

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

**FORM 8-K**

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

Date of Report (Date of earliest event reported): **June 13, 2019**

**AVADEL PHARMACEUTICALS PLC**

(Exact name of registrant as specified in its charter)

<b>Ireland</b> (State or Other Jurisdiction of Incorporation)	<b>001-37977</b> (Commission File Number)	<b>98-1341933</b> (I.R.S. Employer Identification No.)
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<b>Block 10-1</b> <b>Blanchardstown Corporate Park,</b> <b>Ballycoolin</b> <b>Dublin 15, Ireland</b> (Address of Principal Executive Offices)	<b>Not Applicable</b> (Zip Code)
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Registrant's telephone number, including area code: **+353 1 485 1200**

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

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

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

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

On June 13, 2019, Avadel Pharmaceuticals plc (the “Company”) furnished to the holders of its ordinary shares and American Depositary Shares (collectively, “Holders”) a copy of the Company’s Irish statutory financial statements and related reports of the Company for the period beginning January 1, 2018 through December 31, 2018, along with the related directors’ and independent auditor’s reports, which have been prepared pursuant to Irish law (collectively, the “Irish Statutory Accounts”). The Irish Statutory Accounts will be presented by management at the Company’s Annual General Meeting of Shareholders which is scheduled to be held at 10:00 AM (Irish Standard Time) on Tuesday, August 6, 2019 at the offices of Arthur Cox, Ten Earlsfort Terrace, Dublin 2, D02 T380, Ireland. The Irish Statutory Accounts will be sent to Holders in advance of the Company’s Annual General Meeting, as required by Irish law.

The Irish Statutory Accounts are based on the Company’s financial statements which were prepared in accordance with U.S. generally accepted accounting principles (“US GAAP”) and which were filed as part of the Company’s Annual Report on Form 10-K; provided, however, that the Irish Statutory Accounts include disclosures and presentation formats required by the Irish Companies Act 2014 and which may not be required by US GAAP. A copy of the Irish Statutory Accounts is furnished as Exhibit 99.1 to this current report on Form 8-K and is incorporated herein by reference.

The Irish Statutory Accounts will be available on the Company’s website, [www.avadel.com](http://www.avadel.com).

The information in this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or as otherwise subject to liability of that section, nor shall such information be deemed to be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Exchange Act.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 Irish Statutory Accounts for the period beginning January 1, 2018 through December 31, 2018.

**SIGNATURES**

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

**AVADEL PHARMACEUTICALS PLC**

By: /s/ Phillandas T. Thompson

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Phillandas T. Thompson  
Senior Vice President, General Counsel and  
Corporate Secretary

Date: June 13, 2019

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**Exhibit Index**

- 99.1 Irish Statutory Accounts for the period beginning January 1, 2018 through December 31, 2018.





2018 IRISH STATUTORY ACCOUNTS

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**AVADEL PHARMACEUTICALS PLC**

**Directors' Report and Consolidated Financial Statements**

**For the Financial Year Ended 31 December, 2018**



**AVADEL PHARMACEUTICALS PLC**  
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## DIRECTORS' REPORT

**For the Financial Year Ended 31 December, 2018**  
**(dollars in thousands, except share data and where indicated)**

### **Overview**

The directors present their report on the audited consolidated financial statements for the financial year ended 31 December, 2018, which are set out on pages [45](#) to [94](#), and audited parent Company financial statements for the financial period ended 31 December, 2018, which are set out on pages [100](#) to [112](#).

The directors have elected to prepare the Irish statutory group consolidated financial statements of Avadel Pharmaceuticals plc in accordance with Section 279 of the Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position, and profit or loss may be given by preparing the financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of part 6 of the Companies Act 2014.

The directors have elected to prepare the Avadel Pharmaceuticals plc parent Company financial statements in accordance with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* (Generally Accepted Accounting Practice in Ireland) and the Companies Act 2014.

### ***Basis of Presentation***

The accompanying financial statements reflect the consolidated financial position of the parent Company ("Avadel Pharmaceuticals plc" or "the Group") and its subsidiaries (Avadel Pharmaceuticals plc and all its subsidiaries, hereinafter referred to as "Avadel", "the Group", "us", "we", or "our") as an independent, publicly-traded Group.

### ***Trademarks and Trade Names***

Avadel owns or has rights to use trademarks and trade names that it uses in conjunction with the operation of its business. One of the more important trademarks that it owns or has rights to use that appears in this Directors' Report is "Avadel," which is a registered trademark or the subject of pending trademark applications in the United States ("U.S.") and other jurisdictions. Solely for convenience, we only use the <sup>TM</sup> or <sup>®</sup> symbols the first time any trademark or trade name is mentioned. Such references are not intended to indicate in any way that we will not assert, to the fullest extent permitted under applicable law, our rights to our trademarks and trade names. Each trademark or trade name of any other Group appearing in this Directors' Report is, to our knowledge, owned by such other Group.

### ***Forward-Looking Statements***

We have made forward-looking statements in this Directors' Report that are based on management's beliefs and assumptions and on information currently available to management. Forward-looking statements include, but are not limited to, information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, potential growth opportunities, potential operating performance improvements, the effects of competition and the effects of future legislation or regulations. Forward-looking statements include all statements that are not historical facts and can be identified by the use of forward-looking terminology such as the words "believe," "expect," "plan," "intend," "project," "anticipate," "estimate," "predict," "potential," "continue," "may," "should" or the negative of these terms or similar expressions.

Forward-looking statements involve risks, uncertainties and assumptions. Actual results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any forward-looking statements.

The principal risks and uncertainties included in this Directors' Report could cause our results to differ materially from those expressed in forward-looking statements. There may be other risks and uncertainties that we are unable to predict at this time or that we currently do not expect to have a material adverse effect on our business.



These forward-looking statements are made as of the 31 December, 2018. We expressly disclaim any obligation to update these forward-looking statements other than as required by law.

### ***Principal Activities***

Avadel Pharmaceuticals plc (Nasdaq: AVDL) (“Avadel,” the “Group,” “we,” “our,” or “us”) is a branded specialty pharmaceutical Group. Our primary focus is on the development and potential FDA approval for FT218 which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. In addition, we market three sterile injectable drugs used in the hospital setting which were developed under our “unapproved marketed drug” (UMD) program. The Group is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit [www.avadel.com](http://www.avadel.com).

Our current marketed products include:

- *Akovaz*<sup>®</sup> (ephedrine sulfate injection, USP), an alpha- and beta-adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
- *Bloxiverz*<sup>®</sup> (neostigmine methylsulfate injection), a cholinesterase inhibitor, is indicated for the reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery.
- *Vazculep*<sup>®</sup> (phenylephrine hydrochloride injection), an alpha-1 adrenergic receptor agonist indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

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

In 2018, Avadel Specialty Pharmaceuticals LLC (“Specialty Pharma”) marketed *Noctiva*<sup>™</sup>, a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. Due to disappointing results after a substantial investment of resources after *Noctiva*’s commercial launch in March 2018, Specialty Pharma, the Avadel subsidiary responsible for the marketing and sale of *Noctiva*, made a voluntary filing for Chapter 11 bankruptcy protection on 6 February, 2019. As a result of Specialty Pharma’s bankruptcy filing on 6 February, 2019, Avadel has ceded authority for managing the business to the Bankruptcy Court, and Avadel management cannot carry on Specialty Pharma’s activities in the ordinary course of business without Bankruptcy Court approval. Avadel manages the day-to-day operations of Specialty Pharma, but does not have discretion to make significant capital or operating budgetary changes or decisions and purchase or sell significant assets, as Specialty Pharma’s material decisions are subject to review by the Bankruptcy Court. For these reasons, we have concluded that Avadel has lost control of Specialty Pharma, and no longer has significant influence over Specialty Pharma during the pendency of the bankruptcy. Therefore, we deconsolidated Specialty Pharma effective with the filing of the Chapter 11 bankruptcy in February 2019. On 26 April, 2019, Specialty Pharma sold its intangible assets and remaining inventory to an unaffiliated third party in exchange for aggregate cash proceeds of approximately \$250, pursuant to an order approving such sale which was issued by the Bankruptcy Court on 15 April, 2019. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the *Noctiva* business.

### ***Corporate Information***

The Company was incorporated in Ireland on 1 December, 2015 as a private limited Company, and re-registered as an Irish public limited Company on 21 November, 2016 (Company registration number: 572535). Its headquarters are in Dublin, Ireland and it has operations in St. Louis, Missouri, United States, and Lyon, France. The address of its registered office is Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15, Ireland.

The Group is the successor to Flamel Technologies S.A., a French société anonyme (“Flamel”), as the result of the Merger described above, in which Flamel merged with and into the Group at 11:59:59 p.m., Central Europe Time, on 31 December, 2016 (the “Merger”) pursuant to the agreement between Flamel and Avadel

entitled Common Draft Terms of Cross-Border Merger dated as of 29 June, 2016 (the “Merger Agreement”). Immediately prior to the Merger, the Group 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 Group 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 Group, \$0.01 nominal value per share. This change in nominal value of our outstanding shares resulted in our reclassifying \$5,937 on our consolidated balance sheet from ordinary shares to other reserves.
  - 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 Group.

Thus, the Merger changed the jurisdiction of our incorporation from France to Ireland, and an ordinary share of the Group 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 “Group,” “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 Group’s ADSs were listed for and began trading on Nasdaq on 3 January, 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 5 July, 2016.

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

The Group currently has five direct wholly owned operating subsidiaries: Avadel US Holdings, Inc., Flamel Ireland Limited, trading under the name Avadel Ireland, Avadel Investment Company Limited, Avadel France Holding SAS and Avadel Finance Ireland Designated Activity Group. Avadel US Holdings, Inc. is a Delaware corporation, and is the holding entity of FSC Holdings, LLC, Avadel Legacy Pharmaceuticals, LLC (formerly Éclat Pharmaceuticals, LLC), Avadel Management Corporation, Avadel Operations Group, Inc. and Avadel Specialty Pharmaceuticals. Avadel Ireland is a corporation organized under the laws of Ireland and is where all intangible property was relocated on 16 December, 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 Group’s research and development activities take place. A complete list of the Group’s subsidiaries can be found in *Note 29: Subsidiary Undertakings* to the Notes to the consolidated financial statements.

**Dividends**

No dividends have been paid in the current or preceding period, other than the buyback of our shares. We currently do not anticipate paying any cash dividends for the foreseeable future, as we intend to retain earnings to finance R&D, acquisitions and the continued operation and expansion of our business. The recommendation, declaration and payment of any dividends in the future by us will be subject to the sole discretion of our board of directors and will depend upon many factors, including our financial condition, earnings, capital requirements of our operating subsidiaries, covenants associated with certain of our debt obligations, legal requirements, regulatory constraints and other factors deemed relevant by our board of directors. Moreover, if we determine to pay dividends in the future, there can be no assurance that we will continue to pay such dividends.

**Share Capital**

For the changes in share capital, see *Note 18: Equity Instruments and Stock Based Compensation*.

**Share Repurchase Program**

In March 2017, the Board of Directors approved an authorization to repurchase up to \$25,000 of Avadel ordinary shares represented by ADSs. Under this authorization, which has an indefinite duration, share repurchases may be made in the open market, in block transactions on or off the exchange, in privately negotiated transactions, or through other means as determined by the Board of Directors and in accordance with the regulations of the Securities and Exchange Commission. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our shares, cash resources, alternative investment opportunities, corporate and regulatory requirements and market conditions. This share repurchase program may be modified, suspended or discontinued at any time without prior notice. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. Additionally, on February 12, 2018, the Board of Directors approved an authorization to repurchase up to \$18,000 of Avadel ordinary shares represented by American Depository Shares in connection with our Convertible Notes Offering completed on 16 February, 2018. See *Note 15: Long-Term Debt*. In March 2018, the Board of Directors approved an authorization to repurchase up to \$7,000 of Avadel ordinary shares represented by American Depository Shares, bring the total authorization to \$50,000.

As of 31 December, 2018, the Group holds 5,407 of its own shares, of which \$49,998 of consideration paid for these shares has been deducted from the Profit and Loss Account. Out of the total shares acquired during the year ended 31 December 2018, there were no shares sold or canceled during the same period. The Group fully completed its authorized share buyback program.

<b>Reconciliation:</b>	<b>Number of ordinary shares held/acquired</b>	<b>Aggregate consideration paid</b>	<b>% of the Share Capital</b>
Balance at 1 January 2017	—	\$ —	—%
Acquired:	<u>2,117</u>	<u>22,361</u>	<u>5.1%</u>
Balance at 31 December 2017	2,117	\$ 22,361	5.1%
Acquired:	<u>3,290</u>	<u>27,637</u>	<u>7.6%</u>
Balance at 31 December 2018	<u>5,407</u>	<u>\$ 49,998</u>	<u>12.7%</u>

**Business Review and Key Performance Indicators**

Loss after taxation of \$95,304 for fiscal 2018 and profit after taxation of \$68,271 for fiscal 2017 were debited and credited to reserves, respectively. No profits were distributed as dividends, other than the buyback of our shares, during fiscal 2018 and 2017. The following table presents the consolidated profit and loss account, with percentage of turnover:

	Fiscal Year				2018 vs. 2017	
	2018		2017		\$	%
Turnover	\$ 103,269	100.0%	\$173,245	100%	\$ (69,976)	(40.4)%
Cost of sales	(17,516)	(17.0)	(16,301)	(9.4)	(1,215)	7.5%
Gross profit	85,753	83.0	156,944	90.6	(71,191)	(45.4)%
Research and development costs	(39,329)	(38.1)	(33,418)	(19.3)	(5,911)	(17.7)%
Distribution and administrative expenses	(100,359)	(97.2)	(58,860)	(34.0)	(41,499)	(70.5)%
Intangible asset amortization	(6,619)	(6.4)	(3,659)	(2.1)	(2,960)	(80.9)%
Gain – changes in fair value of related party contingent consideration	22,731	22.0	31,040	17.9	(8,309)	26.8%
Impairment of intangible asset	(66,087)	(64.0)	—	—	(66,087)	n/a
Restructuring costs	(1,016)	(1.0)	(2,542)	(1.5)	1,526	60.0%
Operating (loss) profit	(104,926)	(101.6)	89,505	51.7	(194,431)	217.2%
Interest income	1,535	1.5	3,155	1.8	(1,620)	(51.3)%
Interest expense	(10,622)	(10.3)	(1,052)	(0.6)	(9,570)	(909.7)%
Other income – changes in fair value of related party payable	1,899	1.8	2,071	1.2	(172)	8.3%
Foreign exchange gain (loss)	213	0.2	(714)	(0.4)	927	(129.8)%
Other expense	(1,296)	(1.3)	(305)	(0.2)	(991)	324.9%
(Loss) profit on ordinary activities before taxation	(113,197)	(109.6)	92,660	53.5	(205,857)	222.2%
Taxation credit (charge)	17,893	17.3	(24,389)	(14.1)	42,282	(173.4)%
(Loss) profit after taxation	\$ (95,304)	(92.3)	\$ 68,271	39.4	\$ (163,575)	239.6%

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

Turnover:	Fiscal Year				Increase/(Decrease)	
	2018		2017		\$	%
Bloxiverz	\$ 20,850	20.2%	\$ 45,596	26.3%	\$(24,746)	(54.3)%
Vazculep	42,916	41.6	38,187	22.0	4,729	12.4%
Akovaz	33,759	32.7	80,617	46.5	(46,858)	(58.1)%
Noctiva	1,204	1.2	—	n/a	1,204	n/a
Other	2,694	2.6	8,441	4.9	(5,747)	(68.1)%
Sales and service turnover	101,423	98.3	172,841	99.7	(71,418)	(41.3)%
License and research turnover	1,846	1.7	404	0.3	1,442	356.9%
Turnover	\$103,269	100.0	\$173,245	100.0	\$(69,976)	(40.4)%

*Turnover*

Product sales and services revenues were \$101,423 for the year ended 31 December, 2018, compared to \$172,841 for the same prior year period. Bloxiverz's revenue declined \$24,746 when compared to the same period last year, primarily due to lower net selling prices driven largely by new competitors that entered the market in 2017 and 2018 and continued market penetration from an alternative molecule to neostigmine. Vazculep's revenue increased by \$4,729 due primarily an increase in unit volumes partially offset by lower net realized net selling prices when compared to the prior year. Akovaz's revenue decreased \$46,858 driven by lower unit volumes and net selling prices due largely to new competitors that entered the market in 2017. Total product sales during the year ended 31 December, 2018 also include \$1,204 of revenues attributable to Noctiva, which launched in March 2018. Other revenues, which includes the pediatric products which were divested in February 2018, declined when compared to the prior year due to the divestiture of those products.

License and research revenue was \$1,846 for the year ended 31 December, 2018 compared to \$404 in the same period last year. In December 2018, the Group reached an agreement to exit a contract and our remaining performance obligations and recognized the remaining \$1,600 of deferred revenue, which represented the unsatisfied performance obligations associated with a license agreement.

*Gross profit*

Gross profit for fiscal 2018 decreased \$71,191, or 45.4%, to \$85,753, compared with \$156,944 in fiscal 2017. The decrease in gross profit primarily resulted from the previously mentioned decreased turnover of Akovaz and Bloxiverz.

*Research and Development Cost*

Research and development ("R&D") cost increased \$5,911 or (17.7)% and increased as a percentage of turnover to 38.1% during the year ended 31 December, 2018 as compared to the same period in 2017. This increase is largely due to higher spending on the Group's FT218 Phase 3 sodium oxybate clinical study. The Group continues to spend a substantial portion of its R&D spending on this study. Additionally, a portion of this increase was due to increased R&D costs of approximately \$1,100 associated with Noctiva. For amounts of R&D that have been committed in subsequent years, see *Note 19: Contingent Liabilities and Commitments*.

