of $20,250 to Deerfield for all of the equity interests in FSC. The Company will also pay Deerfield a 15% royalty per annum on net sales of the current FSC products, up to $12,500 for a period not exceeding ten years.

NOTE 21 : Subsequent Event

In preparing these consolidated financial statements, subsequent events were evaluated through the time the financial statements were issued. Financial statements are considered issued when they are widely distributed to all stockholders and other financial statement users, or filed with the SEC.

In March 2017, the Board of Directors approved an authorization to repurchase up to $25,000 of Avadel ordinary shares represented by American Depository Receipts in the open market with an indefinite duration. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our shares, cash resources, alternative investment opportunities, corporate and regulatory requirements and market conditions. This share repurchase program may be modified, suspended or discontinued at any time without prior notice. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheet of Avadel Pharmaceuticals PLC and subsidiaries (the "Company") as of December 31, 2016, and the related consolidated statements of income (loss), comprehensive income (loss), shareholders' equity, and cash flows for the year then ended. Our audit also included the 2016 financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and 2016 financial statement schedule based on our audit. The consolidated financial statements of the Company for the years ended December 31, 2015 and December 31, 2014 were audited by other auditors whose report, dated March 15, 2016, except for the effects of the revisions discussed in Note 1 to the consolidated financial statements, as to which the date is March 28, 2017, expressed an unqualified opinion on those statements.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, such 2016 consolidated financial statements present fairly, in all material respects, the financial position of Avadel Pharmaceuticals PLC and subsidiaries at December 31, 2016, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such 2016 financial statement schedule, when considered in relation to the basic 2016 consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2016, based on the criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 28, 2017 expressed an adverse opinion on the Company's internal control over financial reporting because of material weaknesses.

/s/ Deloitte and Touche LLP
St. Louis, Missouri
March 28, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited Avadel Pharmaceuticals PLC and subsidiaries' (the "Company's") internal control over financial reporting as of December 31, 2016, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in Management's Report on Internal Control Over Financial Reporting, management excluded from its assessment the internal control over financial reporting at FSC Holdings, LLC, together with its wholly owned subsidiaries FSC Pediatrics, Inc., FSC Therapeutics, LLC, and FSC Laboratories, Inc., which was acquired in February 2016 and whose financial statements constitute 11.0% of total assets, 4.0% of total net revenues, and 14.2% of total net loss of the consolidated financial statement amounts as of and for the year ended December 31, 2016. Accordingly, our audit did not include the internal control over financial reporting at FSC Holdings, LLC and its subsidiaries. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment: (i) Personnel- Personnel needing to have more time in their roles to have an impact on the system of 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, (ii) Financial Close Process- As the Company has not designed and maintained effective and precise financial close controls over the data and assumptions used in accounting for significant non-routine and complex transactions associated with the financial close process, and (iii) Rebates and Expired Product Reserves- As the Company has not designed or maintained effective and precise controls over the data and assumptions utilized in accounting for rebate and expired product reserves. These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2016, of the Company and this report does not affect our report on such financial statements and 2016 financial statement schedule.

In our opinion, because of the effect of the material weaknesses identified above on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2016, based on the criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet as of December 31, 2016 and the related consolidated statements of income (loss), comprehensive income (loss), shareholders' equity, and cash flows and financial statement schedule for the year ended December 31, 2016, of the Company and our report dated March 28, 2017 expressed an unqualified opinion on those financial statements and 2016 financial statement schedule.

/s/ Deloitte and Touche LLP
St. Louis, Missouri
March 28, 2017

Report of Independent Registered Public Accounting Firm

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

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

Lyon, France,
March 15, 2016, except for the effects of the revisions discussed in Note 1 to the consolidated financial statements, as to which the date is March 28, 2017

PricewaterhouseCoopers Audit

Represented by
/s/ Frédéric Charcosset
Frédéric Charcosset

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

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 15d -15(b) of the Exchange Act, we have evaluated, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed by us in reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure and is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the U.S. Securities and Exchange Commission (the "SEC"). Based on that evaluation, our principal executive officer and principal financial officer concluded that as of the end of the period covered by this report our disclosure controls and procedures were not effective at the reasonable assurance level because of the material weaknesses in our internal control over financial reporting described below.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. The Company’s internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles.

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

The Company’s management assessed the effectiveness of the Company’s internal control over financial reporting as of December 31, 2016. In making this assessment, the Company’s management used the criteria set forth in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2016, the Company’s internal control over financial reporting is not effective based on those criteria.

In February 2016, the Company completed the acquisition of FSC Holdings, together with its wholly owned subsidiaries FSC Pediatrics, Inc., FSC Therapeutics, LLC, and FSC Laboratories, Inc., which was excluded from management's annual report on internal control over financial reporting as of December 31, 2016. The Company acquired the outstanding stock of FSC in February 2016 and its results have been included in our 2016 consolidated financial statements. As of December 31, 2016, FSC Holdings represented 11.0% of total company assets, 4.0% of total net revenues, and 14.2% of total net loss of the consolidated financial statement amounts as of and for the year ended December 31, 2016.

Continuation of Previously Reported Material Weaknesses

As defined in Exchange Act Rule 12b-2 and Rule 1-02 of Regulation S-X, a material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the registrant's annual or interim financial statements will not be prevented or detected on a timely basis. The Company previously reported material weaknesses in its December 31, 2015 Form 10-K. As described below, management has identified the following control deficiencies that resulted in material weaknesses in our internal control over financial reporting as of December 31, 2016.

Personnel

As previously described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015, management had identified a material weakness related to personnel in that we did not maintain a sufficient number of personnel with an appropriate level of knowledge, experience and training in internal control over financial reporting commensurate with our financial reporting requirements. In an effort to remediate the identified material weakness, we hired and trained additional personnel.

As the result of management's internal control design and operational assessments as of December 31, 2016, management noted additional time in role and training of our added personnel is needed for these personnel to have an impact on the system of internal control over financial reporting, in order to gain an appropriate level of knowledge to execute controls consistent with the risk assessment and the required level of precision for management review controls associated with the review of inputs used in the controls, key assumptions utilized in accounting estimates and accounting for significant non-routine and complex transactions.

As of December 31, 2016, management evaluated the design and operational effectiveness of the remediation activities and concluded that the previously reported material weakness remains unremediated.

Financial Close Process

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, management had identified a material weakness in our internal controls over financial reporting related to the financial close process.

As the result of management's internal control design and operational assessments as of December 31, 2016, management noted that we had identified control deficiencies within the Financial Close processes as the Company has not designed or maintained effective and precise controls over the data and assumptions utilized in accounting for non-routine and complex transactions.

As of December 31, 2016, management evaluated the design and operational effectiveness of our internal controls and has concluded that the previously reported material weakness remains unremediated specifically related to significant non-routine and complex transactions.

Rebates and Expired Product Reserves

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, management had identified a material weakness in the revenue process specifically related to controls over the review and approval of product prices and subsequent changes to customer prices, the authorization, review and accounting for rebate arrangements included in customer contracts and the Company's use of service providers in the revenue process.

As the result of management's internal control design and operational assessments as of December 31, 2016, we concluded additional time is necessary to ensure that controls regarding assumptions using historical data for the setting of rebate and expired product reserves are operating with an appropriate level of precision.

As of December 31, 2016, management evaluated the design and operational effectiveness of our internal controls and has concluded that due to the aggregation of the noted control deficiencies that a material weakness continues to exist related to the operational effectiveness of our internal controls around the establishment of rebates and expired product reserves.

Changes in Internal Control over Financial Reporting

Remediation of Previously Reported Material Weaknesses

The Company previously reported material weaknesses in its December 31, 2015 Form 10-K. As more fully described below, we have identified and implemented additional processes, procedures and controls to improve the effectiveness of our internal control over financial reporting and disclosure controls and procedures. We regularly reviewed our progress toward remediating these material weaknesses with our audit committee during 2016. Leading this remediation process was our Senior Vice President and Chief Financial Officer and our Chief Accounting Officer. Assisting management with the remediation process was a nationally recognized consulting firm who, under the direction of management, created and enhanced controls documentation, assisted management in the implementation of improvements or changes to the existing internal control structure and tested such processes, procedures and controls to support management's conclusions surrounding the design and operating effectiveness of management's internal controls over financial reporting.

Segregation of Duties

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, management had identified a material weakness in our internal controls over financial reporting related to segregation of duties. Specifically, due to a lack of sufficient personnel, we had not designed or maintained effective controls over segregation of duties or restricted access for processes, including an assessment of incompatible management responsibilities related to journal entries, third party vendors and third party payments, cash payment process, or payroll and related accounts.

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

- Additional management review controls have been implemented and formalized across the organization in order to add additional levels of review and approval and to enhance segregation of duties at a functional level.

- Supplemented our U.S. based Accounting and Finance organization through adding appropriate levels of subject matter knowledge and training, including hiring a Chief Financial Officer, Chief Accounting Officer, Senior Tax Director and a Head of U.S. Accounting. Each of these individuals has the appropriate experience, certification, education, and training in financial reporting and accounting for their role.

- Implemented a company-wide ERP system to replace previously used accounting software as of January 1, 2016. The ERP system allowed for enhancements to and reliance on system based segregation of duties controls.

- Management performed a comprehensive segregation of duties analysis related to system based roles as part of the ERP implementation and again as of Q4 2016.

As of December 31, 2016, management evaluated the design and operational effectiveness of the remediation activities and concluded that we have sufficient evidence that the Segregation of Duties processes and controls have been adequately designed and were operating effectively. As a result, management has concluded that the previously reported material weakness has been remediated as of December 31, 2016.

Income Taxes

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, management had identified a material weakness in our internal controls over financial reporting related to income taxes. Specifically, we had not designed or maintained effective controls related to the income tax process on a quarterly or year-end basis, including deferred tax reconciliations, valuation allowances, review of state income taxes and related apportionment, review of tax returns and return to provision differences, review of information provided to and received from the outsourced tax provider, review of effective income tax rates and any uncertain tax positions.

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

- Supplemented our U.S. based Accounting and Finance organizations through the hiring of a Senior Tax Director who has the appropriate experience, certification, education, and training in financial accounting and reporting related to accounting for income taxes. The position along with an appropriate level of review by the Chief Financial Officer and Chief Accounting Officer has allowed the Company to enhance reliance on internal procedures and decrease reliance on third parties providing accounting for income tax services.