*Distribution and Administrative Expenses*

Distribution and administrative expenses increased \$41,499 or (70.5)% and increased as a percentage to turnover to 97.2% during the year ended 31 December, 2018 as compared to the same prior year. This increase was primarily due to approximately \$48,500 of sales and marketing costs associated with the March 2018 launch of Noctiva, partially offset by approximately \$8,700 of lower SG&A spend related to the February 2018 divestiture of the Group's pediatric assets.

*Intangible Asset Amortization*

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

*Changes in Fair Value of Related Party Contingent Consideration*

We compute the fair value of the related party contingent consideration using several significant assumptions and when these assumptions change, due to underlying market conditions, the fair value of these liabilities change as well. Each of the underlying assumptions used to determine the fair values of these contingent liabilities can, and often do, change based on adjustments in current market conditions, competition and other factors. These changes can have a material impact on our consolidated profit and loss account and balance sheet.

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

For the year ended 31 December, 2018, as a result of changes to these estimates when compared to the same estimates at 31 December, 2017, we recorded a decrease in the fair value of our contingent consideration liabilities, primarily as a result of a weaker long-term sales and gross profit outlook for Bloxiverz, Vazculep and Akovaz due to more competition and other changes in certain underlying market conditions of the acquisition-related contingent consideration earn-out payments — Éclat.

#### *Impairment of Intangible Asset*

During the fourth quarter of 2018, an impairment charge of \$66,087 was recorded to write-off the remaining carrying value of the acquired developed technology intangible asset related to Noctiva. During the fourth quarter 2018, certain conditions came to light, largely the lack of a meaningful increase in Noctiva prescriptions despite the substantial investment of resources, which indicated that the carrying value of the asset, may not be fully recoverable. As such, the Group performed an impairment test based on a comparison of the pretax discounted cash flows expected to be generated by the asset, which is a Level 3 fair value estimate, to the recorded value of the asset and concluded that the associated cash flows did not support any of the carrying value of the intangible asset and the Group recorded a full impairment charge. The 6 February, 2019 Chapter 11 bankruptcy filing of Specialty Pharma, the subsidiary which markets, sells and distributes Noctiva, confirmed management's conclusion on the impairment. There were no such impairment costs during the year ended December 31, 2017.

#### *Interest Expense*

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

#### *Other Expense — Changes in Fair Value of Related Party Payable*

We recorded income of \$1,899 and \$2,071 to reduce the fair value of these liabilities during the years ended 31 December, 2018 and 2017, respectively, due to the same reasons associated with the Éclat product sales forecasts as described in the section "Changes in Fair Value of Related Party Contingent Consideration" for these periods. As noted in our critical accounting estimates section, there are a number of assumptions and estimates we use when determining the fair value of the related party payable payments. These estimates include pricing, market size, the market share the related products are forecast to achieve and an appropriate discount rate to use when present valuing the related cash flows. These estimates often do change based on changes in current market conditions, competition and other factors.

#### *Foreign Exchange Gains*

We recorded a foreign exchange income of \$213, for the year ended 31 December, 2018 compared to a foreign exchange loss of \$714 for the year ended 31 December, 2017. This increase was driven by an overall decrease in the Euro foreign exchange rate during 2018 when compared to an overall increase in the Euro foreign exchange rate during 2017.

#### *Taxation*

In 2018, the taxation charge decreased by \$2,282 when compared to the same period in 2017. The primary reason for the decrease in the taxation charge is a substantially lower level of pre-tax book income in the United States.

Balance Sheet Data:	Fiscal Year		2018 vs. 2017	
	2018	2017	\$	%
Cash in bank and in hand	\$ 9,325	\$ 16,564	\$ (7,239)	(43.7)%
Investments	90,590	77,511	13,079	16.9%
Intangible assets, net	20,120	110,780	(90,660)	(81.8)%
Creditors	(146,088)	(78,515)	(67,573)	86.1%
Provision for liabilities	(41,432)	(89,182)	47,750	(53.5)%
Shareholders' Funds	2,780	85,580	(82,800)	(96.8)%

#### *Intangible assets, net*

Intangible assets, net decreased \$90,660 due to the \$66,087 impairment of the Noctiva intangible asset in the fourth quarter (see *Note 11: Intangible Assets*), the February 2018 disposition of the pediatric products which eliminated the intangibles related to these products (see *Note 26: Divestiture of the Pediatric Products*) and normal monthly amortization.

#### *Creditors*

Creditors increased \$67,573 driven by the issuance of the 2023 Notes (see *Note 15: Long-Term Debt*), partially offset by the \$20,000 ELAA payment related to Noctiva (see *Note 12*) and the elimination of the \$15,000 long-term liability related to FSC due to the February 2018 disposition of the pediatric products (see *Note 13* and *Note 26*).

#### *Provision for Liabilities*

Decrease is driven by the decrease in the related party payable. See *Note 14* and *Note 16*.

#### *Shareholders' Funds*

Decrease is driven by the 2018 net loss and the repurchase of shares, partially offset by the equity component of the 2023 Notes. See the Consolidated Statement of Changes in Shareholders' Equity and *Note 18*.

### **Business Strategies**

Our primary business strategy is to focus on the development and potential FDA approval for FT218 which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. In addition, we will continue to maximize our current approved hospital products portfolio, including obtaining FDA approval for and the commercialization of our fourth UMD product. Additionally, we will continue to evaluate opportunities to expand our product portfolio. These strategies are described below in greater detail.

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

In preparation for a clinical trial of FT218, Avadel reached an agreement with the FDA for the design and planned analysis of our pivotal Phase 3 study, Rest-On through a Special Protocol Assessment ("SPA"). A SPA is an acknowledgment by the FDA that the design and planned analysis of a pivotal clinical trial adequately addresses the objectives necessary to support a regulatory submission. Pursuant to the SPA, in December 2016, Avadel initiated patient enrollment and dosing for the Rest-On clinical trial to assess the safety and efficacy of a once-nightly formulation of FT218 for the treatment of EDS and cataplexy in

patients suffering from narcolepsy. The study is a randomized, double-blind, placebo-controlled study of 264 patients being conducted in 45 to 55 clinical sites in the U.S., Canada, Western Europe and Australia. Avadel believes that, if successful, this study could demonstrate improved efficacy, safety and patient satisfaction over the current primary product serving this market, which is a twice nightly sodium oxybate formulation, which the marketer generated revenues of approximately \$1.4 billion in 2018.

To date, due in part to narcolepsy being a rare disease with a small patient population with no significant geographic concentration, we have not completed patient enrollment for the FT218 clinical trial. However, we have announced a projected completion date for this clinical trial is estimated to be during the second half of 2020. Recently, we have engaged a third-party pharmaceutical consulting firm to assist us in evaluating our clinical development program for FT218 with the goal of ensuring an approvable and commercially viable FDA submission. This evaluation is currently under way, and while the results are not known at this time, they could cause us to modify our development plan with respect to FT218 in ways that materially increase the ultimate cost of development, further delay its completion or identify presently unknown risks with the product.

In January 2018, the FDA granted FT218 Orphan Drug Designation, which makes the drug eligible for certain development and commercial incentives, including a potential U.S. market exclusivity for up to seven years as the only once-nightly formulation. However, please see the information set forth under the caption “— Risks Related to Regulatory and Legal Matters — If FT218 is approved by the FDA, we may not obtain orphan drug marketing exclusivity” in the “Principal Risks and Uncertainties” included in this Directors Report.

#### ***Development of Micropump<sup>®</sup>-Based Products***

Avadel’s versatile Micropump<sup>®</sup> drug delivery technology presents product development opportunities, representing either “life cycle” opportunities, whereby additional intellectual property can be added to a pharmaceutical product to extend the commercial viability of a currently marketed product, or innovative formulation opportunities for new chemical entities (“NCEs”). FT218 is formulated using this technology. If approved by the FDA, this product will be commercialized either by Avadel and/or by partners via licensing/distribution agreements.

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

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

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

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



- **Vazculep® (phenylephrine hydrochloride injection)** On June 28, 2013, Avadel filed an NDA for Vazculep (phenylephrine hydrochloride injection). The product was approved by the FDA on June 27, 2014 and is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. Avadel started shipping Vazculep (in 1mL single use vials, and 5mL and 10mL pharmacy bulk package vials) to wholesalers in October 2014. There are approximately 7 million vials sold annually in the U.S. Vazculep is the only FDA-approved version of phenylephrine hydrochloride to be available in all three vial sizes. Avadel competes against one other manufacturer who commercializes the 1mL single-dose vial. The volume of sales of Vazculep is dependent upon the competitive landscape in the marketplace, and potential for new competitors that may receive generic approvals in the future.
- **Akovaz® (ephedrine sulfate injection).** On June 30, 2015, Avadel announced that our third NDA was accepted by the FDA; the FDA subsequently approved Akovaz on April 29, 2016. On August 12, 2016, Avadel launched Akovaz, into a market of approximately 7.5 million vials annually in the U.S. Avadel was the first approved formulation of ephedrine sulfate, an alpha- and beta-adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. Avadel began shipping the product to wholesalers in August 2016 in cartons of twenty-five 50 mg/mL 1mL single use vials. During 2016 Akovaz was the only FDA approved version of ephedrine sulfate being commercially sold in the U.S. To date, there are three other approved manufacturers of ephedrine sulfate with whom Avadel competes. The volume of sales of Akovaz is dependent upon the competitive landscape in the marketplace, and potential for new competitors that may receive generic approvals in the future.

*Additional UMD Products.* Avadel is developing and intends to seek FDA approval of a NDA for UMD #4, a sterile injectable product used in the hospital setting. The Group submitted an NDA during the first quarter of 2019 on UMD #4, which, if approved, could contribute revenues to Avadel starting in 2020. On 22 May, 2019, the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for the Company's fourth Hospital Product, AV001. It has been granted Priority Review status by the FDA resulting in a six-month review period. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of September 15, 2019. In addition, Avadel continues to monitor and evaluate other UMDs with large existing markets and limited competition for feasibility of possible future NDAs. Avadel believes its strategy to create opportunities to commercialize UMD products in markets with a limited number of competitors may have a limited number of opportunities given the lack of patent protection from competition. Avadel believes this shorter-term strategy may provide us with near term revenue growth and provide cash flows that can be used to fund R&D and inorganic initiatives for other products.

### Proprietary Product Pipeline

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

Proprietary Product Pipeline			
Platform/Strategy	Drug/Product	Indication	Stage
Micropump®	Sodium oxybate	EDS/Cataplexy	Phase 3 trial ongoing
UMD #4	Sterile Injectable – Drug Undisclosed	Undisclosed	New Drug Application filed and pending FDA review

### Competition and Market Opportunities

#### Competition

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. Avadel competes with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing brand or generic specialty pharmaceutical products or drug delivery platforms. Some of these competitors may also be Avadel's business partners. There can be no assurance that Avadel's competitors will not obtain patent

protection or other intellectual property rights that would make it difficult or impossible for us to compete with their products. Furthermore, major technological changes can happen quickly in the pharmaceutical and biotechnology industries. Such rapid technological change, or the development by Avadel's competitors of technologically improved or differentiated products, could render our products, including our drug delivery technologies, obsolete or noncompetitive.

The pharmaceutical industry has dramatically changed in recent years, largely as a function of the growing importance of generic drugs. The growth of generics (typically small molecules) and of large molecules (biosimilars) has been accelerated by the demand for less expensive pharmaceutical products. As a result, the pricing power of pharmaceutical companies will be more tightly controlled in the future.

In addition, the overall landscape of the Pharma/Biotech industry has changed, as consolidation has reduced Avadel's pool of potential partners and acquisition opportunities within the specialty pharmaceutical space.

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

#### *Potential competition for FT 218*

If FT218 receives FDA approval, it will compete with the current approved twice-nightly sodium oxybate formulation, as well as a number of daytime stimulants including lisdexamfetamine, modafinil, armodafinil, which are widely prescribed, or prescribed concomitantly with sodium oxybate. Sodium oxybate is currently the only product approved for both EDS and cataplexy. In addition, Avadel anticipates that our FT218 product may face competition from manufacturers of generic twice-nightly sodium oxybate formulations, who have reached settlement agreements with the current marketer for entry by 2023. In addition, there are other products in development that may be approved in the future that could have an impact on the sodium oxybate market prior to FT218's potential FDA approval.

#### **Market Opportunities**

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

In particular, in today's environment, a drug has to demonstrate significant therapeutic improvements over the current standard of care in order to obtain third party payer coverage. Alternatively, changes in the delivery of a drug must create a demonstrable reduction in costs. Dosing convenience, by itself, is no longer sufficient to gain reimbursement acceptance. Specialty pharmaceutical companies must now demonstrate, through costly Phase 3 trials, therapeutic efficacy of their new formulations. The FDA has encouraged drug companies developing enhanced formulations to use an abbreviated regulatory pathway: the 505(b)(2) NDA. Many specialty pharmaceutical companies today are using this approach or the supplemental NDA pathway ("sNDA"). An NDA or sNDA is necessary to market an already approved drug for a new indication, or in a different dosage form or formulation. However, the sNDA approach requires cross-referencing the originator's drug dossier, and eventually an alliance with the originator for commercialization.

#### **FT 218**

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

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

#### **Avadel's Drug Delivery Technologies**

Avadel owns drug delivery technologies that address key formulation challenges, potentially allowing the development of differentiated drug products for administration in various forms (e.g., capsules, tablets, sachets or liquid suspensions for oral use; or injectables for subcutaneous administration) that could be applied to a broad range of drugs (novel, already-marketed, or off-patent).

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

**Micropump<sup>®</sup> Technology.** *Micropump<sup>®</sup>* is a microparticulate system that allows the development and marketing of modified and/or controlled release solid, oral dosage formulations of drugs. Micropump<sup>®</sup>-carvedilol and Micropump<sup>®</sup>-aspirin formulations have been approved in the U.S. Avadel's Micropump<sup>®</sup> technology permits either extended or delayed delivery of small molecule drugs via the oral route. Micropump<sup>®</sup> 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<sup>®</sup> microparticles allows an extended release in the Gastro-Intestinal ("GI") tract allowing mean plasma residence times to be extended for up to 24 hours. The microparticles' design can be adapted to each drug's specific characteristics by modifying the coating composition and thickness as well as the composition of the excipients encapsulated with the drug. The resultant formulations can potentially offer improved efficacy (by extending therapeutic coverage), reduced toxicity and/or side effects (by reducing C<sub>max</sub> or peak drug concentration in the plasma, or by reducing intra- and inter-patient variability), and improved patient compliance (by reducing frequency of administration). The platform is applicable to poorly soluble (< 0.01mg/L) as well as highly soluble (> 500g/L) and to low dose (e.g., 4 mg) or high dose (e.g., 1,000 mg) drugs, while providing excellent mouth feel and taste masking properties. Micropump<sup>®</sup> 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<sup>®</sup>), while preserving the targeted release rate over the shelf-life of the product.

**LiquiTime<sup>®</sup>.** *LiquiTime<sup>®</sup>* allows development of modified/controlled release oral products in a liquid suspension formulation particularly suited to children or for patients having issues swallowing tablets or capsules. Avadel's LiquiTime<sup>®</sup> technology uses Micropump's competitive advantages to allow the development of products with modified/controlled release (e.g., zero-order kinetics) in liquid suspension formulations. The LiquiTime<sup>®</sup> products are particularly suitable for dosing to children and for use by patients having issues swallowing tablets or capsules. LiquiTime<sup>®</sup> 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<sup>®</sup>, LiquiTime<sup>®</sup> can be applied to the development of combination products. Avadel believes that LiquiTime<sup>®</sup>, designed to provide a controlled, extended release of oral liquids principally for pediatric and geriatric patients, will enable Avadel to develop improved, patent protected prescription products to serve an unmet medical need in these patient populations. Avadel believes that the increasing

number of geriatric patients and the demand for convenient drug delivery options for children offer opportunities for the development of LiquiTime<sup>®</sup>-based formulations. Although Avadel owns this technology, the Group is currently not pursuing any commercial pharmaceutical drug development opportunities using this technology

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

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

### ***Proprietary Intellectual Property***

Parts of Avadel's product pipeline and strategic alliances utilize our drug delivery platforms and related products of which certain features are the subject of patents or patent applications. As a matter of policy, Avadel seeks patent protection of our inventions and also relies upon trade secrets, know-how, continuing technological innovations and licensing opportunities to maintain and develop competitive positions.

Drug Delivery Technology Patents. Avadel's drug delivery technologies are the subject of certain patents, including: (i) for Micropump<sup>®</sup>, patents relating to an efficacious coating formulation for providing delayed and sustained release of an active ingredient with absorption limited to the upper part of intestinal tract (expiring in 2025 in the U.S. and 2022 in foreign jurisdictions); (ii) for LiquiTime<sup>®</sup>, patents relating to film-coated microcapsules and a method comprising orally administering such microcapsules to a patient (expiring in 2023); (iii) for Trigger Lock<sup>™</sup>, patents relating to a solid oral drug form with at least part of the active ingredient contained in microparticles with anticrushing characteristics to prevent misuse (expiring in 2027); and (iv) for Medusa<sup>™</sup>, patents relating to an aqueous colloidal suspension of low viscosity based on submicronic particles of water-soluble biodegradable polymer PO (polyolefin) carrying hydrophobic groups (expiring in 2023).

The patent positions of biopharmaceutical companies like Avadel are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and patent scope can be reinterpreted by the courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. Avadel cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any of Avadel's licensed or owned patents will provide sufficient protection from competitors. Any of Avadel's licensed or owned patents may be challenged, circumvented, or invalidated by third parties. For more information, please see the information set forth under the caption "— Risks Related to Avadel's Business and Industry — If Avadel cannot adequately protect our intellectual property and proprietary information, Avadel may be unable to sustain a competitive advantage" in the "Principal Risks and Uncertainties" included in this Directors Report.