- Retained an outside consultant to assist the Company in documenting and testing the internal controls over financial reporting that are in place at the Company, including within the income tax process. Through this process, we have designed and maintained effective controls over the accounting and reporting for income taxes.

As of December 31, 2016, management evaluated the design and operational effectiveness of the remediation activities and concluded that we have sufficient evidence that the new processes and controls related to Income Taxes have been adequately designed and were operating effectively. As a result, management has concluded that the previously reported material weakness has been remediated as of December 31, 2016.

Information technology general controls and key spreadsheets

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, management had identified a material weakness in our internal controls over financial reporting related to information technology general control and key spreadsheets. Specifically, we had not designed or maintained effective controls over information technology general controls and key spreadsheets used within certain processes and management's controls to support account balances or in the preparation of the financial statements.

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

- Implemented a more company-wide ERP system to replace previously used accounting software as of January 1, 2016. The new ERP system allowed for significant enhancements within our information technology control environment that were not available under the previous system of record.

- Retained an outside consultant to assist the Company in documenting and testing the internal controls over financial reporting that are in place at the Company, including within the information technology area. Through this process, we have designed and maintained effective controls over the information technology area.

As of December 31, 2016, management evaluated the results of the remediation activities and concluded that we have sufficient evidence that the new processes and controls related to Information technology general controls have been adequately designed and were operating effectively. As a result, management has concluded that the previously reported material weakness has been remediated as of December 31, 2016.

Monitoring controls

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, management had identified a material weakness in our internal controls over financial reporting related to our monitoring controls. We did not design and maintain effective monitoring controls related to the design and operational effectiveness of our internal controls. Specifically, we did not maintain an internal audit function sufficient to monitor control activities.

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

- Retained an outside consultant to assist the Company in documenting and testing the internal controls over financial reporting that are in place at the Company and the serve in the role of the Company's internal audit function. We have assessed the qualifications of the third party provider and determined that they have the appropriate experience, certification education and training in internal audit and controls to serve in this role.

- Implemented a comprehensive and robust internal controls monitoring program in order to assess the design and operational effectiveness of our internal controls. This includes, but is not limited to, new quantitative and qualitative analytical analysis to monitor significant trends and transactions helping to timely detect potential material misstatements to our financial statements.

As of December 31, 2016, management evaluated the design and operational effectiveness of the remediation activities and concluded that we have sufficient evidence that the new processes and controls related to Monitoring Controls have been adequately designed and were operating effectively. As a result, management has concluded that the previously reported material weakness has been remediated as of December 31, 2016.

Actions related to unremediated material weaknesses

As noted in the above management's Report on internal controls section, management has concluded that the identified material weaknesses related to personnel, financial close and the establishment of rebate and expired product reserves, which formed part of the revenue material weakness, that were previously reported as of December 31, 2015 remain, either wholly or in part, unremediated as of December 31, 2016. While management has concluded that these material weaknesses remain unremediated, the Company has identified and implemented additional processes, procedures and controls as noted below to improve the effectiveness of our internal control over financial reporting and disclosure controls and procedures in these areas.

Lack of Sufficient Personnel

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, management had identified a material weakness in our internal controls over financial reporting related to our personnel responsible for internal control and financial reporting. Specifically, we did not maintain a sufficient number of personnel with an appropriate level of knowledge, experience and training in internal control over financial reporting commensurate with our financial reporting requirements.

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

- Supplemented our U.S. based Accounting and Finance organizations through adding appropriate levels of subject matter knowledge and training, including hiring a Chief Financial Officer, Chief Accounting Officer, a Senior Tax Director, a head of U.S. Accounting, an External Reporting Manager and others each of whom has the appropriate experience, certification, education, and training in financial accounting and reporting for their role.

- Retained an outside consultant to assist the Company in documenting and testing the internal controls over financial reporting that are in place at the Company and the serve in the role of the Company's internal audit function. We have assessed the qualifications of the third party provider and determined that they have the appropriate experience, certification education and training in internal audit and controls to serve in this role.

As of December 31, 2016, the remediation activities have had a positive effect on the material weakness and the performance of controls at a more precise level will continue to improve over time. Additional time in role of our added personnel is needed for management to conclude that the remediation actions have been fully effective in remediating this material weakness.

Financial Close

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, management had identified a material weakness in our design and operating effectiveness of the internal controls over financial reporting related to the financial close process.

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

- Supplemented our U.S. based Accounting and Finance organizations through adding appropriate levels of subject matter knowledge and training, including hiring a Chief Financial Officer, Chief Accounting Officer, Senior Tax Director, a Head of U.S. Accounting, an External Reporting Manager and others, each of whom has the appropriate experience, certification, education, and training in financial reporting and accounting for their role.
- Developed, formalized and implemented additional management review controls across the organization in order to add more comprehensive levels of review and approval for significant transactions having complex U.S. GAAP and SEC reporting implications and routine transaction processing.
- Developed new quantitative and qualitative analytical analysis as part of our financial close process to help in the early detection of potential material misstatements to our financial statements.
- Enhanced and refined our quarterly and annual financial analysis and procedures to allow for more timely and substantive review of financial results before the filing of the quarterly reports of Form 10-Q and Annual Report on Form 10-K.
- Implemented a company-wide ERP system to replace previously used accounting software as of January 1, 2016.
- Retained an outside consultant to assist the Company in documenting and testing the internal controls over financial reporting that are in place at the Company, including within the financial close process.

As of December 31, 2016, management evaluated the design and operational effectiveness of the remediation activities and concluded that a material weakness continues to exist in the operational effectiveness of our internal controls related to non-routine transactions.

Revenue

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, management had identified a material weakness in our internal controls over financial reporting related to revenue. Specifically, we had not designed or maintained effective controls over the review and approval of product prices and subsequent changes to customer prices, the authorization, review and accounting for rebate arrangements included in customer contracts and the Company's use of service providers in the revenue process.

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

- Enhanced our documentation and support around product pricing approvals and subsequent changes to customer pricing,
- Enhanced the information supporting the accounting and review process for gross to net accruals related to revenue,
- Expanded procedures to include a comprehensive review of service provider reporting and end user considerations as well as more comprehensive periodic reviews of activities performed by third parties and validation of financial information received from third parties,
- Enhanced the communication protocols between our Sales and Accounting functions to identify rebate arrangements and appropriately account for these arrangements
- Expanded procedures to include more comprehensive quantitative and qualitative financial analysis related to revenue financial accounting and reporting.

As of December 31, 2016, management evaluated the design and operational effectiveness of the remediation activities and concluded that the aspects of the prior year material weakness related to product pricing and use of service providers have been fully remediated. However, we concluded additional time is necessary to ensure that assumptions using historical data for the setting of rebate and expired product reserves are appropriate and operating with an appropriate level of precision.

Other Changes in Internal Control

Other than those actions described above, there have been no other changes in the Company's internal control over financial reporting (as defined by Rule 13a-15(f)) that occurred during the quarter ended December 31, 2016 that have materially affected the Company's internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we intend to file our definitive proxy statement for our 2016 annual general meeting of shareholders pursuant to Regulation 14A of the Securities Exchange Act of 1934 (our "Definitive 2016 Proxy Statement"), not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in our Definitive 2016 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

Information regarding Directors, Executive Officers and Corporate Governance is hereby incorporated by reference to our Definitive 2017 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2016.

Item 11. Executive Compensation.

Information regarding Executive Compensation is hereby incorporated by reference to our Definitive 2017 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2016.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information regarding Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters is hereby incorporated by reference to our Definitive 2017 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2016.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information regarding Certain Relationships and Related Transactions, and Director Independence is hereby incorporated by reference to our Definitive 2017 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2016.

Item 14. Principal Accountant Fees and Services.

Information regarding Principal Accountant Fees and Services is hereby incorporated by reference to our Definitive 2017 Proxy Statement, which we intend to file with the SEC within 120 days after December 31, 2016.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report:

1. *Financial Statements*

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

2. *Financial Statement Schedules*

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

Schedule II

Valuation and Qualifying Accounts

(In thousands)

Deferred Tax Asset Valuation Allowance:	Balance, Beginning of Period	Additions (a)	Deductions (b)	Other Changes (c)	Balance, End of Period
2016	$ 45,516	$ 6,873	$ (42,417)	$ (2,373)	$ 7,599
2015	57,980	4,312	(11,737)	(5,039)	45,516
2014	69,939	8,453	(13,185)	(7,227)	57,980

a. Additions to the deferred tax asset valuation allowance relate to movements on certain French, Irish and U.S. deferred tax assets where we continue to maintain a valuation allowance until sufficient positive evidence exists to support reversal.

b. Deductions to the deferred tax asset valuation allowance include movements relating to utilization and removal of net operating losses and tax credit carryforwards, release in valuation allowance and other movements including adjustments following finalization of tax returns.

c. Other changes to the deferred tax asset valuation allowance relate primarily to currency translation adjustments recorded directly in equity.

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

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

Index to Exhibits

Exhibit Number	Exhibit Description
3.1	Constitution (containing the Memorandum and Articles of Association) of Avadel Pharmaceuticals plc (incorporated by reference to Appendix 15 of Exhibit 2.1 to the registrant's current report on Form 8-K, filed on July 1, 2016)
4.1	Guaranty dated January 1, 2017 by Avadel Pharmaceuticals plc in favor of Breaking Stick Holdings, LLC (f/k/a Éclat Holdings, LLC) with respect to obligations under the Note Agreement filed as Exhibit 10.2 below (filed herewith)
4.2	Warrant to purchase 1,100,000 American Depositary Shares, each representing one ordinary share of Avadel Pharmaceuticals plc (incorporated by reference to Exhibit 4.1 to the registrant's Post-Effective Amendment No. 2 to Form F-3 registration statement (No. 333-183961) on Form S-3, filed on January 6, 2017)

4.3	Warrant to purchase 2,200,000 American Depositary Shares, each representing one ordinary share of Avadel Pharmaceuticals plc (incorporated by reference to Exhibit 4.2 to the registrant's Post-Effective Amendment No. 2 to Form F-3 registration statement (No. 333-183961) on Form S-3, filed on January 6, 2017)
10.1	Deposit Agreement dated as of January 3, 2017 among Avadel Pharmaceuticals plc, The Bank of New York, as Depositary, and holders from time to time of American Depositary Shares issued thereunder (including as an exhibit the form of American Depositary Receipt) (incorporated by reference to Exhibit 1.1 to the registrant's current report on Form 8-K12B, filed on January 4, 2017 and amended January 6, 2017)
10.2*	Note Agreement among Flamel Technologies S.A., Flamel U.S. Holdings, Inc. and Éclat Holdings, LLC dated March 13, 2012 (incorporated by reference to Exhibit 4.1 to the registrant's current report on Form 6-K, filed on March 21, 2012)
10.3	Registration Rights Agreement between Flamel Technologies S.A. and Éclat Holdings, LLC dated March 13, 2012 (incorporated by reference to Exhibit 4.5 to the registrant's current report on Form 6-K, filed on March 21, 2012)
10.4	Facility Agreement among Flamel US Holdings, Inc., Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. dated December 31, 2012 (incorporated by reference to Exhibit 4.7 to the registrant's annual report on Form 20-F for the year ended December 31, 2012, filed on April 30, 2013)
10.5*	Royalty Agreement among Éclat Pharmaceuticals LLC, Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P. dated December 31, 2012 (incorporated by reference to Exhibit 4.8 to the registrant's annual report on Form 20-F for the year ended December 31, 2012, filed on April 30, 2013)
10.6*	Security Agreement between Éclat Pharmaceuticals, LLC and Deerfield Private Design Fund II, L.P. and Horizon Santé FLML, Sarl dated February 4, 2013 (incorporated by reference to Exhibit 4.9 to the registrant's annual report on Form 20-F for the year ended December 31, 2012, filed on April 30, 2013)
10.7	Broadfin Facility Agreement effective as of December 3, 2013 (incorporated by reference to Exhibit 4.9 to the registrant's annual report on Form 20-F for the year ended December 31, 2013, filed on April 30, 2014)
10.8*	Broadfin Royalty Agreement dated as of December 3, 2013 (incorporated by reference to Exhibit 4.10 to the registrant's annual report on Form 20-F for the year ended December 31, 2013, filed on April 30, 2014)
10.9	Asset Purchase Agreement by and among Flamel Technologies S.A. and Recipharm Pessac dated November 26, 2014 (incorporated by reference to Exhibit 4.11 to the registrant's annual report on Form 20-F for the year ended December 31, 2014, filed on April 30, 2015)
10.10	Master Agreement on Supply of Services and Products by and between Avadel Technologies S.A. and Recipharm Pessac dated December 1, 2014 (incorporated by reference to Exhibit 4.12 to the registrant's annual report on Form 20-F for the year ended December 31, 2014, filed on April 30, 2015)
10.11	Service Agreement by and between Flamel Technologies S.A. and Recipharm Pessac dated December 1, 2014 (incorporated by reference to Exhibit 4.13 to the registrant's annual report on Form 20-F for the year ended December 31, 2014, filed on April 30, 2015)
10.12	Supply Agreement by and between Flamel Technologies S.A. and Recipharm Pessac dated December 1, 2014 (incorporated by reference to Exhibit 4.14 to the registrant's annual report on Form 20-F for the year ended December 31, 2014, filed on April 30, 2015)

10.13*	Membership Interest Purchase Agreement by and among Éclat Holdings LLC, Éclat Pharmaceuticals LLC, Flamel Technologies S.A. and Flamel US Holdings Inc. dated March 13, 2012 (incorporated by reference to Exhibit 4.15 to the registrant's annual report on Form 20-F for the year ended December 31, 2014, filed on April 30, 2015)
10.14*	Exclusive License Agreement by and between Elan Pharma International Limited and Flamel Ireland Limited dated September 30, 2015 (incorporated by reference to Exhibit 10.14 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.15	Lease Agreement by and between Nine East, LLC and Eclat Pharmaceuticals LLC dated July 23, 2013 (incorporated by reference to Exhibit 10.15 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.16	Lease Agreement by and between Grove II LLC and Eclat Pharmaceuticals LLC dated October 5, 2015 (incorporated by reference to Exhibit 10.16 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.17	Lease Agreement by and between Channor Limited, Blanchardstown Corporate Park Management Limited, Flamel Ireland Limited, and Flamel Technologies S.A. dated July 3, 2015 (incorporated by reference to Exhibit 10.17 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.18‡	Employment Agreement by and between Flamel Technologies S.A. and Sandra Hatten dated July 8, 2015 (incorporated by reference to Exhibit 10.18 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.19‡	Employment Agreement by and between Flamel Technologies S.A. and Phillandas T. Thompson dated July 7, 2015 (incorporated by reference to Exhibit 10.19 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.20	Membership Interest Purchase Agreement dated as of February 5, 2016 by and among James Flynn, Peter Steelman, Deerfield CSF, LLC, FSC Holding Company, LLC, FSC Therapeutics, LLC, FSC Laboratories, Inc., Flamel Technologies SA, and Flamel US Holdings, Inc. (incorporated by reference to Exhibit 10.20 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.21‡	Rules Governing the Free Share Plan - December 2014 (incorporated by reference to Exhibit 10.21 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.22‡	Rules Governing the Free Share Plan - December 2014 (incorporated by reference to Exhibit 10.22 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.23‡	June 2015 Stock Warrant Rules (incorporated by reference to Exhibit 10.23 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.24‡	Subscription Form of Stock Warrant (incorporated by reference to Exhibit 10.24 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.25‡	December 2015 Stock Option Rules (incorporated by reference to Exhibit 10.25 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)
10.26‡	Form of Stock Option Grant Letter (incorporated by reference to Exhibit 10.26 to the registrant's Annual Report on Form 10-K for the year ended December 31, 2015, filed on March 15, 2016)

10.27	Common Draft Terms of Cross-Border Merger dated as of June 29, 2016 between Flamel Technologies S.A. and Avadel Pharmaceuticals Limited (subsequently renamed Avadel Pharmaceuticals plc) (incorporated by reference to Exhibit 2.1 to the registrant's current report on Form 8-K, filed on July 1, 2016)
10.28‡	Rules Governing the Free Share Plan - August 2016 (incorporated by reference to Exhibit 99.1 to the registrant's Registration Statement (No. 333-213154) on Form S-8, filed on August 16, 2016)
10.29‡	August 2016 Stock Option Rules (incorporated by reference to Exhibit 99.2 to the registrant's Registration Statement (No. 333-213154) on Form S-8, filed on August 16, 2016)
10.30‡	August 2016 Stock Warrant Rules (incorporated by reference to Exhibit 99.3 to the registrant's Registration Statement (No. 333-213154) on Form S-8, filed on August 16, 2016)
10.31‡	Form of stock option grant letter for 2016 Stock Option Rules (filed herewith)
10.32‡	Employment Agreement by and between Avadel Pharmaceuticals plc and Gregory J. Divis, dated January 4, 2017 (filed herewith)
14.1	Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 to the registrant's current report on Form 8-K, filed on March 7, 2017)
14.2	Financial Integrity Policy (incorporated by reference to Exhibit 14.2 to the registrant's current report on Form 8-K, filed on March 7, 2017)
21.1	List of Subsidiaries (filed herewith)
23.1	Consent of PricewaterhouseCoopers Audit (filed herewith)
23.2	Consent of Deloitte & Touche, LLP (filed herewith)
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith)
32.1	Certification of the Chief Executive Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith) (1)
32.2	Certification of the Principal Financial Officer pursuant to USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith) (1)
101.INS	XBRL Instant Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

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

‡ Management contract or compensatory plan or arrangement filed pursuant to Item 15(b) of Form 10-K.

(1) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933 or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Avadel Pharmaceuticals PLC

Dated: March 28, 2017

By: /s/ Michael S. Anderson

Name: Michael S. Anderson

Title: Chief Executive Officer

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

POWER OF ATTORNEY

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

Signature	Title	Date
/s/ Michael S. Anderson Michael S. Anderson	Chief Executive Office (Principal Executive Officer) and Director	March 28, 2017
/s/ Michael F. Kanan Michael F. Kanan	Chief Financial Officer (Principal Financial Officer)	March 28, 2017
/s/ David P. Gusky David P. Gusky	Corporate Controller (Principal Accounting Officer)	March 28, 2017
/s/ Craig R. Stapleton Craig R. Stapleton	Non-Executive Chairman of the Board and Director	March 28, 2017
/s/ Guillaume Cerutti Guillaume Cerutti	Director	March 28, 2017
/s/ Francis J.T. Fildes Francis J.T. Fildes	Director	March 28, 2017
/s/ Benoit Van Assche Benoit Van Assche	Director	March 28, 2017
/s/ Christophe Navarre Christophe Navarre	Director	March 28, 2017

GUARANTY

GUARANTY, dated as of January 1, 2017, made by Avadel Pharmaceuticals plc, a public limited company organized under the laws of Ireland ("**Guarantor**"), in favor of the Holder (as defined below).

WITNESSETH:

Whereas, pursuant to that certain Note Agreement (the "**Note Agreement**") dated as of March 13, 2012 (the "**Closing Date**") between Flamel Technologies S.A., a société anonyme organized under the laws of the Republic of France, and the predecessor of Guarantor (**"Flamel"),** Flamel US Holdings, Inc. (the "**Purchaser**") and the Holder, the Purchaser issued to the Holder an Installment Sale Note dated as of the Closing Date, in the principal amount of $12,000,000 (the "**Note**");

Whereas, the Purchaser has fully repaid the Note;

Whereas, the Purchaser directly holds all of the equity interests in Éclat Pharmaceuticals, LLC ("**Éclat**") pursuant to a membership interest purchase agreement entered into between the Purchaser and the Holder dated as of the Closing Date whereby the Purchaser purchased from the Holder all of equity interests held in Éclat;

Whereas, the Guarantor is the successor by merger to the assets and liabilities of Flamel, and the Guarantor wishes to set forth in this instrument its guaranty of the Obligations (as defined below) in accordance with the terms set forth in this Guaranty;

NOW, THEREFORE, in consideration of the foregoing premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Guarantor hereby agrees with the Holder as follows:

SECTION 1. DEFINED TERMS

1.1 Definitions

(a) Capitalized terms used herein and not otherwise defined herein shall have the meanings given to them in the Note Agreement.