### **Supplies and Manufacturing**

Avadel attempts to maintain multiple suppliers in order to mitigate the risk of shortfall and inability to supply market demand. Nevertheless, for most of our products Avadel relies on a limited number of suppliers, and in certain cases only one supplier, for sourcing active pharmaceutical ingredients (APIs).

The manufacture of our sterile hospital injectable products marketed by Avadel in the U.S. is outsourced to cGMP-compliant and FDA-audited contract manufacturing organization ("CMOs") pursuant to supply agreements. Avadel will continue to outsource to third-party CMOs, and has no present plans to acquire manufacturing facilities. Avadel believes this outsourcing policy is beneficial to us for products to be marketed in the United States.

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

### **Principal Risks and Uncertainties**

*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 Directors' Report and accompanying financial statements, before making an investment decision regarding our securities.*

### **Risks Relating to Our 2018 Net Loss and Recent Restructuring Plan**

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

We reported a net loss of \$95.3 million in 2018 and a net use of cash from operating activities of \$82.7 million, compared to net income of \$68.3 million and net cash provided by operating activities of \$16.7 million reported in the prior financial year. Our cash and marketable securities as of 31 December, 2018 and 2017 totaled \$99.9 million and \$94.1 million, respectively. Our business strategy is to primarily focus on the development and potential FDA approval for FT218 which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from EDS and cataplexy. In addition, we will continue to maximize the value of our current approved hospital products portfolio, including obtaining FDA approval for and the commercialization of our fourth UMD product. Additionally, we will continue to evaluate opportunities to expand our product portfolio. The successful pursuit of all components of our strategy will require substantial financial resources, and there can be no assurance that our existing cash and marketable securities assets and the cash generated by our operations will be adequate for these purposes. Failure to implement any component of our strategy may prevent us from achieving profitability in the future or may otherwise have a material adverse effect on our financial condition and results of operation. See also the discussions elsewhere in these Risk Factors under the captions “We may fail to effectively execute our business strategy” and “We may require additional financing, which may not be available on favorable terms or at all, and which may result in dilution of the equity interest of the holders of our American Depositary Shares (ADSs).”

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

In February 2019 we announced a restructuring plan intended to achieve future cost savings through, among other actions, a reduction of our overall workforce by approximately 50%. In conjunction with the restructuring plan, we also announced the voluntary Chapter 11 bankruptcy filing by our subsidiary, Specialty Pharma, which is responsible solely for the sales, marketing and distribution of the Group's Noctiva™ product for the treatment of nocturia (i.e., waking up two or more times during the night to urinate due to a condition called nocturnal polyuria). On 26 April, 2019, Specialty Pharma sold its intangible assets and remaining inventory to an unaffiliated third party in exchange for aggregate cash proceeds of approximately \$250, pursuant to an order approving such sale which was issued by the Bankruptcy Court on 15 April, 2019. We implemented the restructuring plan in light of disappointing results from the commercial launch of Noctiva, and in order to focus the Group's resources on other product development activities, in particular the ongoing Phase 3 clinical trial of its FT218 product for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from Narcolepsy. The restructuring plan requires the devotion of management attention as well as significant Group resources, including one-time pre-tax cash charges which we estimated at \$10.0 million to \$15.0 million, and may pose significant risks. The restructuring plan may not be as effective as we anticipated and may not fully produce the expected cost savings or the effective re-focusing of our efforts toward completing the development of FT218. In addition, the restructuring plan may result in greater implementation costs than we have estimated or may result in unintended negative consequences. For example, because of the speed and magnitude of the workforce reduction in the February 2019 restructuring, it may be difficult in the near

future to retain certain remaining employees who are critical to our ability to successfully pursue our business plan. See also the discussion elsewhere in these Risk Factors under the caption “We depend on key personnel to execute our business plan. If we cannot attract and retain key personnel, we may not be able to successfully implement our business plan.”

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

Our management may determine that we need to take further restructuring actions to achieve additional cost savings, to generate additional capital needed for our business strategy, or for other purposes. Certain possible future restructuring actions, including sales of assets, that management may consider in this regard could require consents of third parties, such as (but not necessarily limited to) holders of our Exchangeable Senior Notes (the “2023 Notes”). For example, the voluntary Chapter 11 bankruptcy filing by Specialty Pharma required the consent of holders of a majority in principal amount of our 2023 Notes in order to avoid a default under the Indenture governing such 2023 Notes. While we were successful in obtaining that consent, there can be no assurance that we will be successful in obtaining additional consents in the future from such holders or from other third parties whose consents may be necessary for further restructuring actions. Failure to obtain these third-party consents would prevent us from taking the additional restructuring actions, which could have a material adverse effect on our cash flow, financial resources and ability to successfully pursue our business strategy.

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

Our subsidiary Specialty Pharma filed for Chapter 11 bankruptcy protection in February 2019. Avadel US Holdings Inc., which is Specialty Pharma’s immediate parent and is our wholly owned subsidiary, agreed to provide debtor-in-possession financing to Specialty Pharma of up to \$2.7 million. In its bankruptcy proceeding, Specialty Pharma pursued a sale of its Noctiva business to an unrelated third-party purchaser, which was finalized in April 2019. The sale involved the transfer of certain of Specialty Pharma’s rights related to the exclusive license agreement with Serenity Pharmaceuticals. In addition, there could be other unexpected results from the bankruptcy proceeding, including but not limited to greater than expected costs in the case that may exceed the amount of financing that Avadel US Holdings Inc. has committed to provide. Adverse or unexpected results from the bankruptcy proceeding could impair our success in achieving the goals of the restructuring plan we announced in February 2019.

*The clinical trial for our FT218 product has no estimated completion date and a management-directed third-party evaluation of our FT218 development program could result in changes that increase the cost of the program and further delay its completion.*

At present, we have not completed patient enrollment in the clinical trial for our FT218 product, however we have announced an estimated completion date for the clinical trial as being the second half of 2020. Moreover, the FT218 product development program has become substantially more important to our success in the aftermath of the disappointing sales results for Noctiva and the Specialty Pharma bankruptcy filing. Accordingly, management has determined to re-focus on all aspects of the FT218 program with an evaluation assisted by pharmaceutical industry consulting firms. While the final results of this evaluation are not known, such results could cause us to modify our development plan with respect to FT218 in ways that materially increase the ultimate cost of such development or further delay its completion, or could identify unknown risks or problems with the product. Any such cost increases, added delays, risks or problems could have a material adverse effect on our financial condition and results of operation.

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

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

In 2018, we derived \$97.5 million, or 96.2%, of our \$101.4 million in revenues from sales of our three hospital products, Bloxiverz<sup>®</sup>, Vazculep<sup>®</sup> and Akovaz<sup>®</sup>. Sales of these three products declined in the aggregate from 2017 to 2018 by \$66.9 million, or 40.7%, from \$164.4 million to \$97.5 million, although Vazculep<sup>®</sup> sales increased by \$4.7 million, or 12.4%, in 2018 compared to the prior year. Our Noctiva<sup>™</sup> product failed to achieve anticipated revenue levels despite a substantial investment of resources toward its

commercialization, and these disappointing results led to the voluntary Chapter 11 bankruptcy filing by Specialty Pharma in February 2019. In addition, we depend on a small number of customers for the majority of our revenues from our three hospital products. Four customers accounted for approximately 86.8% of total revenues from sales of these products in 2018. These four customers comprise a significant portion of the distribution network for pharmaceutical products in the U.S.

Competition for our hospital products in 2018 caused significant downward pricing pressure and, with the exception of Vazculep, loss of market share by the Group resulting in lower aggregate revenues for these products; and further competition in the future could cause further reductions in prices and market share. The distribution network for pharmaceutical products is continuing to undergo consolidation marked by mergers and acquisitions among wholesale distributors and retail drug store chains. As a result, a small number of large wholesale distributors and large chain drug stores control a significant share of the market. We expect that continuing consolidation may cause competitive pressures on pharmaceutical companies. The loss of any one of our three hospital products, the termination of our relationship with any of these customers or our failure to broaden our customer base could cause our revenues to further decrease significantly and result in further losses from our operations. Further, we may be unable to negotiate favorable business terms with customers that represent a significant portion of our revenues, and any such inability could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to R&D in order to develop new products and enhance our technologies. In 2018, we spent \$39.3 million on R&D, including expenditures related to our FT218 and UMD#4 product candidates. Our ongoing investments in R&D for these two products as well as possible future products could result in higher costs without a proportionate increase, or any increase, in revenues. The R&D process is lengthy and carries a substantial risk of failure. For example, we currently have not completed patient enrollment for the clinical trial of FT218, however, we have announced a projected completion date for this clinical trial as being the second half of 2020. If our R&D does not yield sufficient products that achieve commercial success, our future operating results will be adversely affected.

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

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Successful R&D of pharmaceutical products is difficult, expensive and time consuming. Many product candidates fail to reach the market. Our success will depend on the development and the successful commercialization of new drugs, including additional previously Unapproved Marketed Drug (“UMD”) products and products that utilize our drug delivery technologies. If any of our additional UMD products or products incorporating our drug delivery technologies fails to reach the commercial market, our future revenues would be adversely affected.

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

- the FDA, the European Medicines Agency (“EMA”), the competent authority of an EU Member State or an Institutional Review Board (“IRB”), or an Ethics Committee (EU equivalent to IRB), or our partners may delay or halt applicable clinical trials;
- we or our partners may face slower than expected rate of patient recruitment and enrollment in clinical trials, or may devote insufficient funding to the clinical trials;
- our drug delivery technologies and drug products may be found to be ineffective or to cause harmful side effects, or may fail during any stage of pre-clinical testing or clinical trials;
- we or our partners may find that certain products cannot be manufactured on a commercial scale and, therefore, may not be economical or feasible to produce; or

- our products could fail to obtain regulatory approval or, if approved, could fail to achieve market acceptance, could fail to be included within the pricing and reimbursement schemes of the U.S. or EU Member States, or could be precluded from commercialization by proprietary rights of third parties.

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

The Group expects that the commercialization of some of our products in development which utilize our drug delivery technologies may require collaboration with third-party partners involving strategic alliances, licenses, product divestitures or other arrangements. We may not be successful in entering into such collaborations on favorable terms, if at all, or our collaboration partners may not adequately perform under such arrangements, and as a result our ability to commercialize these products will be negatively affected and our prospects will be impaired.

*Our products may not gain market acceptance.*

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

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

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

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

Currently, Avadel uses a single source provider for the development, supply of clinical materials and potentially the supply of commercial batches for several of our products incorporating our drug delivery technologies. For details see the discussion in the "Business — Information on the Group" in this Directors' Report. Any disruption in the operations of this provider or if this provider fails to supply acceptable quantity and quality materials or services to us for any reason, such disruption or failure could delay our product development and could have a material adverse effect on our business, financial condition and results of operations. In case of a disruption, we may need to establish alternative manufacturing sources for our drug delivery products, and this would likely lead to substantial production delays as we build or locate replacement facilities and seek to satisfy necessary regulatory requirements.



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

Currently, we depend on a limited number of CMOs for three products, Bloxiverz, Vazculep and Akovaz, from which we derive a majority of our revenues and a single contract manufacturer for Noctiva. Additionally, we purchase certain raw materials used in our products from a limited number of suppliers, including a single supplier for certain key ingredients. If the supplies of these products or materials were interrupted for any reason, our manufacturing and marketing of certain products could be delayed. These delays could be extensive and expensive, especially in situations where a substitution was not readily available or required variations of existing regulatory approvals and certifications or additional regulatory approval. For example, an alternative supplier may be required to pass an inspection by the FDA, EMA or the competent authorities of EU Member States for compliance with current Good Manufacturing Practices (“cGMP”) requirements before supplying us with product or before we may incorporate that supplier’s ingredients into the manufacturing of our products by our contract, development, and manufacturing organizations (“CDMOs”). Failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations.

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

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

Our drug delivery technologies compete with technologies provided by several other companies (for details see “Business — Competition and Market Opportunities” in this Director’s Report). In particular, New Biological Entities (“NBEs”) could be developed that, if successful, could compete against our drug delivery technologies or products. Among the many experimental therapies being tested in the U.S. and in the EU, there may be some that we do not now know of that may compete with our drug delivery technologies or products in the future. These new biological or chemical products may be safer or may work better than our products.

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

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

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

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

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

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

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

Our business strategy is to continue our UMD program by obtaining FDA approval for and commercializing our fourth UMD product candidate as well as potentially additional future UMD product candidates, continue to seek FDA approval for FT218 which is in Phase 3 clinical trial. There can be no assurance that we will be successful in any of these objectives; and a failure in any of these objectives could negatively impact our business and operating results.

*If we cannot adequately protect our intellectual property and proprietary information, we may be unable to effectively compete.*

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

To the extent any of Avadel's products may benefit from protections afforded by patents, Avadel faces the risk that patent law relating to the scope of claims in the pharmaceutical and biotechnology fields is continually evolving and can be the subject of uncertainty and may change in a way that would limit protection. Our patents may not be exclusive, valid or enforceable. For example, our patents may not protect us against challenges by companies that submit drug marketing applications to the FDA, or the competent authorities of EU Member States, or other jurisdictions in which we may attempt to compete, in particular where such applications rely, at least in part, on safety and efficacy data from our products or our business partners' products. In addition, competitors may obtain patents that may have an adverse effect on our ability to conduct business, or they may discover ways to circumvent our patents. The scope of any patent protection may not be sufficiently broad to cover our products or to exclude competing products. Any patent applications that we have made or may make relating to our potential products or technologies may not result in patents being issued. Further, patent protection once obtained is limited in time, after which competitors may use the covered product or technology without obtaining a license from us. Because of the time required to obtain regulatory marketing approval, the period of effective patent protection for a marketed product is frequently substantially shorter than the duration of the patent.

Our partnerships with third parties expose us to risks that they will claim intellectual property rights on our inventions or fail to keep our unpatented products or technology confidential. We also rely on trademarks, copyrights, trade secrets and know-how to develop, maintain and strengthen our competitive position.

To protect our products, trade secrets and proprietary technologies, we rely, in part, on confidentiality agreements with our employees, suppliers, consultants, advisors and partners. These agreements may not provide adequate protection for our trade secrets and other proprietary information in the event of any unauthorized use or disclosure, or if others lawfully develop the information. If these agreements are breached, we cannot be certain that we will have adequate remedies. Further, we cannot 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 issued patents in reexamination, inter partes review and post grant proceedings. New bases and procedures may make it easier for competitors to challenge our patents, which could result in increased competition and have a material adverse effect on our business and results of operations. The AIA may also make it harder to challenge third-party patents and place greater importance on being the first inventor to file a patent application on an invention. The AIA amendments to patent filing and litigation procedures in the U.S. may result in litigation being more complex and expensive and divert the efforts of our technical and management personnel.

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

Third parties may claim, infringement of their patents and other intellectual property rights by the manufacture, use, import, offer for sale or sale of our drug delivery technologies or our other products. For example, in connection with us seeking regulatory approval for FT218, companies that produce any branded pharmaceutical versions of such products may allege that FT218 infringes their patents or other intellectual property rights and file suit to prevent us from commercializing FT218. In response to any claim of infringement, we may have to seek licenses, defend infringement actions or challenge the validity or enforceability of those patent rights in court. If we cannot obtain required licenses, are found liable for infringement or are not able to have such patent rights declared invalid, or unenforceable. We may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from the manufacture, use, import, offer for sale or sale of products or methods of drug delivery covered by the patents of others. We may not have identified, or be able to identify in the future, U.S. or foreign patents that pose a risk of potential infringement claims.

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

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

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

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

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

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

The costs of compliance with privacy and security laws, including protecting electronically stored information from cyber-attacks, and potential liability associated with any compliance failures could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to HIPAA. Additionally, we will be required to comply with the General Data Protection Regulation (“GDPR”) (Regulation EU 2016/679) by May 25, 2018. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. GDPR will require Avadel to ensure that personal data Avadel collects is gathered legally and under strict conditions and protect such personal data from misuse and exploitation. If Avadel fails to comply with GDPR, we will face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

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

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

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

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

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

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

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

Our success depends in large part upon our ability to attract and retain highly qualified personnel. During our operating history, we have assigned many key responsibilities within our Group 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. Greg Divis, our Chief Executive Officer, or other members of our senior executive team,

we may have difficulty executing our business plan in the manner we currently anticipate. Further, because each of our key personnel is involved in numerous roles in various components of our business, the loss of any one or more of such individuals could have an adverse effect on our business.

#### **Risks Relating to Regulatory and Legal Matters**

*Our products will generally be subject to regulatory approval. If we or our pharmaceutical and biotechnology Group partners do not obtain such approvals, or if such approvals are delayed, our revenues may be adversely affected.*

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

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

Applicants for FDA approval often must submit to the FDA extensive clinical and pre-clinical data, as well as information about product manufacturing processes and facilities and other supporting information. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. The FDA also may require us, or our partners to conduct additional pre-clinical studies or clinical trials.

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

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

The FDA has substantial discretion in the approval process and may disagree with our or our partners’ interpretations of data and information submitted in an application, which also could cause delays of an approval or rejection of an application. Even if the FDA approves a product, the approval may limit the uses or indications for which the product may be marketed, restrict distribution of the product or require further studies.