(b) The following terms shall have the following meanings:

"**Event of Default**" means (i) until the Obligations (other than contingent indemnification obligations that have not yet been asserted) in respect of the Note Agreement have been paid in full, an "Event of Default" as such term is defined in the Note Agreement and (ii) thereafter if any Obligations remains outstanding, (x) an "Acceleration Trigger Event" as such term is defined in the Interest Agreement and (y) the failure by Guarantor, Eclat (solely in respect of any obligations of Eclat to the Holder under the Purchase Agreement), or the Purchaser to comply with the due observance or performance of any covenant contained in the Interest Agreement after the expiration of any grace periods and the giving of any required notices.

"**Guaranty**" means this Guaranty, as the same may be amended or supplemented from time to time.

"**Holder**" means Breaking Stick Holdings, LLC (formerly known as Éclat Holdings, LLC) and its successors and assigns.

"**Obligations**" mean the collective reference to all obligations and liabilities of the Purchaser and Éclat to the Holder under the Note Agreement, the Security Agreements and the Interest Agreement (including, without limitation, default interest accruing at the then applicable rate provided in the Note and after the maturity thereof interest accruing at the then applicable rate after the filing of any petition in bankruptcy, or the commencement of any insolvency, reorganization or like proceeding, relating to the Purchaser or Éclat, and post-filing or post-petition interest, whether direct or indirect, absolute or contingent, due or to become due, or now existing or hereafter incurred, which may arise under, out of, or in connection with, the Note Agreement, the Security Agreements and the Interest Agreement, or any other document executed and delivered in connection therewith (other than, for the avoidance of doubt, that certain Warrant to Purchase American Depositary Shares of the Guarantor issued to the Holder), in each case whether on account of principal, interest, fees, indemnities, costs, expenses or otherwise (including, without limitation, all reasonable fees and disbursements of counsel to the Holder that are required to be paid by the Purchaser or Éclat pursuant to the terms of any of the foregoing agreements).

"**Person**" shall mean and include an individual, a partnership, a corporation, a limited liability company, an unincorporated association, a joint venture or other entity or a governmental authority.

1.2 Other Definitional Provisions. The words "hereof," "herein", "hereto" and "hereunder" and words of similar import when used in this Guaranty shall refer to this Guaranty as a whole and not to any particular provision of this Guaranty, and Section references are to this Guaranty unless otherwise specified. The meanings given to terms defined herein shall be equally applicable to both the singular and plural forms of such terms.

SECTION 2. GUARANTY

2.1 Guaranty. Guarantor hereby absolutely, unconditionally and irrevocably guarantees to the Holder, the prompt and complete payment and performance by the Purchaser and Éclat of the Obligations when due (whether at the stated maturity, by acceleration or otherwise).

2.2 Nature of Guaranty. Guarantor's liability under this Guaranty shall be unlimited, open and continuous for so long as this Guaranty remains in force. Guarantor intends to guaranty the performance and prompt payment of the Obligations when due, whether at

maturity or earlier by reason of acceleration or otherwise. Accordingly, no payments made upon the Obligations will discharge or diminish the continuing liability of Guarantor in connection with any remaining portions of the Obligations which subsequently arises or is thereafter incurred. No payment made by the Purchaser or Éclat, or any other Person or received or collected by the Holder from the Purchaser or Éclat, or any other Person by virtue of any action or other proceeding or any set-off or appropriation or application at any time or from time to time in reduction of or in payment of the Obligations shall be deemed to modify, reduce, release or otherwise affect the liability of Guarantor hereunder which shall, notwithstanding any such payment (other than payment and performance in full of the Obligations), remain liable for the Obligations until the Obligations are paid and performed in full.

2.3 Duration of Guaranty. This Guaranty will take effect when received by the Holder without the necessity of any acceptance by the Holder, or any notice to Guarantor, and will continue in full force until the Obligations shall have been fully paid and satisfied and all other obligations of Guarantor under this Guaranty shall have been performed in full. All renewals, extensions, substitutions, and modifications of the Obligations, release of any other guarantor or termination of any other guaranty of the Obligations shall not affect the liability of Guarantor under this Guaranty. This Guaranty is irrevocable and is binding upon Guarantor and Guarantor's successors and assigns so long as any of the Obligations remain unpaid.

2.4 No Subrogation. Notwithstanding any payment made by Guarantor hereunder or any set-off or application of funds of Guarantor by the Holder, Guarantor shall not be entitled to be subrogated to any of the rights of the Holder against the Purchaser or Éclat or any other guarantor or guaranty or right of offset held by the Holder for the payment of the Obligations, nor shall Guarantor seek or be entitled to seek any contribution or reimbursement from the Purchaser or Éclat or any other guarantor in respect of payments made by Guarantor hereunder, until all amounts owing to the Holder by the Purchaser or Éclat on account of the Obligations are paid in full. If any amount shall be paid to Guarantor on account of such subrogation rights at any time when all of the Obligations shall not have been paid in full, such amount shall be held in trust for the benefit of the Holder, segregated from other funds of Guarantor, and shall, forthwith upon receipt by Guarantor, be turned over to the Holder in the exact form received by such Guarantor (duly indorsed by Guarantor to the Holder, if required), to be applied against the Obligations, whether matured or unmatured, in such order as the Holder may determine.

2.5 Amendments, Etc. With Respect to The Obligations. Guarantor shall remain obligated hereunder notwithstanding that, without any reservation of rights against Guarantor and without notice to or further assent by Guarantor, any demand for payment or performance of any of the Obligations made by the Holder may be rescinded by the Holder and any of the Obligations continued, and the Obligations, or the liability of any other Person upon or for any part thereof, or guaranty therefor or right of offset with respect thereto, may, from time to time, in whole or in part, be renewed, extended, amended, modified, accelerated, compromised, waived, surrendered or released by the Holder, and the Note Agreement and, the Security Agreements and the Interest Agreement and any other documents executed and delivered in connection therewith may be amended, modified, supplemented or terminated, in whole or in part, as the Holder may deem advisable from time to time, and any guaranty or right of offset at any time held by the Holder for the payment of the Obligations may be sold, exchanged, waived, surrendered or released.

2.6 Guaranty Absolute and Unconditional. Guarantor hereby waives any and all notice of the creation, renewal, extension or accrual of any of the Obligations and notice of or proof of reliance by the Holder upon the guaranty contained in this Section 2 or acceptance of the guaranty contained in this Section 2; the Obligations, and any of them, shall conclusively be deemed to have been created, contracted or incurred, or renewed, extended, amended or waived, in reliance upon the guaranty contained in this Section 2; and all dealings between the Purchaser and Éclat and Guarantor, on the one hand, and the Holder, on the other hand, likewise shall be conclusively presumed to have been had or consummated in reliance upon the guaranty contained in this Section 2. Guarantor hereby waives, to the extent permitted by law, diligence, presentment, protest, demand for payment and notice of default or nonpayment to or upon the Purchaser or Éclat or Guarantor with respect to the Obligations. Guarantor understands that the guaranty contained in this Section 2 shall be construed as a continuing, absolute and unconditional guaranty of payment and performance without regard to (a) the validity or enforceability of the Note Agreement, the Security Agreements and the Interest Agreement, any of the Obligations or any other guaranty or right of offset with respect thereto at any time or from time to time held by the Holder, (b) any defense, set-off or counterclaim (other than a defense of actual payment and performance of all Obligations) which may at any time be available to or be asserted by the Purchaser or Éclat or any other Person against the Holder, or (c) any other circumstance whatsoever (with or without notice to or knowledge of Guarantor) which constitutes, or might be construed to constitute, an equitable or legal discharge of the Purchaser or Éclat for the Obligations, or of Guarantor under the guaranty contained in this Section 2, in bankruptcy or in any other instance. When making any demand hereunder or otherwise pursuing its rights and remedies hereunder against Guarantor, the Holder may, but shall be under no obligation to, make a similar demand on or otherwise pursue such rights and remedies as they may have against the Purchaser or Éclat or any other Person or against any other guaranty for the Obligations or any right of offset with respect thereto, and any failure by the Holder to make any such demand, to pursue such other rights or remedies or to collect any payments from the Purchaser or Éclat or any other Person or to realize upon any such other guaranty or to exercise any such right of offset, or any release of the Purchaser or Éclat or any other Person or any such other guaranty or right of offset, shall not relieve Guarantor of any obligation or liability hereunder, and shall not impair or affect the rights and remedies, whether express, implied or available as a matter of law, of the Holder against Guarantor.

The obligations of the Guarantor are principal and independent obligations from the obligations of the parties to the Note Agreement, the Security Agreements, the Interest Agreement or any other agreement. Therefore, the Guarantor cannot, in order to delay or to avoid the unconditional and immediate performance of its obligations under this Guaranty, invoke any defense or exception relating to or resulting from any current or future relationships (including legal relationships) nor any contentious or non-contentious claims, between the Purchaser and the Holder or any other third party, or any other challenge or the Purchaser or of a third party.

2.7 Reinstatement. The guaranty contained in this Section 2 shall continue to be effective, or be reinstated, as the case may be, if at any time payment, or any part thereof, of any of the Obligations is rescinded or must otherwise be restored or returned by the Holder upon the insolvency, bankruptcy, dissolution, liquidation or reorganization of the Purchaser or Éclat, Guarantor or any other guarantor of the Obligations, or upon or as a result of the appointment of a receiver, intervenor or conservator of, or trustee or similar officer for the Purchaser or Éclat, Guarantor or any other guarantor of the Obligations or any substantial part of its property, or otherwise, all as though such payments had not been made.

2.8 Payments. Guarantor hereby guarantees that payments hereunder will be paid to the Holder without set-off or counterclaim in U.S. dollars at the address set forth in the Note Agreement or by wire transfer pursuant to instructions provided to Guarantor by the Holder.

SECTION 3. REPRESENTATIONS AND WARRANTIES

Guarantor represents and warrants to the Holder that as of the date hereof:

3.1 Organization, Good Standing and Subsidiaries. Guarantor is a legal entity duly organized, validly existing and in good standing under the laws of Ireland and has all requisite power and authority to carry on its business as now conducted and own its properties. Guarantor does not have any Subsidiaries, except as set forth on Schedule A to this Agreement.

3.2 Authorization. Guarantor has full power and authority and has taken all requisite action necessary for (i) the authorization, execution and delivery of this Guaranty and (ii) authorization of the performance of all obligations of Guarantor hereunder. This Guaranty constitutes legal, valid and binding obligations of Guarantor, enforceable against Guarantor in accordance with its terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability, relating to or affecting creditors' rights generally.