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

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

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

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

*Clinical development of drugs is costly and time-consuming, and the outcomes are uncertain. A failure to prove that our product candidates are safe and effective in clinical trials, or to generate data in clinical trials to support expansion of the therapeutic uses for our existing products, could materially and adversely affect our business, financial condition, results of operations and growth prospects.*

We have made significant investments in our REST-ON Phase 3 clinical trial. Clinical trials are expensive and can take many years to complete, and the outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of potential medicine candidates may not be predictive of the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical testing. Any failure or delay in completing our REST-ON Phase 3 clinical trial would prevent or delay the commercialization of our sodium oxybate product, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

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

- adding new sites; or
- manufacturing sufficient quantities of medicine candidates for use in clinical trials.

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

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

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

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

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

- issue warning letters;
- impose fines;
- seize products or request or order recalls;
- issue injunctions to stop future turnover of products;

- refuse to permit products to be imported into, or exported out of, the U.S. or the E.U.;
- suspend or limit our production;
- withdraw or vary approval of marketing applications;
- order the competent authorities of EU Member States to withdraw or vary national authorization; and
- initiate criminal prosecutions.

*If FT218 is approved by the FDA, we may not obtain orphan drug marketing exclusivity.*

Orphan drug status may be granted by the FDA to certain products intended to treat diseases and conditions that affect fewer than 200,000 individuals in the United States or, if they affect more than 200,000 individuals in the United States, there is no reasonable expectation of recovering the cost of developing and making the product available in the United States for the applicable disease or condition.

Our proposed product FT218 obtained orphan drug designation from the FDA in January 2018. A product with orphan drug designation that subsequently receives the first FDA approval for the disease or condition for which it has such designation will be entitled to certain U.S. marketing exclusivity for a period of seven years. FT218 would not be the first product with such FDA approval. However, in limited circumstances, including if the FDA concludes that FT218 is safer, more effective or makes a major contribution to patient care, the FDA could award FT218 with such marketing exclusivity. The orphan drug designation for FT218 does not guaranty that the FDA would ultimately award this product with orphan drug status for purposes of marketing exclusivity. Among other factors, the FDA will consider the results of our FT218 Phase 3 clinical trial with respect to the efficacy and safety of the product. Thus, there can be no assurance that the FDA will ultimately grant orphan drug status, or marketing exclusivity, for FT218. In addition, even if such orphan drug marketing exclusivity rights were granted by the FDA, such rights may be lost if the FDA later determines that our request for such designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition to be treated with the product.

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

We are subject to extensive and complex U.S. federal and state and international laws and regulations, including but not limited to, health-care “fraud and abuse” laws, such as anti-kickback and false claims laws and regulations pertaining to government benefit program reimbursement, price reporting and regulations, and turnover 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 turnover 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 Group executives. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

Our ability to successfully commercialize our products and technologies may depend on the extent to which the government health administration authorities, the health insurance funds in the EU Member States, private health insurers and other third-party payor in the U.S. will reimburse consumers for the cost of these products, which would affect the volume of drug products sold by pharmaceutical and biotechnology



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

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

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

Any such changes could have a significant impact on the path to approval of our proposed products or of competing products, and on our obligations and those of our pharmaceutical industry partners.

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

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

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

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

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

The testing, including through clinical trials, manufacturing and marketing, and the use of our products may expose us to potential product liability and other claims. If any such claims against us are successful, we may be required to make significant compensation payments. Any indemnification that we have obtained, or may obtain, from CROs or pharmaceutical and biotechnology companies or hospitals conducting human clinical trials on our behalf may not protect us from product liability claims or from the costs of related litigation. Insurance coverage is expensive and difficult to obtain, and we may be unable to obtain coverage in the future on acceptable terms, if at all. We currently maintain general liability insurance 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 Related to Ownership of Our Securities***

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

The trading price of our ADSs has been, and is likely to continue to be, highly volatile. The market value of an investment in our ADSs may fall sharply at any time due to this volatility. During the year ended 31 December, 2018, the closing sale price of our ADSs as reported on the Nasdaq Global ranged from \$1.74 to \$11.70. During the year ended 31 December, 2017, the closing sale price of our ADSs as reported on the NASDAQ National Market ranged from \$8.03 to \$11.57. The market prices for securities of drug delivery, specialty pharma, biotechnology and pharmaceutical companies historically have been highly volatile. Factors that could adversely affect our share price include, among others:

- fluctuations in our operating results;
- announcements of technological partnerships, innovations or new products by us or our competitors;
- actions with respect to the acquisition of new or complementary businesses;
- governmental regulations;
- developments in patent or other proprietary rights owned by us or others;

- public concern as to the safety of drug delivery technologies developed by us or drugs developed by others using our platform;
- the results of pre-clinical testing and clinical studies or trials by us or our competitors;
- adverse events related to our products or products developed by pharmaceutical and biotechnology Group partners that use our drug delivery technologies;
- lack of efficacy of our products;
- litigation;
- decisions by our pharmaceutical and biotechnology Group partners relating to the products incorporating our technologies;
- the perception by the market of specialty pharma, biotechnology, and high technology companies generally;
- general market conditions, including the impact of the current financial environment; and
- the diluted impact of any new equity securities we may issue

*We incurred a net loss in 2018 and we will likely incur a net loss in 2019, and if we are not able to regain profitability in the future, the value of our shares may fall.*

We reported net loss of \$95.3 million for the year ended 31 December, 2018 and net profit of \$68.3 million for the year ended 31 December, 2017. In addition, in part because we expect sales of our hospital products to suffer further substantial declines during 2019 and we will incur substantial expenses to develop our products, we will likely incur a net loss in 2019 as well, the amount of which is not known to us at this time. We cannot predict if we will be able to regain profitability. If we are unable to earn a profit in future periods, the market price of our shares may fall. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

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

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

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

- the development and acquisition of new products and drug delivery technologies;
- the progress of our research and product development programs; and
- the timing of, and amounts received from, future product turnover, 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 turnover, increased costs and reduced revenues. Alternatively, to obtain needed funds for acquisitions or operations, we may choose to issue additional ADSs representing our ordinary shares, or issue equity-linked debt, or we may choose to issue preferred shares, in either case through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of such equity financings, may result in dilution to the holders of our ADSs.

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

Our management has broad discretion in the use of our cash, and may not apply our cash in ways that ultimately increases the value of any investment in our securities. We currently intend to use our cash to fund marketing activities for our commercialized products, to fund certain clinical trials for product candidates, to fund R&D activities for potential new product candidates, and for working capital, capital expenditures and general corporate purposes. As in the past we expect to invest our excess cash in available-for-sale marketable securities, including corporate bonds, U.S. government securities, other fixed income securities and equities; and these investments may not yield a favorable return. If we do not invest or apply our cash effectively, our financial position and the price of our ADSs may decline.

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

We have never declared or paid a cash dividend on any of our ordinary shares or ADSs, other than share buybacks, 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 constitution could delay or prevent a third-party's effort to acquire us.*

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

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

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

In addition, several mandatory provisions of Irish law could prevent or delay our acquisition by a third party. For example, Irish law does not permit shareholders of an Irish public limited Group 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 Group, 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 Group are generally owed to the Group 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 Group must act with due care and skill, honestly and in good faith with a view to the best interests of the Group. Directors must not put themselves in a position in which their duties to the Group and their personal interests conflict and must disclose any personal interest in any contract or arrangement with the Group or any of our subsidiaries. A director or officer can be held personally liable to the Group in respect of a breach of duty to the Group.

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

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

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

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

We have been advised by our Cayman Islands legal counsel, Maples and Calder, that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against us or Avadel judgments of courts of the United States predicated upon the civil liability provisions of the securities laws of the United States or any State; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against us or Avadel predicated upon the civil liability provisions of the securities laws of the United States or any State, so far as the liabilities imposed by those provisions are penal in nature. In those circumstances, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States, the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, and or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands Court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

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

Holders of ADSs do not have the same rights as shareholders and, accordingly, cannot exercise rights of shareholders against us. The Bank of New York Mellon, as depositary, or the “Depositary”, is the registered shareholder of the deposited shares underlying the ADSs. Therefore, holders of ADSs will

generally have to exercise the rights attached to those shares through the Depositary. We will use reasonable efforts to request that the Depositary notify the holders of ADSs of upcoming votes and ask for voting instructions from them. If a holder fails to return a voting instruction card to the Depositary by the date established by the Depositary for receipt of such voting instructions, or if the Depositary receives an improperly completed or blank voting instruction card, or if the voting instructions included in the voting instruction card are illegible or unclear, then such holder will be deemed to have instructed the Depositary to vote its shares, and the Depositary shall vote such shares in favor of any resolution proposed or approved by our Board of Directors and against any resolution not so proposed or approved.

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

As of 25 April, 2019, Brandes Investment Partners L.P. owned approximately 19.1% of Avadel's outstanding shares (in the form of ADRs), Broadfin Capital and certain of its affiliates beneficially owned approximately 8.3% of our outstanding shares (in the form of ADRs) and Deerfield Capital and certain of its affiliates beneficially owned approximately 7.3% of Avadel's outstanding shares (in the form of ADRs). To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, they will remain in a position to exert heightened influence in the election of the directors of the Group and in other corporate actions that require shareholder approval, including change of control transactions.

#### **Risks Related to the 2023 Notes**

*Servicing our 2023 Notes may require a significant amount of cash, and we may not have sufficient cash or the ability to raise the funds necessary to settle exchanges of the 2023 Notes in cash, repay the Notes at maturity, or repurchase the 2023 Notes as required following a fundamental change.*

In February 2018 we issued \$143.75 million aggregate principal amount of our Senior Exchangeable Notes. Prior to February 2023, the 2023 Notes are convertible at the option of the holders only under certain conditions or upon the occurrence of certain events. If holders of the 2023 Notes elect to exchange their 2023 Notes, unless we elect to deliver solely our ADSs to settle such exchanges, we will be required to make cash payments in respect of the 2023 Notes being exchanged. Holders of the 2023 Notes also have the right to require us to repurchase all or a portion of their 2023 Notes upon the occurrence of a fundamental change (as defined in the applicable indenture governing the 2023 Notes) at a repurchase price equal to 100% of the principal amount of the 2023 Notes to be repurchased, plus accrued and unpaid interest. If the 2023 Notes have not previously been exchanged or repurchased, we will be required to repay the 2023 Notes in cash at maturity. Our ability to make cash payments in connection with exchanges of the 2023 Notes, repurchase the 2023 Notes in the event of a fundamental change, or to repay or refinance the 2023 Notes at maturity will depend on market conditions and our future performance, which is subject to economic, financial, competitive, and other factors many of which are beyond our control. We incurred significant net losses in 2018 and we may continue to incur significant losses. As a result, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase or repay the 2023 Notes or in the event we elect to pay cash with respect to 2023 Notes being exchanged.

*The conditional exchange feature of the 2023 Notes, if triggered, may adversely affect our financial condition and operating results.*

In the event the conditional exchange feature of the 2023 Notes is triggered, holders of 2023 Notes will be entitled to exchange the 2023 Notes at any time during specified periods at their option (see the discussion in *Note 15: Long-Term Debt*). If one or more holders elect to exchange their 2023 Notes, unless we elect to satisfy our exchange obligation by causing to be delivered solely ADSs (other than paying cash in lieu of any fractional ADS), we would be required to settle a portion or all of our exchange obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to exchange their 2023 Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2023 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

*The accounting method for convertible and exchangeable debt securities that may be settled in cash, such as the 2023 Notes, could have a material effect on Avadel's reported financial results.*

Under Accounting Standards Codification 470-20, Debt with Conversion and Other Options, which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of the

convertible or exchangeable debt instruments (such as the 2023 Notes) that may be settled entirely or partially in cash upon conversion or exchange in a manner that reflects the issuer's economic interest cost. However, entities must first consider the guidance in ASC 815-15, Embedded Derivatives ("ASC 815-15"), to determine if an instrument contains an embedded feature that should be separately accounted for as a derivative. ASC 815 provides for an exception to this rule when convertible notes, as host instruments, are deemed to be conventional, as defined by ASC 815-40. Should this exception apply, the effect of ASC 470-20 on the accounting for the 2023 Notes is that the equity component would be required to be included in the additional paid-in capital section of stockholders' equity on Avadel's consolidated balance sheet, and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the 2023 Notes. As a result, Avadel would be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the 2023 Notes to their face amount over the term of the 2023 Notes. Avadel would report lower net income in its financial results because ASC 470-20 would require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect Avadel's reported or future financial results, the trading price of the ADSs and the trading price of the 2023 Notes.

In addition, under certain circumstances, convertible or exchangeable debt instruments (such as the 2023 Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the ADSs deliverable upon exchange of the 2023 Notes are not included in the calculation of diluted earnings per share except to the extent that the exchange value of the 2023 Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of ADSs that would be necessary to settle such excess, if we elected to settle such excess in ADSs, are issued. Neither we nor Avadel can be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If Avadel is unable to use the treasury stock method in accounting for the ADSs deliverable upon exchange of the 2023 Notes, then Avadel's diluted earnings per share would be adversely affected.

*Exchanges of the 2023 Notes will dilute the ownership interest of Avadel's existing shareholders and holders of the ADSs, including holders who had previously exchanged their 2023 Notes and received ADSs upon exchange, to the extent our exchange obligation includes ADSs.*

The exchange of some or all of the 2023 Notes will dilute the ownership interests of Avadel's existing shareholders and holders of the ADSs to the extent our exchange obligation includes ADSs. Any sales in the public market of the ADSs issuable upon such exchange of the 2023 Notes could adversely affect prevailing market prices of the ADSs and, in turn, the price of the 2023 Notes. In addition, the existence of the 2023 Notes may encourage short selling by market participants because the exchange of the 2023 Notes could depress the price of the ADS.

*The fundamental change repurchase feature of the 2023 Notes may delay or prevent an otherwise beneficial takeover attempt of Avadel.*

The indenture governing the 2023 Notes will require us to repurchase the 2023 Notes for cash upon the occurrence of a fundamental change and, in certain circumstances, to increase the exchange rate for a holder that exchanges its 2023 Notes in connection with a make-whole fundamental change. A takeover of Avadel may trigger the requirement that we repurchase the 2023 Notes and/or increase the exchange rate, which could make it more costly for a potential acquirer to engage in a combinatory transaction with us or Avadel. Such additional costs may have the effect of delaying or preventing a takeover of Avadel that would otherwise be beneficial to investors.

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

In certain circumstances, as an Irish tax resident Group, Avadel will be required to deduct Irish dividend withholding tax (currently at the rate of 20%) from dividends paid to its shareholders. Shareholders that are resident in the U.S., EU countries (other than Ireland) or other countries with which Ireland has signed a tax treaty (whether the treaty has been ratified or not) generally should not be subject to Irish withholding tax so long as the shareholder has provided its broker, for onward transmission to Avadel's qualifying intermediary or other designated agent (in the case of shares held beneficially), or Avadel or its transfer

agent (in the case of shares held directly), with all the necessary documentation by the appropriate due date prior to payment of the dividend. However, some shareholders may be subject to withholding tax, which could adversely affect the price of ordinary shares and the value of their 2023 Notes.

#### **Risks Related to Recent Tax Legislation**

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

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

#### **Financial Risk Management**

Our operations include activities in the U.S. and countries outside of the U.S. These operations expose us to a variety of market risks, including the effects of changes in interest rates and currency exchange rates. We monitor and manage these financial exposures as an integral part of our overall risk management program. We do not utilize derivative instruments for trading or speculative purposes.

#### ***Interest Rate Risk***

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

#### ***Foreign Exchange Risk***

We are exposed to foreign currency exchange risk as the functional currency financial statements of a foreign subsidiary is translated to U.S. dollars. The assets and liabilities of this foreign subsidiary having a functional currency other than the U.S. dollar is translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders’ equity. The reported results of this foreign subsidiary will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposure is related to one subsidiary that has functional currencies denominated in Euro. A 10% strengthening/weakening in the rates used to translate the results of our foreign subsidiaries that have functional currencies denominated in the euro as of December 31, 2018 would have had an immaterial impact on net loss for the year ended 31 December, 2018.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in foreign exchange gain (loss) in the consolidated profit and loss account. As of 31 December,



2018, our primary exposure is to transaction risk related to Euro net monetary assets and liabilities held by subsidiaries with a U.S. dollar functional currency. Realized and unrealized foreign exchange gains resulting from transactional exposure were immaterial for the year ended 31 December, 2018.

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

The adequacy of our cash resources depends on the outcome of certain business conditions including the funding required and timing to complete our FT218 development program, the ultimate resolution associated with the exit of Noctiva and other factors set forth in “Risk Factors”. The FT218 development program will require us to commit substantial resources. Our cash and marketable securities is anticipated to be sufficient to fund operations into 2021. This is based on the current level of cash and marketable securities, the full year run rate of anticipated cost reductions resulting from our recent restructuring actions and exit of Noctiva of \$80 to \$90 million and long-range revenue projections for our sterile hospital injectable products. Our assumptions concerning our long range revenue forecast, the ultimate success of our restructuring actions, the timing, outcome and ultimate cost to complete the FT218 development program may prove to be wrong or other factors may adversely affect our business. The outcome of these and other business conditions, could exhaust or significantly decrease our available cash and marketable securities which could, among other things, force us to raise additional funds and/or force us to further reduce our cost structure, either of which could have a material adverse effect on our business. If available to us, raising additional capital may be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders.

#### ***Accounting records***

The directors are responsible for ensuring that the Group and Company keep adequate accounting records and appropriate accounting systems. The measures taken by the directors to ensure compliance with the Group’s and Company’s obligation to keep adequate accounting records include the use of appropriate systems and procedures and the employment of competent persons. The directors have appointed a Chief Financial Officer who makes regular reports to the directors and ensures compliance with the requirements of Sections 281 to 285 of the Companies Act 2014. The Group also has a Chief Accounting Officer, who works closely with the Chief Financial Officer and who makes regular reports to the Audit Committee. The Audit Committee, in turn, briefs the directors on significant financial matters arising from reports of the Chief Financial Officer, the Chief Accounting Officer and the external auditor.