3.3 Consents. The execution, delivery and performance by Guarantor of this Guaranty require no consent of, action by or in respect of, or filing with, any Person.

3.4 No Conflict, Breach, Violation or Default; Compliance with Law. The execution, delivery and performance of this Guaranty by Guarantor will not conflict with or result in a breach or violation of any of the provisions of, or constitute a default under, Guarantor's organizational documents as in effect on the date hereof. Guarantor (i) is not in violation of any statute, rule or regulation applicable to Guarantor or its assets, (ii) is not in violation of any judgment, order or decree applicable to Guarantor or its assets, and (iii) is not in breach or violation of any agreement to which it or its assets are a party or are bound or subject, excluding, in each case described in clauses (i), (ii) and (iii) above, violations and breaches which would not have a Material Adverse Effect. Guarantor has not received notice from any Person of any claim or investigation that, if adversely determined, would render the preceding sentence untrue or incomplete.

3.5 No Limitation of Guaranty. No representations, warranties or agreements of any kind have been made to or with Guarantor that would limit or qualify in any way the terms of this Guaranty.

3.6 Borrower's Request. This Guaranty is executed at request of the Purchaser and Éclat and not at the request of the Holder.

3.7 Obtaining Borrower Information. Guarantor has established adequate means of obtaining from the Purchaser and Éclat on a continuing basis information regarding the Purchaser's and Éclat's financial condition.

3.8 Solvency. As of the date hereof and after giving effect to the transactions contemplated hereby, (a) the property of Guarantor, at a fair valuation, will not exceed its debt; (b) the capital of Guarantor will not be unreasonably small to conduct its business; (c) Guarantor will not have incurred debts, or have intended to incur debts, beyond its ability to pay such debts as they mature; and (d) the present fair salable value of the assets of Guarantor will be greater than the amount that will be required to pay its probable liabilities (including debts) as they become absolute and matured. For purposes of this Section 3.8, "debt" means any liability on a claim, and "claim" means (i) the right to payment, whether or not such right is reduced to judgment, liquidated, unliquidated, fixed, contingent, matured, unmatured, undisputed, legal, equitable, secured or unsecured, or (ii) the right to an equitable remedy for breach of performance if such breach gives rise to a right to payment, whether or not such right to an equitable remedy is reduced to judgment, liquidated, unliquidated, fixed, contingent, matured, unmatured, undisputed, secured or unsecured.

3.9 Litigation Matters. There are no actions, suits or other proceedings by or before any arbitrator or Governmental Authority pending against or threatened against or affecting Guarantor which would have a Material Adverse Effect.

3.10 Compliance with Laws and Agreements. Guarantor is in compliance with all laws applicable to it or its property and all agreements binding upon it or its Property except where such noncompliance would not have a Material Adverse Effect.

3.11 Taxes. Guarantor has timely filed or caused to be filed all tax returns and reports required to have been filed and has paid or caused to be paid all taxes required to have been paid, except taxes that are being contested in good faith by appropriate proceedings and for which Guarantor has set aside on its books adequate reserves.

3.12 Disclosure. None of the written reports on financial or other information, in each case furnished by Guarantor to Holder in connection with the negotiation of this Guaranty (as modified or supplemented by other information so furnished) contains any material misstatement of fact or omits to state any fact necessary to make the statements therein, in the light of the circumstances under which they were made, not materially misleading.

SECTION 4. COVENANTS

The provisions of Sections 4.1 and 4.2 of the Note Agreement applicable to the Purchaser, Éclat and Guarantor are incorporated herein by reference, mutatis mutandis, such incorporation to continue after the termination of the Note Agreement.

SECTION 5. WAIVERS; SUBORDINATION

5.1 Guarantor's Waivers.

(a) *Holder's Actions*. Guarantor waives any right to require the Holder to resort for payment from, or to proceed directly or at once against, any Person, including the Purchaser and Éclat or any other guarantor.

(b) *Insolvency*. If the Purchaser or Éclat shall become insolvent, until such time as the Obligations have been paid and performed in full, Guarantor hereby waives and relinquishes in favor of the Holder and its respective successors and assigns, any claim or right to payment Guarantor may now have or hereafter have or acquire against the Purchaser or Éclat, by subrogation or otherwise, such that at no time shall Guarantor be or become a "creditor" of the Purchaser or Éclat at such time that Holder is a creditor with respect to the Obligations.

(c) *Guarantor's Rights and Defenses*. Guarantor also waives any and all rights or defenses arising by reason of (i) any law that may prevent the Holder from bringing any action, including a claim for deficiency, against Guarantor, before or after the commencement or completion of any foreclosure action, either judicially or by exercise of a power of sale, (ii) any election of remedies by the Holder which

destroys or otherwise adversely affects Guarantor's subrogation rights or Guarantor's rights to proceed against the Purchaser or Éclat for reimbursement, including without limitation, any loss of rights Guarantor may suffer by reason of any law limiting, qualifying, or discharging the Obligations, (iii) any disability or other defense of the Purchaser and Éclat, of any other guarantor, or of any other Person, or by reason of the cessation of the Purchaser's or Éclat's liability from any cause whatsoever, other than payment in full of the Obligations, (iv) any statute of limitations, if at the time any action or other suit brought by the Holder against Guarantor is commenced there is outstanding Obligations which are not barred by any applicable statute of limitations, (v) any defenses given to guarantors at law or in equity other than actual payment and performance of the Obligations, or (vi) any act, omission, election or waiver by the Holder of the type set forth in this Guaranty.

(d) *No Set-off, Counterclaim, Etc*. Guarantor further waives and shall not assert or claim at any time any deductions to the amount guaranteed under this Guaranty for any claim of set-off, counterclaim, counter demand, recoupment or similar right.

5.2 Guarantor's Understanding With Respect to Waivers. Each of the waivers set forth herein is made with Guarantor's full knowledge of its significance and consequences and that, under the circumstances, the waivers are reasonable and not contrary to public policy or law. If any such waiver is determined to be contrary to any applicable law or public policy, such waiver shall be effective only to the extent permitted by law or public policy.

5.3 Subordination of Debts to Guarantor. The Obligations shall be prior to any claim that Guarantor may now have or hereafter acquire against the Purchaser or Éclat, whether or not the Purchaser or Éclat becomes insolvent. Guarantor hereby expressly subordinates to the Obligations any claim Guarantor may have against the Purchaser or Éclat, upon any account whatsoever (including without limitation all intercompany obligations owing to Guarantor from the Purchaser or Éclat), to any claim that the Holder may now or hereafter have against the Purchaser or Éclat; *provided, however*, that the Purchaser and Éclat may make payments on, and Guarantor may receive payments with respect to, such claims that represent bona fide claims for money lent to, property transferred to, or services performed for, the Purchaser or Éclat in the ordinary course of the business of Guarantor, the Purchaser and Éclat or in respect of any other obligation of the Purchaser and Éclat permitted under the Note Agreement, and Guarantor may receive dividends and other distributions from the Purchaser, in each case unless and until an Event of Default shall have occurred and be continuing. In the event of any dissolution, winding up, liquidation, readjustment, reorganization or similar proceedings, through bankruptcy, by an assignment for the benefit of creditors, by voluntary liquidation, or otherwise, the assets of the Purchaser and Éclat applicable to the payment of the claims of both the Holder and Guarantor shall be paid to the Holder.

SECTION 6. MISCELLANEOUS

6.1 Amendments In Writing. None of the terms or provisions of this Guaranty may be amended, supplemented or otherwise modified except by an instrument in writing signed by Guarantor and the Holder, and no provision hereof may be waived other than by an instrument in writing signed by the party against whom enforcement is sought.

6.2 Notices. All notices, requests and demands to or upon the Guarantor and the Holder shall be effected in the manner provided for in the Note Agreement.

6.3 No Waiver By Course Of Conduct; Cumulative Remedies. The Holder shall not by any act (except by a written instrument pursuant to Section 6.1), be deemed to have waived any right, power or privilege hereunder or to have acquiesced in any Event of Default. No failure to exercise, nor any delay in exercising, on the part of the Holder, any right, power or privilege hereunder shall operate as a waiver thereof. No single or partial exercise of any right, power or privilege hereunder shall preclude any other or further exercise thereof or the exercise of any other right, power or privilege. A waiver by the Holder of any right, power or privilege hereunder on any one occasion shall not be construed as a bar to any right, power or privilege that the Holder would otherwise have on any future occasion. The rights, powers and privileges hereunder provided are cumulative, may be exercised singly or concurrently and are not exclusive of any other rights and remedies provided by law.

6.4 Enforcement Expenses; Indemnification

(a) If any amount owing to the Holder under this Guaranty shall be collected through enforcement thereof, any refinancing or restructuring in the nature of a work-out, settlement, negotiation, or any process of law, or shall be placed in the hands of third Persons for collection, Guarantor shall pay (in addition to all monies then due or otherwise payable under this Guaranty all reasonable and documented out-of-pocket attorneys' and other fees and expenses incurred in respect of such collection**.**

(b) Guarantor shall pay, and save the Holder harmless from, any and all liabilities with respect to, or resulting from any delay in paying, any and all stamp, excise, sales or other taxes (other than any taxes based upon the Holder's net income) that may be payable or determined to be payable in connection with any of the transactions contemplated by this Guaranty.

(c) Guarantor shall pay, and save the Holder harmless from, any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind or nature whatsoever with respect to the execution, delivery, enforcement, performance and administration of this Guaranty.

(d) The agreements in this Section shall survive repayment of the Obligations.

6.5 Successors And Assigns. This Guaranty shall be binding upon the successors of Guarantor and shall inure to the benefit of the Holder; *provided* that Guarantor may not assign, transfer or delegate any of its rights or obligations under this Guaranty without the written consent of the Holder..

6.6 Set-Off. Guarantor hereby irrevocably authorizes the Holder at any time and from time to time while an Event of Default shall have occurred and be continuing, without notice to Guarantor or any other guarantor of the Obligations, any such notice being expressly waived by Guarantor, to set-off and appropriate and apply any and all amounts, credits, indebtedness or claims, in any currency, in each case whether direct or indirect, absolute or contingent, matured or unmatured, at any time held or owing by the Holder to or for the credit or the account of Guarantor, or any part thereof, in such amounts as the Holder may elect, against and on account of the Obligations, whether or not the Holder has made any demand for payment and although the Obligations may be contingent or unmatured. The Holder shall notify Guarantor promptly of any such set-off and the application made by the Holder of the proceeds thereof, *provided* that the failure to give such

notice shall not affect the validity of such set-off and application. The rights of the Holder under this Section are in addition to other rights and remedies (including, without limitation, other rights of set-off) which the Holder may have.

6.7 Facsimile. This Guaranty may be executed by facsimile.

6.8 Severability. Any provision of this Guaranty which is unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such unenforceability without invalidating the remaining provisions hereof, and any such unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

6.9 Section Headings. The Section headings used in this Guaranty are for convenience of reference only and are not to affect the construction hereof or be taken into consideration in the interpretation hereof.

6.10 Integration. This Guaranty represent the agreement of Guarantor and the Holder with respect to the subject matter hereof, and there are no promises, undertakings, representations or warranties by the Holder relative to subject matter hereof not expressly set forth or referred to herein.

6.11 Acknowledgements. Guarantor hereby acknowledges that:

(a) it has been advised by counsel in the negotiation, execution and delivery of this Guaranty;

(b) the Holder has no fiduciary relationship with or duty to Guarantor arising out of or in connection with this Guaranty or otherwise, and the relationship between Guarantor, on the one hand, and the Holder, on the other hand, in connection herewith or therewith is solely that of debtor and creditor; and

(c) no joint venture is created hereby or otherwise exists by virtue of the transactions contemplated hereby among Guarantor and the Holder.

6.12 Applicable Law and Consent to Non-Exclusive New York Jurisdiction.

(a) This Guaranty shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to the conflicts of laws principles thereof other than Sections 5-1401 and 5-1402 of the General Obligations Law of such State.

(b) Guarantor hereby irrevocably agrees that any legal action, suit or other proceeding arising out of this Guaranty may be brought in the courts of the State of New York or of the United States of America for the Southern District of New York. Guarantor irrevocably consents to the service of any process in any such legal action, suit or other proceeding by the mailing of copies of such process to such Party at its address specified in Section 6.2 by registered mail, return receipt requested. By the execution and delivery of this Agreement, Guarantor hereby irrevocably consents and submits to the jurisdiction of any such court in any such action, suit or other proceeding. Final judgment against Guarantor in any such action, suit or other proceeding shall be conclusive and may be enforced in any other jurisdiction by suit on the judgment. Nothing contained in this Guaranty shall affect the right of the Holder to commence legal proceedings in any court having jurisdiction, or concurrently in more than one jurisdiction, or to serve process, pleadings and other legal papers upon Guarantor in any manner authorized by the laws of any such jurisdiction.

(c) Guarantor irrevocably waives, to the fullest extent permitted by applicable law, any objection which it may now or hereafter have to the laying of venue of any action, suit or other proceeding arising out of or relating to this Guaranty, brought in the courts of the State of New York or in the United States District Court for the Southern District of New York, and any claim that any such action, suit or other proceeding brought in any such court has been brought in an inconvenient forum.

(d) Guarantor hereby waives any and all rights to demand a trial by jury in any action, suit or other proceeding arising out of this Guaranty or the transactions contemplated hereby.

(e) To the extent that Guarantor, in any suit, action or other proceeding brought in any court arising out of or in connection with this Guaranty, be entitled to the benefit of any provision of law requiring the Holder in such suit, action or other proceeding to post security for the costs of Guarantor, or to post a bond or to take similar action, Guarantor hereby irrevocably waive such benefit, in each case to the fullest extent now or hereafter permitted under any applicable law.

(f) The Guarantor waives its rights (a) under Article 14 and Article 15 of the French Civil Code and (b) to object to an action for summary judgment in lieu of a complaint pursuant to NY CPLR Section 3213

6.13 Currency. All amounts owing under this Guaranty shall be paid in United States Dollars.

6.14 Judgment Currency.

(a) If, for the purpose of obtaining or enforcing judgment against Flamel or the Purchaser in any court in any jurisdiction with respect to this Agreement, the Note and/or the Security Agreement, it becomes necessary to convert into any other currency (such other currency being hereinafter in this Section 6.14(a) referred to as the "Judgment Currency") an amount due in United States dollars, the conversion shall be made at the last exchange rate published in the Wall Street Journal on the business day immediately preceding (the "Exchange Rate"):

(i) the date actual payment of the amount is due, in the case of any proceeding in the courts of New York or in the courts of any other jurisdiction that will give effect to payment being due on such date; or

(ii) the date on which the Irish or any other non U.S. court determines, in the case of any proceeding in the courts of any other jurisdiction (the date as of which such payment is made pursuant to this Section 6.14 being hereinafter referred to as the "Judgment Payment Date").

(b) If in the case of any proceeding in the court of any jurisdiction referred to above, there is a change in the Exchange Rate on the date of calculation prevailing between the Judgment Payment Date and the date of actual payment of the amount due, Guarantor shall pay such adjusted amount as may be necessary to ensure that the amount paid in the Judgment Currency, when converted at the Exchange Rate prevailing on the date of payment, will produce the amount of United States dollars which could have been purchased with the amount of Judgment Currency stipulated in the judgment or judicial order at the Exchange Rate prevailing on the Judgment Payment Date.

(c) Any amount due from Guarantor under this Section 6.14 shall be due as a separate debt and shall not be affected by judgment being obtained for any other amount due under or in respect of the Note.

6.15 Indirect Taxes. If and whenever the Holder shall be subject to any VAT, goods and services tax, sales tax or any other indirect tax (together, the "Indirect Taxes") imposed, levied or assessed by any Governmental Authority measured, in whole or in part, by reference to any payments due hereunder to the Holder, then the amount of such sums due to the Holder hereunder shall be increased by the amount of such Indirect Taxes assessed so that after the withholding of such Indirect Taxes, the Holder shall receive the sum it would have received had no such Indirect Taxes been assessed. If any Indirect Taxes are later refunded or credited by the applicable Government Authority directly to the Holder, the Holder will refund such amounts to the Purchaser.

6.16 Direct Taxes. (a) Guarantor shall be responsible for any Irish income, profits or withholding taxes that may apply to any payments by Guarantor due under this Guaranty.

(b) If and whenever the Holder shall be subject to any Irish income, profits or withholding taxes imposed on any payments due hereunder to the Holder, then the amount of any such sums due to the Holder hereunder shall be increased by the amount of such income, profits or withholding tax or taxes assessed so that after the withholding of such income, profits or withholding tax or taxes, the Holder shall receive the sum it would have received had no such income, profits or withholding tax or taxes been assessed.

(c) Guarantor and the Holder shall reasonably cooperate to eliminate or reduce any taxes payable with regard to any payments due hereunder by way of any double tax treaty exemption or reduction application.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the undersigned has caused this Guaranty to be duly executed and delivered as of the date first above written.

GUARANTOR:

AVADEL PHARMACEUTICALS PLC

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

ACCEPTED:

BREAKING STICK HOLDINGS, LLC

By: /s/ David Clark
Name: David Clark
Title: Authorized Signatory

SCHEDULE A
[To Guaranty by Avadel Pharmaceuticals PLC]

List of the Guarantor and its Subsidiaries

Name of Entity	Jurisdiction
Avadel Pharmaceuticals plc (the "Guarantor")	Ireland
1) Flamel Ireland Limited	Ireland
2) Avadel Investment Company Limited	Cayman Islands
3) Avadel France Holding SAS	France
a) Avadel Reseach SAS	France
4) Flamel U.S. Holdings, Inc.	United States (Delaware)
a) Eclat Pharmaceuticals, LLC	United States (Delaware)

i) Talec Pharmaceuticals, LLC	United States (Delaware)
b) FSC Holdings, LLC	United States (Delaware)
i) FSC Therapeutics, LLC	United States (Delaware)
ii) FSC Laboratories, Inc.	United States (Delaware)
x) FSC Pediatrics, Inc.	United States (Delaware)
c) Avadel Operations Company, Inc.	United States (Delaware)
d) Avadel Management Company	United States (Delaware)

Company Name and Address

[# of shares]
[City] [Date]

Re: Stock options

Dear _____,

We are pleased to inform you that you were granted [_____] stock options in the Company at the Board meeting of the Company held on _____ ___, 201_ according to authorizations provided by the shareholders meetings on August 10, 2016 and according to the rules governing the stock options plan of _____ (the "Rules"), as attached.

Subject to condition of continued employment provided in Section 2.5 of the Rules, these stock options may be exercised for shares according to the following vesting schedule:

- Options for [# of shares] (25%) may be exercised from [date of first anniversary of grant] to [date of ninth anniversary of grant] inclusive
- Options for an additional [# of shares] (25%) may be exercised from [date of second anniversary of grant] to [date of ninth anniversary of grant] inclusive
- Options for an additional [# of shares] (25%) may be exercised from [date of third anniversary of grant] to [date of ninth anniversary of grant] inclusive
- Options for an additional [# of shares] (25%) may be exercised from [date of fourth anniversary of grant] to [date of ninth anniversary of grant] inclusive

The exercise price of the options granted is USD _____.

These stock options are not transferable. We invite you to refer to the Rules for more detail with regard to the rules applicable to your options.

We thank you in advance to duly sign and write "Read and Approved", on the present letter and attached copy of the "Rules" and return them to our HR Department (Evelyne Beauzon or Michelle Moore).

Yours sincerely,

[COMPANY]

By: _____
Name:
Title:

Signature: _____
[Name of Beneficiary]

Attachment: Rules governing the Stock Option Plan 201__

EXECUTION COPY

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into as of the 4th of January, 2017, (the "Effective Date"), by and among Gregory J. Divis ("Executive"), a citizen of the United States currently residing at 1146 Greystone Manor Parkway, Chesterfield, MO 63005; AVADEL PHARMACEUTICALS PLC with a principal office located at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15 Ireland ("Avadel"); and Avadel Management Corporation, a Delaware corporation and affiliate of the Company with a principal office located at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005 ("Avadel Mgt.") together with Avadel (the "Company").