The accounting records of Avadel are maintained at 16640 Chesterfield Grove Rd., St. Louis, Missouri 63005, United States. In accordance with Section 283(2) of the Companies Act 2014, sufficient accounting records are also maintained in the Republic of Ireland to disclose, with reasonable accuracy, the assets, liabilities, financial position and profit or loss of the Company. The accounting records are available at Block 10-1 Blanchardstown Corporate Park, Ballycoolin, Dublin 15, Ireland.

#### ***Directors***

The remuneration of statutory directors of the Company during the year is set forth in *Note 23* of the Notes to Consolidated Financial Statements. No director or Company secretary of the Company had an interest in shares or debentures required to be disclosed under Section 329 of the Companies Act 2014 either at the beginning of the financial year, or date of appointment if later, or at the end of the financial year, other than the Directors listed below. Note that where the aggregate interest in shares of any director or secretary (and his or her spouse (or civil partner) and children) represents less than 1% in nominal value of the Group’s ordinary shares, the only interests of that director or secretary that are required to be disclosed constitute a right to subscribe for shares in the Company or that arise as a result of the exercise of such a right. Performance stock units where the director or secretary is an employee of the Company and does not make any payment to the Company in respect of the shares are not considered to be rights to subscribe for the purposes of this disclosure and no disclosure is required where they form part of an aggregate less than 1% holding.

Director or Company Secretary	% interest in Group's ordinary shares	
	01/01/2018 or appointment date if during 2018	31/12/2018
Craig R. Stapleton	1.3%	1.3%
Kevin Kotler (*)	8.4%	8.3%

  

Kevin Kotler (*)	% interest in Group's 2023 Notes	
	01/01/2018 or appointment date if during 2018	31/12/2018
Kevin Kotler (*)	8.3%	8.3%

(\*) Mr. Kotler, Founder and Managing Partner of Broadfin Capital, LLC, in which Broadfin Capital, LLC also holds the same interest in the ordinary shares and 2023 Notes, disclaims beneficial ownership of the ordinary shares and 2023 Notes except to the extent of his pecuniary interest therein.

Set forth below are the names of the individuals serving as statutory directors during fiscal 2018 through the date of this report:

Nominee	Principal Occupation or Experience	Nationality	Committees
Michael S. Anderson	Former Chief Executive Officer of Avadel Pharmaceuticals plc	American	(5)
Francis J.T. Fildes	Former senior executive in the pharmaceutical industry	British	(1)(2)(7)
Christophe Navarre	Former Chief Executive Officer of Moët Hennessy	Belgian	(1)(3)(7)
Craig R. Stapleton	Former U.S. Ambassador to France, Senior Advisor to Stone Point Capital, Director of Abercrombie & Fitch Co.	American	(1)(2)(3)
Benoit Van Assche	Former senior executive in the chemical, pharmaceutical and healthcare industries	Belgian	(1)(2)(3)(7)
Peter Thornton	Chief Financial Officer, Director at Technopath Clinical Diagnostics	Irish	(2)(3)
Geoffrey Glass	President, Clear Sciences, LLC	American	(1)(2)(3)(4)(6)
Linda Palczuk	Former COO of Verrica Pharmaceuticals, Inc.	American	(1)(3)(6)
Dr. Eric Ende	President, Ende BioMedical Consulting Group	American	(1)(2)(8)
Kevin Kotler	Founder and Managing Partner, Broadfin Capital, LLC	American	(1)(3)(9)
Gregory J. Divis	Chief Executive Officer of Avadel Pharmaceuticals plc	American	(10)

(1) Member of the Compensation Committee

(2) Member of the Audit Committee

(3) Member of the Nominating and Corporate Governance Committee

(4) Appointed as a Non-Executive Chairman of the Board of Directors in 2018

(5) Resigned on 27 December, 2018

(6) Appointed on 18 July, 2018

(7) Resigned on 18 July, 2018

(8) Appointed on 27 December, 2018

(9) Appointed on 7 December, 2018

(10) Appointed on 3 June, 2019

***Political Donations***

No political contributions that require disclosure under Irish law were made during the year.

***Subsidiary Companies and Branches***

Information regarding subsidiary undertakings, including information regarding branches, is provided in Note 29 of Notes to Consolidated Financial Statements.

***Disclosure of Information to Auditor***

Each of the persons who is a director at the date of approval of this report confirms that:

- so far as that director is aware, there is no relevant audit information of which the Group's auditor is unaware, and
- that director has taken all the steps that ought to have been taken as a director in order to be aware of any relevant audit information and to establish that the Group's auditor is aware of that information.

This confirmation is given and should be interpreted in accordance with the provisions of Section 330 of the Companies Act 2014.

***Directors' Compliance Statement***

As required by section 225 of the Companies Act 2014, the directors acknowledge that they are responsible for securing the Avadel Pharmaceutical plc's compliance with its "relevant obligations" (as defined in that legislation). The directors further confirm that a compliance policy statement has been drawn up, and that appropriate arrangements and structures have been put in place that are, in the directors' opinion, designed to secure material compliance with the relevant obligations. A review of those arrangements and structures has been conducted in the financial year to which this report relates. In discharging their responsibilities under section 225, the directors relied on the advice of persons who the directors believe have the requisite knowledge and experience to advise Avadel Pharmaceutical plc on compliance with its relevant obligations.

***Audit Committee***

The Board has established an Audit committee that in all material respects meets the requirements of Section 167 of the Companies Act 2014.

***Events Since the Balance Sheet Date***

***Management Changes.*** On 9 May 2019, The Honorable Craig R. Stapleton notified the Board of Directors of the Group of his decision to resign from the Group's Board of Directors, effective immediately. On 3 June, 2019 the Company announced the appointment of Gregory J. Divis as Chief Executive Officer and member of the Board of Directors. Mr. Divis has served as Interim CEO since January 2019.

***Corporate Restructuring.*** In February 2019, Avadel announced a corporate restructuring in order to focus efforts and resources on the clinical development of FT218. In conjunction with the restructuring, Avadel will reduce its workforce by more than 50% and expected to be substantially complete by the end of the financial year 2019. These restructuring actions were taken to exit Noctiva™ quickly and efficiently, and are not expected to materially impact any other aspect of the Group's business, including the ability to operate its sterile injectables hospital business, complete the FT218 Phase 3 clinical trial, and complete development

of the Group's fourth UMD product. The Group estimates that it will incur approximately \$10 to \$15 million of one-time pre-tax charges for severance and other costs related to the restructuring. See *Note 27: Post Balance Sheet Events* in the accompanying notes to the consolidated financial statements for additional information.

*Chapter 11 Bankruptcy.* On 6 February, 2019, Specialty Pharma made a voluntary filing for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code on 6 February, 2019. As noted above, Specialty Pharma is a special-purpose entity and wholly-owned subsidiary responsible solely for the sales, marketing and distribution of Noctiva. As a result of Specialty Pharma's bankruptcy filing, Avadel has ceded authority for managing the business to the Bankruptcy Court, and Avadel management cannot carry on Specialty Pharma's activities in the ordinary course of business without Bankruptcy Court approval. Avadel manages the day-to-day operations of Specialty Pharma, but does not have discretion to make significant capital or operating budgetary changes or decisions and purchase or sell significant assets, as Specialty Pharma's material decisions are subject to review by the Bankruptcy Court. For these reasons, we have concluded that Avadel has lost control of Specialty Pharma, and no longer has significant influence over Specialty Pharma during the pendency of the bankruptcy. Therefore, we deconsolidated Specialty Pharma effective with the filing of the Chapter 11 bankruptcy in February 2019. On 26 April, 2019, Specialty Pharma sold its intangible assets and remaining inventory to an unaffiliated third party in exchange for aggregate cash proceeds of approximately \$250, pursuant to an order approving such sale which was issued by the Bankruptcy Court on 15 April, 2019. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business.

*2019 French Restructuring.* In May 2019, the Group initiated a plan to reduce substantially all of its workforce at its Vénissieux, France site. This reduction is an effort to align the Group's cost structure with our ongoing and future planned projects. The reduction in workforce is projected to be substantially complete by the end of the fiscal year 2019, and to result in employee severance, benefits and other costs of up to approximately \$3,000, which are likely to be recognized through December 31, 2019.

#### ***Going Concern***

The directors have a reasonable expectation that Avadel Pharmaceuticals plc and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, the directors continue to adopt the going concern basis in preparing the financial statements.

#### ***Auditors***

The auditors, Deloitte Ireland LLP, Chartered Accountants and statutory Audit Firm, continue in office in accordance with Section 383(2) of the Companies Act 2014.

On behalf of the Directors

/s/ Geoffrey M. Glass

Geoffrey M. Glass  
Director  
13 June, 2019

/s/ Gregory J. Divis

Gregory J. Divis  
Director  
13 June, 2019

## AVADEL PHARMACEUTICALS PLC

### DIRECTORS' RESPONSIBILITIES STATEMENT

The directors are responsible for preparing the directors' report and financial statements in accordance with the Companies Act 2014.

Irish company law requires the directors to prepare financial statements for each financial year. Under the law, the directors have elected to prepare the Irish statutory group consolidated financial statements of Avadel Pharmaceuticals plc in accordance with U.S. GAAP, as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the group financial statements does not contravene any provision of Part 6 of the Companies Act 2014.

The directors have elected to prepare the Avadel Pharmaceuticals plc parent company financial statements in accordance with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* issued by the Financial Reporting Council ("relevant financial reporting framework").

Under company law, the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position of the group and company as at the financial year end date and of the profit or loss of the group for the financial year and otherwise comply with the Companies Act 2014.

In preparing the financial statements, the directors are required to:

- select suitable accounting policies for the group and company financial statements and then apply them consistently;
- make judgments and estimates that are reasonable and prudent;
- state whether the financial statements have been prepared in accordance with the applicable accounting standards, identify those standards, and note the effect and the reasons for any material departure from those standards; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for ensuring that the company keeps or causes to be kept adequate accounting records which correctly explain and record the transactions of the company; enable at any time the assets, liabilities, financial position and profit or loss of the company to be determined with reasonable accuracy; enable them to ensure that the financial statements and directors' report comply with the Companies Act 2014; and enable the financial statements to be audited. They are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The directors are responsible for the maintenance and integrity of the corporate and financial information included on the company's website. Legislation in Ireland concerning the preparation and dissemination of Financial Statements may differ from legislation in other jurisdictions.

**Independent auditor’s report to the members of Avadel Pharmaceuticals Public Limited Company**

**Report on the audit of the financial statements**

**Opinion on the financial statements of Avadel Pharmaceuticals Public Limited Company (the ‘Group’)**

In our opinion the Group financial statements:

- give a true and fair view of the assets, liabilities and financial position of the Group as at 31 December 2018 and of the loss of the Group for the year then ended; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The financial statements we have audited comprise:

- the Consolidated Profit and Loss Account;
- the Consolidated Statement of Other Comprehensive (Loss)/Income;
- the Consolidated Balance Sheet;
- the Consolidated Statement of Cash Flows
- the Consolidated Statement of Changes in Equity; and
- the related notes 1 to 29, including a summary of significant accounting policies as set out in note 1.

The relevant financial reporting framework that has been applied in the preparation of the Group financial statements is the Companies Act 2014 and US Generally Accepted Accounting Principles (US GAAP), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene Part VI of the Companies Act (“the relevant financial reporting framework”).

We have reported separately on the parent company financial statements of Avadel Pharmaceuticals Public Limited Company for the year ended 31 December 2018.

**Basis for opinion**

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are further described in the “Auditor’s responsibilities for the audit of the financial statements” section of our report.

We are independent of the Group in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

**Conclusions relating to going concern**

We have nothing to report in respect of the following matters in relation to which ISAs (Ireland) require us to report to you where:

- the directors’ use of the going concern basis of accounting in preparation of the financial statements is not appropriate; or
- the directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the Group’s ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

**Key Audit Matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current financial period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

<u>Key Audit Matter Description</u>	<u>How the scope of our audit responded to the key audit matter</u>
<p><b>Revenue gross to net adjustments (Net Turnover \$103.3 million)</b></p> <p>Revenue is stated net of certain deductions such as estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances. These gross to net adjustments require judgement with expired product returns requiring a higher degree of estimation.</p> <p>The Group has an expired product return policy which allows customers and end users to return products six months prior to and twelve months subsequent to the expiration date.</p> <p>Estimating expected future product returns is a complex process, requiring significant estimation and judgement by management as it relates to estimated future trends and other competitive factors.</p> <p>There is a risk that these estimates and judgements relating to gross to net adjustments are incorrect or are manipulated resulting in incorrect reserves and adjustment to revenues being recorded.</p> <p>Refer also to Note 2 (accounting policy for Revenue) and Note 4 (Revenue Recognition).</p>	<p>In order to assess the revenue gross to net adjustments, we performed the following specific procedures:</p> <ul style="list-style-type: none"> <li>• We obtained an understanding of Group's controls in respect of gross to net adjustments and, assessed the design and implementation, and tested the operating effectiveness of relevant controls and where applicable updated our approach.</li> <li>• We obtained an understanding of the Group's methodology for estimating these adjustments, testing the inputs to the models, recalculating managements estimates and testing the arithmetical accuracy.</li> <li>• We developed an independent estimate of the expired product reserve by lot based on historical return patterns and compared our independent estimate to the recorded reserve.</li> <li>• We performed a retrospective analysis of actual returns experience for expired products versus prior period recorded reserves to assess whether the Group's methodology has historically resulted in accurate estimates.</li> <li>• We evaluated the Group's accounting and classification for gross to net adjustments through a combination of detail testing and analytical procedures.</li> <li>• We also assessed the adequacy of the disclosures provided for compliance with US GAAP.</li> </ul>

<u>Key Audit Matter Description</u>	<u>How the scope of our audit responded to the key audit matter</u>
<p><b>Long-term related party payables of \$28.8 million</b></p> <p>As detailed in Note 16 the Group has entered into a number of financing (\$3.2 million) and acquisition (\$25.6 million) arrangements with related parties.</p> <p>These obligations are recorded at fair value and adjusted at each respective balance sheet date.</p> <p>The determination of fair value in respect of these liabilities is dependent upon projections and a number of assumptions.</p> <p>A significant level of estimation is associated with the valuation of these liabilities in particular assumptions relating to market share. A risk exists that the fair value of these long-term related party liabilities are determined using inappropriate assumptions.</p> <p>Refer also to Note 2 (accounting policy for finance and acquisition related contingent consideration) and Note 16 Long-Term Related Party Payable.</p>	<p>In order to assess the provisions for related party liabilities, we performed the following specific procedures:</p> <ul style="list-style-type: none"> <li>• We obtained an understanding of group’s controls in respect of determining fair values of long-term related party payables and, assessed the design and implementation, and tested the operating effectiveness of controls.</li> <li>• We assessed the group’s methodology used in determining these liabilities, testing the inputs to the models, recalculating managements estimates and testing the arithmetical accuracy of the models used;</li> <li>• We tested each of the key assumptions used in the fair value calculations including but not limited to the percentage of market share and discount rate;</li> <li>• We, assisted by our internal valuation specialists, evaluated the key discount rate assumption and methodologies used;</li> <li>• We assessed post balance sheet events; and</li> <li>• We performed a retrospective review of revenue projections used in previous fair value calculations.</li> <li>• We also assessed the adequacy of the disclosures provided for compliance with US GAAP.</li> </ul>
<p><b>Noctiva Intangible Asset Impairment \$66 million</b></p> <p>During the fourth quarter of 2018, due to lack of a meaningful increase in Noctiva prescriptions despite the substantial investment of resources, an impairment charge of \$66 million was recorded to write-off the remaining carrying value of the acquired developed technology intangible asset related to Noctiva.</p> <p>There is a risk the group’s impairment assessment uses business and valuation assumptions that are not based on the best and most supportable estimates. A risk also exists that the impairment charge is not recorded in the correct period.</p> <p>Refer to Note 11 Goodwill and Intangible Assets.</p>	<p><u>How the scope of our audit responded to the key audit matter</u></p> <p>In order to assess the appropriateness and timing of the impairment charge we performed the following specific procedures:</p> <ul style="list-style-type: none"> <li>• We assessed the design and implementation, and tested the operating effectiveness of controls over the process for determining the appropriateness and timing for the impairment.</li> <li>• We obtained an understanding of group’s business and valuation assumptions and examined underlying data used to develop those assumptions.</li> <li>• We evaluated the group’s process and tested the underlying assumptions including timing of recording the impairment.</li> <li>• We reviewed all relevant support and evaluated information that contradicts management’s assertions.</li> <li>• We also assessed the adequacy of the disclosures provided for compliance with US GAAP.</li> </ul>



Our audit procedures relating to these matters were designed in the context of our audit of the financial statements as a whole, and not to express an opinion on individual accounts or disclosures. Our opinion on the financial statements is not modified with respect to any of the risks described above, and we do not express an opinion on these individual matters.

**Our application of materiality**

We define materiality as the magnitude of misstatement that makes it probable that the economic decisions of a reasonably knowledgeable person, relying on the financial statements, would be changed or influenced. We use materiality both in planning the scope of our audit work and in evaluating the results of our work.

We determined materiality for the Group to be \$1.8 million which represents approximately 2% of net sales and approximately 5% of adjusted pre-tax income. We have considered these two benchmarks of net income and adjusted pre-tax income in determining materiality as we determined these results to be of most importance to the members of the company. We have considered quantitative and qualitative factors such as our understanding of the Group and its environment, history of misstatements and complexity of the Group.

We agreed with the Audit Committee that we would report to the Audit Committee any audit differences in excess of \$0.09 million or 5% of materiality, as well as differences below that threshold that, in our view, warranted reporting on qualitative grounds. We also report to the Audit Committee on disclosure matters that we identified when assessing the overall presentation of the Group financial statements.