W I T N E S S E T H

WHEREAS, Executive is a citizen of the United States and a resident of the State of Missouri; and

WHEREAS, the Company desires to employ Executive as its Executive Vice President and Chief Commercial Officer; and

WHEREAS, Executive desires to accept such employment with the Company on the terms and conditions contained in this Agreement.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1.EMPLOYMENT TERMS

1.1. Position.

(a) Position at the Company. Executive shall act as Executive Vice President and Chief Commercial Officer for the Company and shall carry out such work reasonably required by the Company in the course of its business consistent with this position. Executive shall work from the Company's offices in the St. Louis, Missouri area (currently in Chesterfield, MO), but shall also travel to and work from the Company's offices in Lyon, France and Dublin, Ireland, to the extent required and appropriate, with the costs associated with such travel borne by the Company. The Executive will devote substantially all of Executive's business hours to the Company, and during such time will make the best use of Executive's energy, knowledge, and training, to advancing the Company's interests. The Executive will accept no other employment during his employment with the Company.

(b) Reporting. In his capacity as Executive Vice President and Chief Commercial Officer for the Company, Executive shall report directly to the Chief Executive Officer, currently Michael S. Anderson.

(c) Confidentiality.

(i) (I) To the fullest extent under applicable law, Executive agrees at all times during the term of this Agreement and for a period of five (5) years after termination of this Agreement, and any applicable extensions thereof, to hold in strictest confidence, and not to use, except for the benefit of the Company to the extent necessary to perform his obligations to the Company under this Agreement, and not to disclose to any person, firm, corporation or other entity without written authorization of the Chief Executive Officer or Board of Directors of the Company, any confidential information of the Company that Executive obtains or creates. Any breach of this obligation will be considered a material breach of this Agreement.

(A) For the avoidance of doubt, confidential information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by Executive in violation of the provisions hereof; or (3) was already in the possession of Executive without an obligation of confidentiality prior to becoming a party to this Agreement.

(d) Non-Disparagement. Executive agrees not to disparage or otherwise refer to Company, its Executives, officers or directors in an unfavorable manner before, during and after the term of this Agreement, including verbal remarks in public or private and written remarks in paper or electronic format (*e.g.*, e-mail, Twitter, Facebook, etc). Violation of this provision will result in termination of Employment and any benefits paid hereunder. Company, together with its executives, officers and directors, agrees not to disparage or otherwise refer to Executive in an unfavorable manner before, during and after the term of this Agreement, including verbal remarks in public or private and written remarks in paper or electronic format (e.g., e-mail, Twitter, Facebook, etc).

(e) Non-Solicitation. For a period of one (1) year after the termination of this Agreement or Executive's employment with the Company, Executive will not directly or indirectly solicit any Company employee to perform services for the Executive or for any other business or entity, whether as an Executive, consultant, partner or participant in any such business or entity. This Section 1.1(e) shall cease to be applicable to any activity of the Executive from and after such time as the Company has ceased all business activities or has made a decision to cease all business activities.

1.2. Status. For as long as he remains an Executive of the Company, Executive's employment shall be governed by the laws of the United States and the State of Missouri to the fullest extent permitted by law. It is the intent of the parties that at all times during Executive's employment with the Company, he will remain a citizen of the United States.

1.3. Duration. This term of this Agreement shall be one (1) year, beginning on the Effective Date, with the Agreement automatically renewing for successive one (1) year periods, unless Executive or the Company provides written notice to the other of his or its intention not to renew the Agreement at least thirty (30) days prior to the next upcoming expiration date. At the

termination of this Agreement, Executive's employment with the Company shall terminate simultaneously.

2. COMPENSATION; BENEFITS

2.1. **Base Salary**. The Company shall pay to Executive a gross annual base salary of Three Hundred Seventy-Five Thousand Dollars ($375,000) per year payable in accordance with the Company's normal payroll practices as are in effect from time to time. The Company will review the base salary on or about the first of every year, and in the Company's sole discretion, make any increases that the Company deems warranted. If the Executive's base salary is increased, the new increased base salary will be the base salary for purposes of this Agreement.

2.2. **Bonus**. The Executive shall be eligible for an annual bonus of up to fifty percent (50%) of Executive's base salary. Payment of the annual bonus will be based upon Executive's achievement of certain business and individual performance objectives as well as the Company's performance against the Company's objectives.

2.3. **Stock Option**.

(a) Grant of Options. Upon approval of the Board of Directors, the Company shall grant to Executive the option ("Option") to purchase One Hundred Fifty Thousand (150,000) shares of the Company's common stock. From time to time, the Company, in its sole discretion, may grant Executive additional shares of Company's common stock in accordance with the Company's stock option plans ("Option Shares")

(b) Vesting. Executive shall vest in the Option Shares in accordance with the Company's approved vesting schedule in accordance with the stock option plan (or other applicable plan).

(c) Exercise of Option. The Option may be exercised as set forth in the Company's stock option plan (or other applicable plan). All shares of the Company's common stock issuable upon the exercise of the Option shall, when issued, be validly issued, fully paid and non-assessable.

2.4. **Auto Allowance**. The Company shall provide Executive an automobile allowance of One Thousand dollars ($1000.00) per month.

2.5. **Insurance and Benefits**.

(a) Plan Participation. The Company shall facilitate Executive's and his family's participation in any group medical, health, vision, dental, hospitalization, and accident insurance, retirement, pension, disability, or similar welfare or pension plan or program of the Company now existing or hereafter established. Executive acknowledges that the current insurance plans are offered through Avadel Mgt. and are subject to reasonable changes at the business discretion of the Company and/or Avadel Mgt.

(b) Vacation and Paid Time Off. Executive shall be eligible for paid vacation and time off in accordance with the policies of the Company applicable to other Executives at similar levels of authority (currently twenty (20) days). Executive shall also be entitled to the Company's usual and customary holidays, including two (2) floating holidays each year, to be taken at Executive's discretion.

(c) Indemnification; General Liability.

(i) To the fullest extent permitted by applicable law, the Company, its receiver, or its trustee shall indemnify, defend, and hold Executive harmless from and against any expense, loss, damage, or liability incurred or connected with any claim, suit, demand, loss, judgment, liability, cost, or expense (including reasonable attorneys' fees) arising from or related to the services performed by him under the terms of this Agreement and amounts paid in settlement of any of the foregoing; provided that the same were not the result of Executive's fraud, gross negligence, or reckless or intentional misconduct. The Company may advance to Executive the costs of defending any claim, suit, or action against him if he undertakes to repay the funds advanced, with interest, should it later be determined that he is not entitled to indemnification under this Section 2.5(c).

(ii) The Company shall provide coverage to Executive for his general liability, director and officer liability, and professional liability insurance at the same levels and on the same terms as provided to its other executive officers.

3. TERMINATION AND SEVERANCE

3.1. Termination.

(a) Nothing in this Agreement shall prevent the Company from terminating Executive's employment with the Company at any time, with or without "Cause." "Cause" means: (i) conviction of Executive or plea to a felony or crime involving moral turpitude; (ii) fraud, theft, or misappropriation by Executive of any asset or property of the Company, including, without limitation, any theft or embezzlement or any diversion of any corporate opportunity; (iii) breach of any of the material obligations contained in this Agreement; (iv) conduct by Executive materially contrary to the material policies of the Company; (v) material failure by Executive to meet the goals and objectives established by the Company; provided that Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such failure; or (vi) conduct by Executive that results in a material detriment to the Company, its program, or goals or is inimical to the Company's reputation and interests; provided that Executive has failed to cure such failure within a reasonable period of time after written notice to him regarding such conduct. Any reoccurrence of such acts constituting Good Cause within one (1) year of the original occurrence will require no such pre-termination right of the Executive to cure.

(b) Executive may terminate Executive's employment with the Company with or without "Good Reason". "Good Reason" means: (i) the failure of the Company to timely pay to the Executive any compensation owed to him under this Agreement; (ii) the Company's diminution in the Executive's duties in any material respect or the Company's assignment to the Executive of

duties that are materially inconsistent with the duties stated in this Agreement; (iii) the relocation of the Company's offices of the Executive's employment more than sixty (60) miles outside the greater St. Louis metropolitan area; (iv) a material breach by the Company of this Agreement; (v) the failure of the Company to have this Agreement assumed in full by any successor in the case of any merger, consolidation, or sale of all or substantially all of the assets of the Company.

(c) In the event that Executive desires to resign from the Company, he shall promptly give the Company written notice of the date that such resignation will be effective, provided that the notice period shall be no less than thirty (30) days. In the event that Executive desires to resign from the Company for Good Reason, he shall provide the Company with written notice setting forth the acts constituting Good Reason within ninety (90) days of the initial occurrence of the Good Reason condition and providing that the Company may cure such acts within thirty (30) days of receipt of such notice. Any reoccurrence of such acts constituting Good Reason within one (1) year of the original occurrence will require no such pre-termination right of the Company to cure.

(d) In the event that the Company desires to terminate Executive's employment, with or without Cause, the Company shall promptly give Executive written notice of the date that such termination will be effective, provided that the notice period shall be no less than thirty (30) days.

3.2. **Severance**. If Executive terminates this Agreement or his employment with the Company for Good Reason or if Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company, the Company shall pay to Executive a severance indemnity of: (i) severance pay equal to Executive's then-current annual base salary, paid in continuous payments in accordance with the Company's normal payroll practices for a period of twelve (12) months; and (ii) all accrued but unpaid vacation, expense reimbursement, wages and other benefits due to Executive under any Company provided plans, policies and arrangements; and (iii) if Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), then the Company will pay for Executive's COBRA premiums for such coverage (at coverage levels in effect immediately prior to Executive's termination) until the earlier of: (A) a period of twelve (12) months from the date of termination or (B) the date upon which Executive becomes covered under similar plans. Executive's receipt of the Severance Indemnity is conditioned upon his and the Company's execution of a reasonable settlement agreement governing the termination of the employment relationship between Executive and the Company. All payments set forth in this Section 3.2(i), (ii) and (iii) are defined as (the "Severance Indemnity").