**An overview of the scope of our audit**

Our Group audit was scoped by obtaining an understanding of the Group and its environment, including Group — wide controls, and assessing the risks of material misstatement at the Group level. Based on that assessment, we focused our Group audit scope primarily with a full scope audit, predominately performed in the United States, on the Group's US operations which represented 99% of the revenue and 97% of long lived assets. The group's remaining Non US international components were subject to specified audit procedures, where the extent of our testing was based on our assessment of the risks of material misstatement and of the materiality of the Group's operations in those areas.

These components were selected based on coverage achieved and to provide an appropriate basis for undertaking audit work to address the risks of material misstatements identified above. Our audit work at the Non US International component was executed at levels of materiality applicable to each individual component which were lower than Group materiality at \$1.8 million.

**Other information**

The directors are responsible for the other information. The other information comprises the information included in the Directors' Report and Consolidated Financial Statements, other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

**Responsibilities of directors**

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

**Auditor's responsibilities for the audit of the financial statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (Ireland), we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error; design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the entity (or where relevant, the Group) to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the business activities within the group to express an opinion on the consolidated financial statements. The group auditor is responsible for the direction, supervision and performance of the group audit. The group auditor remains solely responsible for the audit opinion.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that the auditor identifies during the audit.

For listed entities and public interest entities, the auditor also provides those charged with governance with a statement that the auditor has complied with relevant ethical requirements regarding independence, including the Ethical Standard for Auditors (Ireland) 2016, and communicates with them all relationships and other matters that may reasonably be thought to bear on the auditor's independence, and where applicable, related safeguards.

Where the auditor is required to report on key audit matters, from the matters communicated with those charged with governance, the auditor determines those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. The auditor describes these matters in the auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, the auditor determines that a matter should not be communicated in the auditor's report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

This report is made solely to the company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

#### **Report on other legal and regulatory requirements**

##### **Opinion on other matters prescribed by the Companies Act 2014**

Based solely on the work undertaken in the course of the audit, we report that:

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- The financial statements are in agreement with the accounting records.
- In our opinion the information given in the directors' report is consistent with the financial statements and the directors' report has been prepared in accordance with the Companies Act 2014.

##### **Matters on which we are required to report by exception**

Based on the knowledge and understanding of the Group and its environment obtained in the course of the audit, we have not identified material misstatements in the directors' report that have been specified for our review.

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

/s/ Cathal Treacy

\_\_\_\_\_  
Cathal Treacy  
For and on behalf of Deloitte Ireland LLP  
Chartered Accountants and Statutory Audit Firm  
Deloitte & Touche House, Earlsfort Terrace, Dublin 2  
Date: 13 June, 2019

**AVADEL PHARMACEUTICALS PLC**  
**CONSOLIDATED PROFIT AND LOSS ACCOUNT**  
(In thousands, except per share data)

	Note	Years Ended 31 December,	
		2018	2017
Turnover	21	\$ 103,269	\$173,245
Cost of sales		(17,516)	(16,301)
Gross profit		85,753	156,944
Research and development costs	19	(39,329)	(33,418)
Distribution and administrative expenses		(100,359)	(58,860)
Intangible asset amortization	11	(6,619)	(3,659)
Gain – changes in fair value of related party contingent consideration	16	22,731	31,040
Impairment of intangible asset	11	(66,087)	—
Restructuring costs		(1,016)	(2,542)
Operating (loss) profit		(104,926)	89,505
Interest income		1,535	3,155
Interest expense	15	(10,622)	(1,052)
Other income – changes in fair value of related party payable	16	1,899	2,071
Foreign exchange gain (loss)		213	(714)
Other expense		(1,296)	(305)
(Loss) profit on ordinary activities before taxation		(113,197)	92,660
Taxation credit (charge)	5	17,893	(24,389)
(Loss) profit after taxation		\$ (95,304)	\$ 68,271
(Loss) earnings per share – basic:		\$ (2.55)	\$ 1.69
(Loss) earnings per share – diluted:		\$ (2.55)	\$ 1.63

*See accompanying notes to consolidated financial statements.*

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

	<u>Years ended 31 December,</u>	
	<u>2018</u>	<u>2017</u>
Profit (loss) after taxation	\$(95,304)	\$68,271
Other comprehensive profit (loss), net of taxation:		
Foreign currency translation (loss) gain	(419)	134
Net other comprehensive profit on marketable securities, net of (\$18), and \$28, tax, respectively	269	165
Total other comprehensive (loss) profit, net of taxation	<u>(150)</u>	<u>299</u>
Total comprehensive (loss) profit	<u><u>\$(95,454)</u></u>	<u><u>\$68,570</u></u>

*See accompanying notes to consolidated financial statements.*

**AVADEL PHARMACEUTICALS PLC**

**CONSOLIDATED BALANCE SHEET**  
(In thousands, except per share data)

	Note	31 December,	
		2018	2017
<b>Fixed Assets</b>			
Intangible assets	11	\$ 20,120	\$110,780
Tangible assets	10	1,911	3,001
		22,031	113,781
<b>Current Assets</b>			
Stocks	7	4,770	6,157
Debtors	8	63,584	39,264
Investments	9	90,590	77,511
Cash at bank and in hand		9,325	16,564
		168,269	139,496
<b>Creditors (amounts falling due within one year)</b>	12	(28,408)	(61,532)
<b>Net Current Assets</b>		139,861	77,964
<b>Total Assets Less Current Liabilities</b>		161,892	191,745
<b>Creditors (amounts due after more than one year)</b>	13	(117,680)	(16,983)
<b>Provision for Liabilities</b>	14	(41,432)	(89,182)
<b>Net Assets</b>		\$ 2,780	\$ 85,580
<b>Capital and Reserves</b>			
Called-up share capital presented as equity	18	\$ 453	\$ 440
Share premium account	18	84,748	81,182
Other reserves	18	31,728	(4,984)
Profit and loss account	18	(114,149)	8,942
<b>Shareholders' Funds</b>		\$ 2,780	\$ 85,580

Approved by the board of directors on 13 June, 2019 and signed on its behalf by:

/s/ Geoffrey M. Glass

Geoffrey M. Glass  
Director

/s/ Gregory J. Divis

Gregory J. Divis  
Director

*See accompanying notes to consolidated financial statements.*

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

	<b>Years ended 31 December,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities:</b>		
(Loss) Profit	\$ (95,304)	\$ 68,271
<b>Adjustments to reconcile net profit (loss) to net cash provided by operating activities:</b>		
Depreciation and amortization	7,430	4,883
Impairment of intangible asset	66,087	—
Amortization of premiums on marketable securities	2,823	732
Remeasurement of related party acquisition-related contingent consideration	(22,731)	(31,040)
Remeasurement of related party financing-related royalty agreements	(1,899)	(2,071)
Amortization of debt discount and debt issuance costs	4,830	—
Change in deferred tax and income tax deferred charge	(19,152)	3,556
Stock-based compensation expense	7,852	8,072
Other adjustments	1,365	(968)
<b>Increase (decrease) in cash from:</b>		
Trade debtors	3,452	3,054
Stocks	711	(2,899)
Prepaid expenses and other current assets	3,577	(3,741)
Research and development tax credit receivable	(2,545)	(3,141)
Trade creditors & other current liabilities	(2,032)	595
Deferred revenue	(1,892)	(216)
Accrued expenses	(10,640)	13,187
Accrued income taxes	(341)	(786)
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(19,468)	(31,636)
Royalty payments for related party payable in excess of original fair value	(2,838)	(4,429)
Other long-term assets and liabilities	(2,001)	(4,761)
<b>Net cash (used in) provided by operating activities</b>	<b>(82,716)</b>	<b>16,662</b>
<b>Cash flows from investing activities:</b>		
Purchases of tangible assets	(178)	(591)
Purchase of intangible assets	(20,000)	(53,111)
Proceeds from turnover of marketable securities	359,507	189,009
Purchases of marketable securities	(376,310)	(151,005)
<b>Net cash used in investing activities</b>	<b>(36,981)</b>	<b>(15,698)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from debt issuance	143,750	—
Payments for debt issuance costs	(6,190)	—
Earn-out payments for related party contingent consideration	(645)	(1,246)
Exercise of warrants	2,911	—
Cash proceeds from issuance of ordinary shares and warrants	577	404
Repurchase of ordinary shares	(27,637)	(22,361)
Other financing activities, net	(107)	(115)
<b>Net cash provided by (used in) financing activities</b>	<b>112,659</b>	<b>(23,318)</b>
Effect of exchange rate changes on cash and cash equivalents	(201)	(297)
<b>Net change in cash and cash equivalents</b>	<b>(7,239)</b>	<b>(22,651)</b>
Cash and cash equivalents at January 1	16,564	39,215
<b>Cash and cash equivalents at December 31</b>	<b>\$ 9,325</b>	<b>\$ 16,564</b>
<b>Supplemental disclosures of cash flow information:</b>		
Income tax paid	\$ 776	\$ 19,143
Interest paid	3,359	1,050

*See accompanying notes to consolidated financial statements.*

**AVADEL PHARMACEUTICALS PLC**

**CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY**  
(In thousands)

	Called-up Share Capital		Share Premium Account	Other Reserves	Profit and Loss Account	Total
	Number	Amount				
Balance, 31 December, 2016	41,396	\$ 440	\$ 398,040	\$(13,046)	\$ (343,365)	\$ 42,069
Net income	—	—	—	—	68,271	68,271
Other comprehensive income	—	—	—	—	299	299
Exercise of stock options	69	—	396	—	—	396
Vesting of restricted shares	23	—	—	—	—	—
Stock-based compensation expense	—	—	—	8,062	—	8,062
Repurchase of ordinary shares	—	—	—	—	(22,361)	(22,361)
Transfer to profit and loss account	—	—	(317,254)	—	317,254	—
Impact of accounting standard adoptions	—	—	—	—	(11,156)	(11,156)
Balance, 31 December, 2017	<u>41,488</u>	<u>\$ 440</u>	<u>\$ 81,182</u>	<u>\$ (4,984)</u>	<u>\$ 8,942</u>	<u>\$ 85,580</u>
Net loss	—	—	—	—	(95,304)	(95,304)
Other comprehensive loss	—	—	—	—	(150)	(150)
Exercise of stock options	82	1	534	—	—	535
Vesting of restricted shares	547	6	—	(6)	—	—
Stock-based compensation expense	—	—	—	7,852	—	7,852
Repurchase of ordinary shares	—	—	—	—	(27,637)	(27,637)
Exercise of warrants	603	6	2,905	—	—	2,911
Expiration of warrants	—	—	—	2,167	—	2,167
Employee share purchase plan issuance	25	—	127	—	—	127
Equity component of 2023 Notes	—	—	—	26,699	—	26,699
Balance, 31 December, 2018	<u>42,745</u>	<u>\$ 453</u>	<u>\$ 84,748</u>	<u>\$ 31,728</u>	<u>\$ (114,149)</u>	<u>\$ 2,780</u>

*See accompanying notes to consolidated financial statements.*



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

**NOTE 1: Background and Basis of Presentation**

**Background.** Avadel Pharmaceuticals plc (Nasdaq: AVDL) (“Avadel,” the “Group,” “we,” “our,” or “us”) is a branded specialty pharmaceutical Group. Our primary focus is on the development and potential FDA approval for FT218 which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. In addition, we market three sterile injectable drugs used in the hospital setting which were developed under our “unapproved marketed drug” (UMD) program. The Group is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit [www.avadel.com](http://www.avadel.com).

Our current marketed products include:

- *Akovaz*<sup>®</sup> (ephedrine sulfate injection, USP), an alpha- and beta-adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
- *Bloxiverz*<sup>®</sup> (neostigmine methylsulfate injection), a cholinesterase inhibitor, is indicated for the reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery.
- *Vazculep*<sup>®</sup> (phenylephrine hydrochloride injection), an alpha-1 adrenergic receptor agonist indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

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

*Noctiva*<sup>™</sup>, a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. Due to disappointing results after a substantial investment of resources after *Noctiva*’s commercial launch in March 2018, Avadel Specialty Pharmaceuticals LLC, (“Specialty Pharma”), the Avadel subsidiary responsible for the marketing and sale of *Noctiva*, made a voluntary filing for Chapter 11 bankruptcy protection on 6 February, 2019. As a result of Specialty Pharma’s bankruptcy filing on 6 February, 2019, Avadel has ceded authority for managing the business to the Bankruptcy Court, and Avadel management cannot carry on Specialty Pharma’s activities in the ordinary course of business without Bankruptcy Court approval. Avadel manages the day-to-day operations of Specialty Pharma, but does not have discretion to make significant capital or operating budgetary changes or decisions and purchase or sell significant assets, as Specialty Pharma’s material decisions are subject to review by the Bankruptcy Court. For these reasons, we have concluded that Avadel has lost control of Specialty Pharma, and no longer has significant influence over Specialty Pharma during the pendency of the bankruptcy. Therefore, we deconsolidated Specialty Pharma effective with the filing of the Chapter 11 bankruptcy in February 2019. On 26 April, 2019, Specialty Pharma sold its intangible assets and remaining inventory to an unaffiliated third party in exchange for aggregate cash proceeds of approximately \$250, pursuant to an order approving such sale which was issued by the Bankruptcy Court on 15 April, 2019. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the *Noctiva* business.

The Company was incorporated in Ireland on 1 December, 2015 as a private limited Company, and re-registered as an Irish public limited Company on 21 November, 2016 (Company registration number: 572535). Its headquarters are in Dublin, Ireland and it has operations in St. Louis, Missouri, United States, and Lyon, France. The address of its registered office is Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15, Ireland. Its registered number is 572535.

The Company is the successor to Flamel Technologies S.A., a French société anonyme (“Flamel”), as the result of the Merger, in which Flamel merged with and into the Company at 11:59:59 p.m., Central Europe Time, on 31 December, 2016 (the “Merger”) pursuant to the agreement between Flamel and Avadel entitled

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

Common Draft Terms of Cross-Border Merger dated as of 29 June, 2016 (the “Merger Agreement”). Immediately prior to the Merger, the Company was a wholly owned subsidiary of Flamel. In accordance with the Merger Agreement, as a result of the Merger:

- Flamel ceased to exist as a separate entity and the Company continued as the surviving entity and assumed all of the assets and liabilities of Flamel.
- our authorized share capital is \$5,500 divided into 500,000 ordinary shares with a nominal value of \$0.01 each and 50,000 preferred shares with a nominal value of \$0.01 each
  - all outstanding ordinary shares of Flamel, €0.122 nominal value per share, were canceled and exchanged on a one-for-one basis for newly issued ordinary shares of the Group, \$0.01 nominal value per share. This change in nominal value of our outstanding shares resulted in our reclassifying \$5,937 on our balance sheet from ordinary shares to additional paid-in capital
  - our Board of Directors is authorized to issue preferred shares on a non-pre-emptive basis, for a maximum period of five years, at which point such an authorization may be renewed by shareholders. The Board of Directors has discretion to dictate terms attached to the preferred shares, including voting, dividend, conversion rights, and priority relative to other classes of shares with respect to dividends and upon a liquidation.
- all outstanding American Depositary Shares (ADSs) representing ordinary shares of Flamel were canceled and exchanged on a one-for-one basis for ADSs representing ordinary shares of the Group.

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

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

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

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

**Basis of Presentation.** These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The consolidated financial statements include the accounts of the Group and all subsidiaries. All interGroup accounts and transactions have been eliminated. The format of consolidated profit and loss account has been adopted where necessary to better reflect the nature of the business.

Our results of operations for the period 1 January, 2018 through 16 February, 2018 and for the year ended 31 December, 2017 include the results of FSC Therapeutics and FSC Laboratories, Inc., (collectively “FSC”), prior to its 16 February, 2018 disposition date. See *Note 26: Divestiture of the Pediatric Assets*, for additional information. All interGroup accounts and transactions have been eliminated.

**AVADEL PHARMACEUTICALS PLC**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
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The directors have elected to prepare the Irish statutory group consolidated financial statements of Avadel Pharmaceuticals plc in accordance with Section 279 of the Companies Act 2014, which provides that a true and fair view of the assets and liabilities, financial position, and profit or loss may be given by preparing the financial statements in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of part 6 of the Companies Act 2014.

The directors have elected to prepare the Avadel Pharmaceuticals plc parent Company financial statements in accordance with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* (Generally Accepted Accounting Practice in Ireland) and the Companies Act 2014.

**NOTE 2: Critical Accounting Estimates and Related Accounting Policies**

**Critical Accounting Estimates and the related Accounting Policies**

***Turnover Recognition***

The Group recognizes turnover for sales of pharmaceutical products, licensing fees and, if any, milestone payments for R&D achievements.

Effective 1 January, 2018, the Group adopted Accounting Standards Codification (“ASC”) Topic 606, “Revenue from Contracts with Customers” using the modified retrospective transition method applied to all open contracts as at 31 December, 2017. The adoption of the new standard did not have a material effect on the overall timing or amount of revenue recognized when compared to prior accounting standards. See *Note 4: Revenue Recognition* for expanded disclosures related to this new pronouncement.

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

***Product Sales***

The Group sells products primarily through wholesalers and considers these wholesalers to be its customers. Revenue from product sales is recognized when the customer obtains control of the Group’s product, which occurs typically upon receipt by the customer. As is customary in the pharmaceutical industry, the Group’s gross product sales are subject to a variety of price adjustments in arriving at reported net product sales. These adjustments include estimates of product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated based on analysis of historical data for the product or comparable products, future expectations for such products and other judgments and analysis.

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For generic products and branded products where the ultimate net selling price to customer is estimable, the Group recognizes revenues upon delivery to the wholesaler. For new product launches the Group recognizes revenue if sufficient data is available to determine product acceptance in the marketplace such that product returns may be estimated based on historical or analog product data and there is probable evidence of reorders and consideration is made of wholesaler inventory levels.

*License Revenue*

The Group from time to time may enter into out-licensing agreements under which it licenses to third parties certain rights to its products or intellectual property. The terms of these arrangements typically include payment to the Group of one or more of the following: non-refundable, upfront license fees; development, regulatory, and commercial milestone payments; and sales-based royalty payments. Each of these payments results in license revenue.

For a complete discussion of the accounting for net product revenue and license revenues, see *Note 4: Revenue Recognition*.

*Goodwill and Intangible Assets*

Intangible assets consist primarily of purchased licenses and intangible assets recognized as part of the Éclat and FSC acquisitions. Acquired in-process research and development (“IPR&D”) is not amortized until completion and development of the project, at which time the IPR&D becomes an amortizable asset, for which amortization of such intangible assets is computed using the straight-line method over the estimated useful life of the assets. Intangible assets are reviewed for impairment whenever conditions indicate that the carrying value of the assets may not be fully recoverable. Such impairment tests are based on a comparison of the pretax undiscounted cash flows expected to be generated by the asset to the recorded value of the asset or other market based value approaches. If impairment is indicated, the asset value is written down to its market value if readily determinable or its estimated fair value based on discounted cash flows. Any significant changes in business or market conditions that vary from current expectations could have an impact on the fair value of these assets and any potential associated impairment. During the fourth quarter of 2018, we recorded a \$66,087 impairment charge to the entire acquired developed technology related to Noctiva (see *Note 11: Intangible Assets*). The Group had determined that no impairment existed at 31 December, 2017.

Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. The Group has determined that we operate in a single segment and has a single reporting unit associated with the development and commercialization of pharmaceutical products. Irish company law requires goodwill to be amortized; however, the directors do not believe that this gives a true and fair value because not all of the goodwill declines in value. In addition, goodwill that does decline in value rarely declines on a straight-line basis, as such straight-line amortization of goodwill over an arbitrary period does not reflect the economic reality. Therefore, to present a true and fair value of the economic reality, under U.S. GAAP, goodwill is considered to be indefinite-lived and are not amortized. Rather, the Group tests goodwill for impairment on an annual basis. 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 Group tests goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. During the fourth quarter of 2018, we performed our required annual impairment test of goodwill and have determined that no impairment of goodwill existed at 31 December, 2018 or 2017.

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

***Fixed Assets***

Fixed assets are reviewed for impairment whenever conditions indicate that the carrying value of the assets may not be fully recoverable. Such impairment tests are based on a comparison of the pretax undiscounted cash flows expected to be generated by the asset to the recorded value of the asset or other market based value approaches. If impairment is indicated, the asset value is written down to its market value if readily determinable or its estimated fair value based on discounted cash flows. Any significant changes in business or market conditions that vary from current expectations could have an impact on the fair value of these assets and any potential associated impairment. The Group had determined that no impairment existed at 31 December, 2018 and 2017 related to fixed assets.

***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 14: Provision for Liabilities* and *Note 16: 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 profit and loss account, balance sheet and statements of cash flows. Changes in fair value of these liabilities are recorded in the consolidated profit and loss account 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 16: 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 profit and loss account, balance sheet and statements of cash flows. Changes in the fair value of this liability are recorded in the consolidated profit and loss account as other expense — changes in fair value of related party payable.

***Going Concern Assessment***

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

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significantly decrease our available cash and marketable securities which could, among other things, force us to raise additional funds and/or force us to further reduce our cost structure, either of which could have a material adverse effect on our business. If available to us, raising additional capital may be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders.

On this basis, the directors have a reasonable expectation that the group has adequate resources to continue in operational existence for the foreseeable future. Thus, they continue to adopt the going concern basis in preparing the annual financial statements.

***Embedded Derivatives***

The Company considered the guidance in ASC 815-15, Embedded Derivatives, to determine if this instrument contains an embedded feature that should be separately accounted for as a derivative. ASC 815 provides for an exception to this rule when convertible notes, as host instruments, are deemed to be conventional, as defined by ASC 815-40. The Company determined that this exception applies due, in part, to our ability to settle the 2023 Notes in cash, ADSs or a combination of cash and ADSs, at our option. The Company has therefore applied the guidance provided by ASC 470-20, Debt with Conversion and Other Options which requires that the 2023 Notes be separated into debt and equity components at issuance and a value be assigned to each. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the 2023 Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the 2023 Notes and the fair value of the liability of the 2023 Notes on its issuance date. The excess of the principal amount of the liability component over its carrying amount (the "Debt Discount") is amortized to interest expense using the effective interest method over the term of the 2023 Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

**Summary of Other Accounting Policies**

***Cash at Bank and In Hand***

The Group classifies cash on hand and deposited in banks including commercial paper, money market accounts and other investments it may hold from time to time, with an original maturity to the Group of three months or less, as cash at bank and in hand.

***Marketable Securities***

The Group's marketable securities are carried at fair value, with unrealized gains and losses, net of taxes, reported as a component of other reserves in shareholders' funds, 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. See *Note 20: Fair Value Measurements* for a discussed on how fair value is determined.

***Trade Debtors***

Trade debtors are stated at amounts invoiced net of allowances for doubtful accounts and certain other gross to net deductions. The Group 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 trade debtors is due from three significant customers. See *Note 21: Group Operations by Product, Customer and Geographic Area*.

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***Stocks***

Stocks consist of raw materials and finished products, which are stated at lower of cost or net realizable value 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 Group establishes reserves for stock estimated to be obsolete, unmarketable or slow-moving on a case by case basis.

***Goodwill***

See Critical Accounting Estimates and Judgments section located above in this note.

***Tangible Assets***

Tangible assets are 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

***Government Grants***

The Group 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 Group is released of our obligation to repay the funds and as such the funds are recognized in the consolidated profit and loss account as an offset to R&D expense. The absence of commercial success must be formally confirmed by the granting authority. Should the Group wish to discontinue the R&D to which the funding is associated, the granting authority must be informed and a determination made as to how much, if any, of the grant must be repaid.

***Research and Development (R&D)***

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

The Group recognizes R&D tax credits received from the French government for spending on innovative R&D as an offset of R&D expenses. The amount offset to expense was \$2,621 and \$3,135 for the financial years ended December 31, 2018 and 2017, respectively.

***Advertising Expenses***

We expense the costs of advertising as incurred. Advertising expenses were \$17,562 and \$2,214 for the years ended 31 December, 2018 and 2017, respectively.

***Stock-based Compensation***

The Group accounts for stock-based compensation based on the estimated grant-date fair value. The fair value of stock options and warrants is estimated using Black-Scholes option-pricing valuation models (“Black-Scholes model”). As required by the Black-Sholes model, estimates are made of the underlying

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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 Group recognizes compensation cost, net of an estimated forfeiture rate, using the accelerated method over the requisite service period of the award. See *Note 18* for additional detail on the value of estimates.

***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. See *Note 5: Taxation*.

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

We recognize interest and penalties related to unrecognized tax benefits in the income tax expense line in the accompanying consolidated profit and loss account. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheets.

***Foreign Currency Translation***

At 31 December, 2018, the reporting currency of the Group and our wholly-owned subsidiaries is the U.S. dollar. 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 profit and loss account.

***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.



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**NOTE 3: Effect of New Accounting Standards**

***Recently Adopted Accounting Guidance***

In March 2017, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“ASU”) No. 2017-07, “Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Costs.” The standard requires the service component of pension and other postretirement benefit expense to be presented in the same statement of income lines as other employee compensation costs, however, the other components will be presented outside of operating income. In addition, only the service cost component will be eligible for capitalization in assets. The Group adopted this standard in the first quarter of 2018 and it had an immaterial impact on our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, “*Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments.*” ASU 2016-15 identifies how certain cash receipts and cash payments are presented and classified in the Statement of Cash Flows under Topic 230. ASU 2016-15 is effective for the Group for fiscal years beginning after 15 December, 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 Group adopted this standard in the first quarter of 2018 and it had an immaterial impact on our consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09 “*Revenue from Contracts with Customers*” which supersedes the most current revenue recognition requirements. This ASU requires entities to recognize revenue in a way that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services. Through May 2016, the FASB issued ASU 2016-08 “Principal versus Agent Considerations (Reporting Revenue Gross versus Net),” ASU 2016-10 “Identifying Performance Obligations and Licensing,” and ASU 2016-12, “Narrow-Scope Improvements and Practical Expedients,” which provide supplemental adoption guidance and clarification to ASU 2014-09, respectively. The Group adopted this pronouncement under the modified retrospective method of transition in the first quarter of 2018. The adoption of the new standard did not have a material effect on the overall timing or amount of revenue recognized when compared to current accounting standards. The impact to the Group of adopting the new revenue standard primarily relates to additional and expanded disclosures. See *Note 4: Revenue Recognition*.

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

***Recent Accounting Guidance Not Yet Adopted***

In August 2018, the FASB issued ASU 2018-13, “*Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirement for Fair Value Measurement*” which amends certain disclosure requirements over Level 1, Level 2 and Level 3 fair value measurements. The amendments in ASU 2018-13 are effective for fiscal years beginning after 15 December, 2019, with early adoption permitted. The Group is currently evaluating the impact of adopting ASU 2018-13.

In January 2017, the FASB issued ASU 2017-04, “*Intangibles — Goodwill and Other: Simplifying the Test for Goodwill Impairment.*” This update eliminates step 2 from the goodwill impairment test, and requires the goodwill impairment test to be performed by comparing the fair value of a reporting unit with its carrying

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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 Group in the first quarter of 2020. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after 1 January, 2017. The Group will assess the timing of adoption and impact of this guidance to future impairment considerations.

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

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

**NOTE 4: Revenue Recognition**

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

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

*Product Sales and Services*

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

*Licensing Revenues*

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

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

*Product Sales and Services*

Effective 1 January, 2018, the Group implemented ASC 606, Revenue From Contracts With Customers. The Group sells products primarily through wholesalers and considers these wholesalers to be its customers.

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Under ASC 606, revenue from product sales is recognized when the customer obtains control of the Group's product and the Group's performance obligations are met, which occurs typically upon receipt of delivery to the customer. As is customary in the pharmaceutical industry, the Group's gross product sales are subject to a variety of price deductions in arriving at reported net product sales. These adjustments include estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated when the product is delivered based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

*Reserves to reduce Gross Revenues to Net Revenues*

Revenues from product sales are recorded at the net selling price, which includes estimated reserves to reduce gross product sales to net product sales resulting from product returns, chargebacks, payment discounts, rebates, and other sales allowances that are offered within contracts between the Group and its customers and end users. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable if the amount is payable to the customer, except in the case of the estimated reserve for future expired product returns, which are classified as a liability. The reserves are classified as a liability if the amount is payable to a party other than a customer. Where appropriate, these estimated reserves take into consideration relevant factors such as the Group's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Group's best estimates to reduce gross selling price to net selling price to which it expects to be entitled based on the terms of its contracts. The actual selling price ultimately received may differ from the Group's estimates. If actual results in the future vary from the Group's estimates, the Group adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

*Product Returns*

Consistent with industry practice, the Group maintains a returns policy, that generally offers customers a right of return for product that has been purchased from the Group. The Group estimates the amount of product returns and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Group currently estimates product return liabilities based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

*Chargebacks, Discounts and Rebates*

Chargebacks, discounts and rebates represent the estimated obligations resulting from contractual commitments to sell products to its customers or end users at prices lower than the list prices charged to our wholesale customers. Customers charge the Group for the difference between the gross selling price they pay for the product and the ultimate contractual price agreed to between the Group and these end users. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargebacks, discounts and rebates are estimated at the time of sale to the customer.

*Revenue from licensing arrangements*

The terms of the Group's licensing agreements may contain multiple performance obligations, including certain R&D activities. The terms of these arrangements typically include payment to the Group of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments. Each of these payments results in license revenues.

*License of Intellectual Property*

If the license to the Group's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Group recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and

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benefit from the license. For licenses that are bundled with other promises, the Group utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Group evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

***Disaggregation of revenue***

The Group's primary source of revenue is from the sale of pharmaceutical products, which are equally affected by the same economic factors as it relates to the nature, amount, timing, and uncertainty of revenue and cash flows. For further detail about the Group's revenues by product, see *Note 21: Group Operations by Product, Customer and Geography*.

***Contract Balances***

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

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

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

There were no material deferred contract costs at 31 December, 2018.

***Transaction Price Allocated to the Remaining Performance Obligation***

For product sales, the Group generally satisfies its performance obligations within the same period the product is delivered. Product sales recognized in 2018 from performance obligations satisfied (or partially satisfied) in previous periods were immaterial.

For certain licenses of intellectual property, specifically those with performance obligations satisfied over time, the Group allocates a portion of the transaction price to that performance obligation and recognizes revenue using an appropriate measure of progress towards development of the product. In December 2018, the Group reached an agreement to exit a contract and our remaining performance obligations and recognized the remaining \$1,600 of deferred revenue, which represented the unsatisfied performance obligations associated with a license agreement. At 31 December, 2018, the deferred revenue balance related to this obligation is \$0.

The Group has elected certain of the practical expedients from the disclosure requirement for remaining performance obligations for specific situations in which an entity need not estimate variable consideration to recognize revenue. Accordingly, the Group applies the practical expedient in ASC 606 to its stand-alone contracts and does not disclose information about variable consideration from remaining performance obligations for which the Group recognizes revenue.

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**NOTE 5: Taxation**

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

<u>(Loss) profit on Ordinary Activities Before Taxation</u>	<u>2018</u>	<u>2017</u>
Ireland	\$ (42,604)	\$ (3,123)
United States	(70,340)	92,754
France	(253)	3,029
Total (loss) profit before taxation	<u>\$ (113,197)</u>	<u>\$ 92,660</u>

The taxation (credit) charge for the years ended 31 December, is as follows:

<u>Taxation (Credit) Charge</u>	<u>2018</u>	<u>2017</u>
<b>Current:</b>		
United States – Federal	\$ —	\$ 18,064
United States – State	330	331
France	—	265
Total current	<u>330</u>	<u>18,660</u>
<b>Deferred:</b>		
United States – Federal	(19,503)	4,686
United States – State	1,280	1,043
France	—	—
Total deferred	<u>(18,223)</u>	<u>5,729</u>
Taxation (credit) charge	<u>\$ (17,893)</u>	<u>\$ 24,389</u>

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The items accounting for the difference between the taxation charge computed at the jurisdiction of incorporation statutory rate and the Group's effective tax rate are as follows for the years ended 31 December:

<b>Reconciliation to Effective Income Tax Rate:</b>	<b>2018</b>	<b>2017</b>
Statutory tax rate <sup>(1)</sup>	12.5%	12.5%
Non-deductible changes in fair value of contingent consideration	4.0%	(11.6)%
Change in valuation allowance	(5.3)%	(0.7)%
International tax rates differential	8.0%	22.2%
Nondeductible stock based compensation	(1.3)%	(0.4)%
Cross-border merger	—%	0.3%
Unrecognized tax benefit	(1.3)%	1.4%
State and local taxes (net of federal)	(0.3)%	0.3%
Change in U.S. tax law	(0.2)%	3.8%
Nondeductible interest expense	(1.1)%	—%
Other	0.7%	(1.5)%
Effective income tax rate	<u>15.7%</u>	<u>26.3%</u>
Taxation (credit) charge – at statutory tax rate	\$(14,149)	\$ 11,582
Non-deductible changes in fair value of contingent consideration	(4,559)	(10,779)
Change in valuation allowance	5,998	(610)
International tax rates differential	(9,039)	20,557
Nondeductible stock based compensation	1,499 <sup>)</sup>	(375)
Cross-border merger	—	265
Unrecognized tax benefit	1,440	1,296
State and local taxes (net of federal)	299	252
Change in U.S. tax law	274	3,513
Nondeductible interest expense	1,269	—
Other	(925)	(1,312)
Taxation (credit) charge – at effective income tax rate	<u>\$(17,893)</u>	<u>\$ 24,389</u>

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

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

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***Unrecognized Tax Benefits***

The Group or one of its subsidiaries files income tax returns in Ireland, France, United States and various states. With few exceptions, the Group is no longer subject to Irish, French, U.S. Federal, and state and local examinations for years before 2014. The Internal Revenue Service (IRS) commenced an examination of the Group's U.S. income tax return for 2015 in the 4<sup>th</sup> quarter of 2016. The French tax authority commenced an examination of the Company's French tax return for 2017 in the first quarter of 2019.

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

<b>Unrecognized Tax Benefit Activity</b>	<b>2018</b>	<b>2017</b>
Balance at January 1:	\$3,954	\$1,686
Additions based on tax positions related to the current year	1,087	2,268
Additions for tax positions of prior years	274	—
Balance at December 31:	<u>\$5,315</u>	<u>\$3,954</u>

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

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

The Group recognizes interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the years ended 31 December, 2018, and 2017, the Group recognized approximately \$725, and \$304 in interest and penalties. The Group had approximately \$1,057, and \$331 for the payment of interest and penalties accrued at 31 December, 2018, and 2017 respectively.

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**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 31 December, 2018 and 2017 resulted from the following temporary differences:

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

At 31 December, 2018, the Group had \$72,453 of net operating losses in Ireland and \$3,259 of operating losses in France that do not have an expiration date and \$25,840 of net operating losses in the U.S., \$10,365 were acquired due to the acquisition of FSC in 2016 and \$15,475 is due to the losses and carryforwards generated at U.S. Holdings in 2018. The portion due to the acquisition of FSC will expire 2034 through 2035. A valuation allowance is recorded if, based on the weight of available evidence, it is more likely than not that a deferred tax asset will not be realized. This assessment is based on an evaluation of the level of historical taxable income and projections for future taxable income. While the Group believes it is more likely than not that it will be able to realize the deferred tax assets in the U.S., the Group continues to monitor changes in the U.S. hospital products market as unfavorable changes could ultimately impact our assessment of the realizability of our U.S. deferred tax assets. The U.S. net operating losses are subject to an annual limitation as a result of the FSC acquisition under Internal Revenue Code Section 382 and may not be fully utilized before they expire.