3.3. **Change of Control**. If Executive terminates this Agreement or his employment with the Company for Good Reason or if Executive's employment with the Company is terminated by the Company for any reason other than for Cause, including non-renewal of this Agreement by the Company, and such termination occurs during a Change of Control Period, the Company shall pay to Executive a change of control indemnity of: (i) the Severance Indemnity as defined in Section 3.2; and (ii) a lump-sum payment equal to one hundred percent (100%) of the higher of: (A) the greater of (x) Executive's target bonus as in effect for the fiscal year in which the Change of Control

occurs or (y) Executive's target bonus as in effect for the fiscal year in which Executive's termination of employment occurs; or (B) Executive's actual bonus for performance during the calendar year prior to the calendar year during which the termination of employment occurs. For avoidance of doubt, the amount paid to Executive pursuant to this Section 3.3 will not be prorated based on the actual amount of time Executive is employed by the Company during the fiscal year (or the relevant performance period if something different than a fiscal year) during which this termination occurs; and (iii) one hundred percent (100%) of Executive's outstanding and unvested Option Shares will become vested in full. Notwithstanding any other provision in any applicable equity compensation plan and/or individual stock option plan or agreement, Executive's outstanding and vested stock options as of the Executive's termination of employment date will remain exercisable until the eighteen (18) month anniversary of the termination of employment date; provided, however, that the post-termination exercise period for any individual stock option right will not extend beyond its original maximum term of the original date of the grant. All payments set forth in this Section 3.3 (i), (ii) and (iii) defined as (the "Change of Control Indemnity").

3.4. Change of Control Definitions. For purposes of Section 3.3 above, the following definitions shall apply: (I) "Change of Control" means the occurrence of any of the following events: (i) A change in the ownership of the Company which occurs on the date that any one person, or more than one person acting as a group ("Person"), acquires ownership of the stock of the Company that, together with the stock held by such Person, constitutes more than fifty percent (50%) of the total voting power of the stock of the Company; provided, however, that for purposes of this subsection, the acquisition of additional stock by any one Person, who is considered to own more than fifty percent (50%) of the total voting power of the stock of the Company will not be considered a Change or Control; or (ii) A change in the effective control of the Company which occurs on the date that a majority of the members of the Board is replaced during any twelve (12) month period by Directors whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purposes of this subsection (ii), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change of Control; or (iii) A change in the ownership of a substantial portion of the Company's assets which occurs on the date that any Person acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than fifty percent (50%) of the total gross fair market value of all of the assets of the Company immediately prior to such acquisition or acquisitions.

(a) "Change of Control Period" means the period beginning six (6) months prior to, and ending eighteen (18) months following, a Change of Control.

4. MISCELLANEOUS

4.1. Entire Agreement. This Agreement (including any exhibits hereto) supersedes any and all other understandings and agreements, either oral or in writing, among the parties with respect to the subject matter hereof and constitutes the sole agreement among the parties with respect to the subject matter hereof.

4.2. **Scverability**. If any term or provision of this Agreement or any application of this Agreement shall be declared or held invalid, illegal, or unenforceable, in whole or in part, whether generally or in any particular jurisdiction, such provision shall be deemed amended to the extent, but only to the extent, necessary to cure such invalidity, illegality, or unenforceability, and the validity, legality, and enforceability of the remaining provisions, both generally and in every other jurisdiction, shall not in any way be affected or impaired thereby.

4.3. **Survival**. Notwithstanding expiration or termination of this Agreement, Sections1.1(c), 1.1(d), 2.3, 2.5(c), Section 3 and Section 4 shall survive such expiration or termination.

4.4. **Interpretation of Agreement**.

(a) Unless otherwise indicated to the contrary herein by the context or use thereof: (i) the words, "herein," "hereto," "hereof," and words of similar import refer to this Agreement as a whole and not to any particular Article, Section, subsection, or paragraph hereof; (ii) words importing the masculine gender shall include the feminine and neuter genders and vice versa; and (iii) words importing the singular shall include the plural, and vice versa.

(b) All parties to this Agreement have participated fully in the negotiation of this Agreement. This Agreement has been prepared by all parties equally, and is to be interpreted according to its terms. No inference shall be drawn that the Agreement was prepared by or is the product of any particular party or parties.

4.5. **Taxes**. The parties hereto acknowledge that the requirements of Section 409A of the Internal Revenue Code ("Section 409A") are still being developed and interpreted by government agencies and that the parties hereto have made a good faith effort to comply with current guidance under Section 409A. Notwithstanding anything in this Agreement to the contrary, in the event that amendments to this Agreement are necessary in order to continue to comply with future guidance or interpretations under Section 409A, including amendments necessary to ensure that compensation will not be subject to tax under Section 409A (which may require deferral of severance or other compensation), the Company and the Executive agree to negotiate in good faith the applicable terms of such amendments and to implement such negotiated amendments, on a prospective and/or retroactive basis as needed. Further, to the extent any amount or benefit under this Agreement is subject to the requirements of Section 409A, then, with respect to such amount or benefit, this Agreement will be interpreted in a manner to comply with the requirements of Section 409A. Further, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or as a result of a termination of employment unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination", "termination of employment", "Termination Date", or the like shall mean "separation from service".

The Company makes no warranty regarding the tax treatment to the Executive of payments provided for under this Agreement, including the tax treatment of such payments that may be subject to Section 409A. The Executive will be responsible for paying all federal, state, and local income

and employment taxes that may be due on such payment, provided that the Company will be responsible for any withholding obligations under applicable law.

4.6. Governing Law. Notwithstanding the place where this Agreement may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be construed in accordance with and governed by the laws of the State of Missouri, without giving effect to the principles of choice or conflicts of laws thereof. Each of the parties hereto consents and agrees to the exclusive personal jurisdiction of any state or federal court sitting in the State of Missouri, and waives any objection based on venue or forum non conveniens with respect to any action instituted therein, and agrees that any dispute concerning the conduct of any party in connection with this Agreement shall be heard only in the courts described above.

4.7. Binding Arbitration.

(a) All disputes arising under this Agreement or arising out of or relating to Executive's employment relationship with the Company shall be submitted to final and binding arbitration. Arbitration of such matters shall proceed consistent with the National Rules for the Resolution of Employment Disputes as established by the American Arbitration Association. Venue for any arbitration shall be St. Louis, Missouri or any other location mutually agreed upon by Executive and the Company.

(b) The arbitration shall be conducted using the Expedited Procedures of the AAA Rules, regardless of the amount in dispute.

(c) The disputing parties shall agree on an arbitrator qualified to conduct American Arbitration Association ("AAA") arbitration. If the disputing parties cannot agree on the choice of arbitrator, then each party shall choose one independent arbitrator. The two arbitrators so chosen shall jointly select a third arbitrator, who shall conduct the arbitration.

(d) All disputes relating to this Agreement shall be governed by the laws of the State of Missouri, and the arbitrator shall apply such law without regard to the principles of choice or conflicts of laws thereof.

(e) All aspects of the arbitration shall be treated as confidential.

(f) The prevailing party, as determined by the arbitrator, shall recover his or its reasonable costs and attorneys' fees associated with the arbitration. The non-prevailing party shall be liable for the arbitrator's fees and costs.

(g) The decision of the arbitrator shall be final, and the parties agree to entry of such decision as judgments in all courts of appropriate jurisdiction.

4.8. Amendments. This Agreement shall not be modified or amended except by a writing signed by all of the parties.

4.9. Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the successors and assigns of each party hereto.

4.10. No Assignment.

(a) This Agreement and all of Executive's rights and obligations hereunder are personal to Executive and may not be transferred or assigned by him at any time, except that any assets accruing to Executive in connection with this Agreement shall accrue to the benefit of Executive's heirs, executors, administrators, successors, permitted assigns, trustees, and legal representatives.

(b) The Company may assign its rights under this Agreement to any entity that assumes the Company's obligations hereunder in connection with merger, consolidation or sale or transfer of all or substantially all of the Company's assets to such entity.

4.11. Waiver. Any of the terms or conditions of this Agreement may be waived at any time by the party or parties entitled to the benefit thereof, but only by a writing signed by the party or parties waiving such terms or conditions. No waiver of any provision of this Agreement or of any right or benefit arising hereunder shall be deemed to constitute or shall constitute a waiver of any other provision of this Agreement (whether or not similar), nor shall any such waiver constitute a continuing waiver, unless otherwise expressly so provided in writing.

4.12. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Agreement may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Agreement.

[*Signature page follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date and year first above written.

THE COMPANY

AVADEL PHARMACEUTICALS PLC

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

AVADEL MANAGEMENT CORPORATION

By: /s/ Phil Thompson
Name: Phil Thompson
Title: Senior Vice President and General Counsel

EXECUTIVE

By: /s/ Gregory J. Divis
Name: Gregory J. Divis

Exhibit 21.1

List of Subsidiaries

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

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-177591, 333-212585 and 333-213154) and on Form S-3 (No. 333-183961) of Avadel Pharmaceuticals PLC (formerly Flamel Technologies S.A.) of our report dated March 15, 2016, except for the effects of the revisions discussed in Note 1 to the consolidated financial statements, as to which the date is March 28, 2017, relating to the financial statements and financial statement schedule, which appears in this Form 10-K.

Lyon, France,
March 28, 2017

PricewaterhouseCoopers Audit

Represented by
/s/ Frédéric Charcosset
Frédéric Charcosset

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No.'s 333-213154, 333-212585 and 333-177591 on Form S-8 and No. 333-183961 on Form S-3 of our report dated March 28, 2017, relating to the 2016 consolidated financial statements and 2016 financial statement schedule of Avadel Pharmaceuticals PLC (the "Company") and the effectiveness of the Company's internal control over financial reporting (which internal control report expresses an adverse opinion on the Company's internal control over financial reporting because of material weaknesses), appearing in the Annual Report on Form 10-K of Avadel Pharmaceuticals PLC for the year ended December 31, 2016.

/s/ Deloitte and Touche LLP
St. Louis, Missouri
March 28, 2017

Exhibit 31.1
CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Michael S. Anderson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Avadel Pharmaceuticals plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2017

/s/ Michael S. Anderson
Michael S. Anderson
Chief Executive Officer

Exhibit 31.2
CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Michael F. Kanan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Avadel Pharmaceuticals plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2017

/s/ Michael F. Kanan

Michael F. Kanan

Senior Vice President and Chief Financial Officer

Exhibit 32.1

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

In connection with the annual report of Avadel Pharmaceuticals plc (the "Company") on Form 10-K for the period ending December 31, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael S. Anderson, Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. §1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ Michael S. Anderson

Michael S. Anderson
Chief Executive Officer
Avadel Pharmaceuticals plc
March 28, 2017

Exhibit 32.2

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

In connection with the annual report of Avadel Pharmaceuticals plc (the "Company") on Form 10-K for the period ending December 31, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael F. Kanan, Senior Vice President and Chief Financial Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ Michael F. Kanan

Michael F. Kanan
Senior Vice President and Chief Financial Officer
Avadel Pharmaceuticals plc
March 28, 2017