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



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

At 31 December, 2018 and 2017, the Group has unremitted earnings of \$2,798 and \$3,038, respectively, 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 Group 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 and Irish governments provide tax credits to companies for spending on innovative R&D. These credits are recorded as an offset of R&D expenses and are credited against income taxes payable in years after being incurred or, if not so utilized, are recoverable in cash after a specified period of time, which may differ depending on the tax credit regime. As of 31 December, 2018, the Group's net Research tax credit receivable amounts to \$7,555 and represents a French gross research tax credit of \$6,922 and an Irish gross research tax credit of \$633. As of 31 December, 2017, the Group's net research tax credit receivable amounted to \$5,272 and represented a French gross research tax credit of \$4,754 and an Irish gross research tax credit of \$518.

***Income Tax Deferred Charge***

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

***Cross-Border Merger***

In 2016, we changed our jurisdiction of incorporation from France to Ireland by merging with and into our wholly owned Irish subsidiary. Information about the reincorporation was included in the definitive proxy statement filed with the Securities and Exchange Commission on 5 July, 2016. Prior to the merger, the Group submitted a request to the French tax authorities seeking to benefit from a special regime for mergers and demergers, conditional upon a formal consent of the French tax authority which would allow for the deferral of a portion of the tax cost of the cross-border merger. In 2017, the Group received a letter from the French tax authorities indicating that our request to benefit from the special regime had been declined. Completion of the cross-border merger resulted in the recognition of a net taxation charges of

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\$4,266, after considering tax benefits from the utilization of current and prior year French net operating losses. The Group was able to utilize \$4,266 of French research and development tax credits to offset the remaining cost of the transaction. The Group also removed \$111,495 of French net operating losses as the carryforward of these losses was contingent on receiving favorable consent from the French tax authority. The French net operating losses had a full valuation allowance resulting in no impact to the taxation charge.

**2017 Tax Cuts and Jobs Act**

On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act (the “Tax Act”). The Tax Act includes significant changes to the U.S. corporate income tax system including: a federal corporate rate reduction from 35% to 21%; limitations on the deductibility of interest expense and executive compensation; creation of the base erosion anti-abuse tax (“BEAT”) and a new minimum tax. As a result of the Act being signed into law, the Group recognized a charge of \$274 and \$3,513 in 2018 and 2017, respectively, related to the re-measurement of its U.S. net deferred tax assets and certain unrecognized tax benefits at the lower enacted corporate tax rates. A majority of the provisions in the Tax Act are effective 1 January, 2018.

**NOTE 6: (Loss) Earnings Per Ordinary Share**

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

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

<b>Basic and Diluted (Loss) Earnings Per Share:</b>	<b>2018</b>	<b>2017</b>
<b>(Loss) earnings per share numerator:</b>		
(Loss) profit from ordinary operations attributable to common shareholders before allocation of earnings to participating securities	\$(95,304)	\$68,271
Less: earnings allocated to participating securities	—	—
(Loss) profit attributable to common shareholders, after allocation of earnings to participating securities	<u>\$(95,304)</u>	<u>\$68,271</u>
<b>(Loss) earnings per share denominator:</b>		
Weighted-average shares outstanding – basic	\$ 37,325	\$40,465
Impact of dilutive securities	—	1,330
Weighted-average shares outstanding – dilute	<u>\$ 37,325</u>	<u>\$41,795</u>
Basic (loss) earnings per share attributable to common shareholders:	<u>\$ (2.55)</u>	<u>\$ 1.69</u>
Diluted (loss) earnings per share attributable to common shareholders:	\$ (2.55)	\$ 1.63

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

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**NOTE 7: Stocks**

The principal categories of stocks, net of reserves of \$4,757 and \$1,039 in 2018 and 2017, respectively, are comprised of the following as of 31 December:

<b>Stocks:</b>	<b>2018</b>	<b>2017</b>
Raw materials	\$ 500	\$1,383
Finished goods	4,270	4,774
Total stocks	<u>\$4,770</u>	<u>\$6,157</u>

The replacement cost of stocks as at 31 December, 2018 does not significantly differ from the total amount at which they are stated in the balance sheet.

**NOTE 8: Debtors**

At the end of fiscal 2018 and 2017, debtors were comprised of:

	<b>2018</b>	<b>2017</b>
<b><u>Debtors (amounts receivable within one year):</u></b>		
Value-added tax recoverable	\$ 1,378	\$ 1,206
Prepaid and other expenses	2,145	7,106
Guarantee from Armistice (see Note 26)	534	—
Income tax receivable	921	518
Trade debtors	11,330	14,785
Research and development tax credit receivable	283	—
Short-term deposit	3,350	—
Other	225	128
Total	<u>\$20,166</u>	<u>\$23,743</u>
<b><u>Debtors (amounts receivable after one year):</u></b>		
Deferred tax assets	\$23,029	\$ 3,877
Research and development tax credit receivable	7,272	5,272
Long-term deposit	1,477	3,350
Guarantee from Armistice (see Note 26)	5,697	—
Right of use assets at contract manufacturing organizations	5,894	2,909
Other	49	113
Total	<u>\$43,418</u>	<u>\$15,521</u>
Total	<u>\$63,584</u>	<u>\$39,264</u>

**NOTE 9: Investments**

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

Under Irish company law, investments are considered fixed assets in nature while the treatment for US GAAP purposes considers the balance current in nature. As such, no reconciliation has been provided.

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The following tables show the Group's available-for-sale securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category as of 31 December, 2018 and 2017, respectively:

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

  

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

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

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 31 December, 2018:

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

The Group has classified our investment in available-for-sale marketable securities as current assets in the consolidated balance sheet at 31 December, 2018 and 2017, 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.

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**NOTE 10: Tangible Assets**

Tangible asset activity for fiscal year 2018 and 2017 was as follows:

	Laboratory Equipment	Office and Computer Equipment	Furniture, Fixtures, and Fittings	Total Tangible Assets
<b>Cost:</b>				
At 31 December, 2016	\$ 9,019	\$ 2,519	\$ 4,239	\$ 15,777
Additions	262	312	17	591
Disposals	(364)	—	—	(364)
Transfers	26	—	(26)	—
Currency translation and other	1,192	284	549	2,025
At 31 December, 2017	<u>\$ 10,135</u>	<u>\$ 3,115</u>	<u>\$ 4,779</u>	<u>\$ 18,029</u>
Additions	94	48	51	\$ 193
Disposals	(966)	(274)	(1,146)	(2,386)
Transfers	43	(289)	246	—
Currency translation and other	(442)	(113)	(215)	(770)
At 31 December, 2018	<u>\$ 8,864</u>	<u>\$ 2,487</u>	<u>\$ 3,715</u>	<u>15,066</u>
<b>Depreciation:</b>				
At 31 December, 2016	\$ (7,131)	\$ (1,697)	\$ (3,629)	\$ (12,457)
Depreciation expense	(677)	(229)	(318)	(1,224)
Disposal of tangible assets	350	—	—	350
Currency translation and other	(993)	(193)	(511)	(1,697)
At 31 December, 2017	<u>\$ (8,451)</u>	<u>\$ (2,119)</u>	<u>\$ (4,458)</u>	<u>\$ (15,028)</u>
Depreciation expense	(270)	(411)	(130)	(811)
Disposal of tangible assets	769	2	1,198	1,969
Transfers	—	109	(109)	—
Currency translation and other	340	176	199	715
At 31 December, 2018	<u>\$ (7,612)</u>	<u>\$ (2,243)</u>	<u>\$ (3,300)</u>	<u>\$ (13,155)</u>
<b>Net Book Value</b>				
At 31 December, 2017	\$ 1,684	\$ 996	\$ 321	\$ 3,001
At 31 December, 2018	\$ 1,252	\$ 244	\$ 415	\$ 1,911

Gain or loss on disposal of tangible assets was immaterial in both fiscal 2018 and 2017.

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**NOTE 11: Goodwill and Intangible Assets**

Intangible asset activity for fiscal 2018 and 2017 was as follows:

	<u>Goodwill</u>	<u>Acquired Product Marketing Rights</u>	<u>Acquired Developed Technology</u>	<u>Total Intangible Assets</u>
<b>Cost:</b>				
At 31 December, 2016	\$18,491	\$ 16,600	\$ 51,609	\$ 86,700
Additions	—	—	73,111	73,111
At 31 December, 2017	<u>\$18,491</u>	<u>\$ 16,600</u>	<u>\$124,720</u>	<u>\$159,811</u>
Additions	—	—	—	—
Disposals	—	(16,600)	(4,300)	(20,900)
Impairment	—	—	(73,111)	(73,111)
At 31 December, 2018	<u>\$18,491</u>	<u>\$ —</u>	<u>\$ 47,309</u>	<u>\$ 65,800</u>
<b>Amortization:</b>				
At 31 December, 2016	\$ —	\$ (1,019)	\$ (44,353)	\$ (45,372)
Amortization expense	—	(1,113)	(2,546)	(3,659)
At 31 December, 2017	<u>\$ —</u>	<u>\$ (2,132)</u>	<u>\$ (46,899)</u>	<u>\$ (49,031)</u>
Amortization expense	—	(139)	(6,480)	(6,619)
Disposals	—	2,271	675	2,946
Impairment	—	—	7,024	7,024
At 31 December, 2018	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (45,680)</u>	<u>\$ (45,680)</u>
<b>Net Book Value</b>				
At 31 December, 2017	\$18,491	\$ 14,468	\$ 77,821	\$110,780
At 31 December, 2018	\$18,491	\$ —	\$ 1,629	\$ 20,120

During the year ended 31 December, 2017, the Group acquired \$73,111 in developed technology as part of the Exclusive License and Assignment Agreement (ELAA) with Serenity Pharmaceuticals, LLC. The aggregate cost was composed of an upfront payment of \$50,000, an accrued payment of \$20,000 which was paid for Noctiva during the year ended 31 December, 2018, and \$3,111 of transaction costs. The Group amortizes the developed technology over a 13 year period, which began 1 October, 2017. During the fourth quarter 2018, certain conditions came to light, largely the lack of a meaningful increase in Noctiva prescriptions despite the substantial investment of resources, which indicated that the carrying value of the asset, may not be fully recoverable. As such, the Group performed an impairment test based on a comparison of the pretax discounted cash flows expected to be generated by the asset, which is a Level 3 fair value estimate, to the recorded value of the asset and concluded that the associated cash flows did not support any of the carrying value of the intangible asset and the Group recorded a full impairment charge of \$66,087 at 31 December, 2018 related to the acquired developed technology associated with Noctiva. The 6 February, 2019 Chapter 11 bankruptcy filing of Specialty Pharma, the subsidiary which markets, sells and distributes Noctiva, confirmed management's conclusion on the impairment. This impairment charge is included in the line "Impairment of intangible asset" in the consolidated profit and loss account.

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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:

<u>Estimated Amortization Expense:</u>	<u>Balance</u>
Fiscal 2019	\$815
Fiscal 2020	814
Fiscal 2021	—
Fiscal 2022	—
Fiscal 2023	—

**NOTE 12: Creditors (amounts falling due within one year)**

At the end of fiscal 2018 and 2017, creditors (amounts falling due within one year) were comprised of:

<u>Creditors (amounts falling due within one year):</u>	<u>2018</u>	<u>2017</u>
Debt (see <i>Note 15</i> )	\$ 106	\$ 111
Trade creditors	3,503	7,477
Deferred revenue	114	2,007
Accrued compensation	3,971	3,157
Accrued social charges	1,009	1,204
Accrued employee severance	879	1,000
Customer allowances	6,541	10,613
Accrued ELAA payment	—	20,000
Accrued CMO charges	2,028	2,327
Accrued contract sales organization and marketing costs	3,469	7,641
Income taxes	73	414
Accrued contract research organization	1,000	156
Other	5,715	5,425
Total	<u>\$28,408</u>	<u>\$61,532</u>

**NOTE 13: Creditors (amounts falling due after more than a year)**

At the end of fiscal 2018 and 2017, creditors (amounts falling due after more than a year) were comprised of:

<u>Creditors (amounts falling after more than a year):</u>	<u>2018</u>	<u>2017</u>
Debt ( <i>Note 15</i> )	\$115,734	\$ 156
Long-term liability – FSC ( <i>Note 16</i> )	—	15,000
Customer allowances	1,352	1,636
Other	594	191
Total	<u>\$117,680</u>	<u>\$16,983</u>

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**NOTE 14: Provisions for Liabilities**

	Related Party Payable (Note 16)	Unrecognized Tax Benefits (Note 5)	Provision for Retirement Indemnity (Note 17)	Guarantee to Deerfield (Note 26)	Provision for Liabilities
At 31 December, 2016	\$ 154,347	\$ 1,686	\$ 2,431	\$ —	\$ 158,464
Additions during the year	—	2,268	153	—	2,421
Amounts charged against the provision	(37,311)	—	(1,546)	—	(38,857)
Changes in the fair value	(33,111)	—	(25)	—	(33,136)
Foreign currency exchange adjustment	—	—	290	—	290
At 31 December, 2017	<u>\$ 83,925</u>	<u>\$ 3,954</u>	<u>\$ 1,303</u>	<u>\$ —</u>	<u>\$ 89,182</u>
Additions during the year	—	1,361	110	6,643	8,114
Amounts charged against the provision	(30,455)	—	(160)	(390)	(31,005)
Changes in the fair value	(24,630)	—	(178)	—	(24,808)
Foreign currency exchange adjustment	—	—	(51)	—	(51)
At 31 December, 2018	<u>\$ 28,840</u>	<u>\$ 5,315</u>	<u>\$ 1,024</u>	<u>\$ 6,253</u>	<u>\$ 41,432</u>

**NOTE 15: Long-Term Debt**

Long-Term debt is summarized as follows:

	December 31, 2018	December 31, 2017
Principal amount of 4.50% exchangeable senior notes due 2023	\$ 143,750	\$ —
Less: unamortized debt discount and issuance costs, net	(28,059)	—
Net carrying amount of liability component	115,691	—
Other debt	149	267
Subtotal	115,840	267
Less: current maturities	(106)	(111)
Long-term debt	<u>\$ 115,734</u>	<u>\$ 156</u>
Equity component:		
Equity component of exchangeable notes, net of issuance costs	\$ (26,699)	\$ —

*Issuance of Debt Securities*

On February 16, 2018, Avadel Finance Cayman Limited, a Cayman Islands exempted company (the “Issuer”) and an indirect wholly-owned subsidiary of the Group, issued \$125,000 aggregate principal amount of 4.50% exchangeable senior notes due 2023 (the “2023 Notes”) in a private placement (the “Offering”) to qualified institutional buyers pursuant to Rule 144A under the Securities Act. In connection with the Offering, the Issuer granted the initial purchasers of the 2023 Notes a 30-day option to purchase up to an additional \$18,750 aggregate principal amount of the 2023 Notes, which was fully exercised on 16 February, 2018. Net proceeds received by the Company, after issuance costs and discounts, were approximately \$137,560. The Group intends to use the net proceeds from the Offering for working capital and general corporate purposes. The Group also used cash on-hand to purchase approximately \$18,000 of Avadel ordinary shares represented by American Depository Shares.



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

The 2023 Notes are the Group's senior unsecured obligations and rank equally in right of payment with all of the Group's existing and future senior unsecured indebtedness and effectively junior to any of the Group's existing and future secured indebtedness, to the extent of the value of the assets securing such indebtedness.

The 2023 Notes will be exchangeable at the option of the holders at an initial exchange rate of 92.6956 ADSs per \$1 principal amount of 2023 Notes, which is equivalent to an initial exchange price of approximately \$10.79 per ADS. Such initial exchange price represents a premium of approximately 20% to the \$8.99 per ADS closing price on The Nasdaq Global Market on 13 February, 2018. Upon the exchange of any 2023 Notes, the Issuer will pay or cause to be delivered, as the case may be, cash, ADSs or a combination of cash and ADSs, at the Issuer's election. Holders of the 2023 Notes may convert their 2023 Notes, at their option, only under the following circumstances prior to the close of business on the business day immediately preceding 1 August, 2022, under the circumstances and during the periods set forth below and regardless of the conditions described below, on or after 1 August, 2022 and prior to the close of business on the business day immediately preceding the maturity date:

- Prior to the close of business on the business day immediately preceding 1 August, 2022, a holder of the 2023 Notes may surrender all or any portion of its 2023 Notes for exchange at any time during the five business day period immediately after any five consecutive trading day period (the "Measurement Period") in which the trading price per \$1 principal amount of 2023 Notes, as determined following a request by a holder of the 2023 Notes, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the ADSs and the exchange rate on each such trading day.
- If a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs prior to the close of business on the business day immediately preceding 1 August, 2022, regardless of whether a holder of the 2023 Notes has the right to require the Company to repurchase the 2023 Notes, or if Avadel is a party to a merger event that occurs prior to the close of business on the business day immediately preceding 1 August, 2022, all or any portion of a the holder's 2023 Notes may be surrendered for exchange at any time from or after the date that is 95 scheduled trading days prior to the anticipated effective date of the transaction (or, if later, the earlier of (x) the business day after the Company gives notice of such transaction and (y) the actual effective date of such transaction) until 35 trading days after the actual effective date of such transaction or, if such transaction also constitutes a fundamental change, until the related fundamental change repurchase date.
- Prior to the close of business on the business day immediately preceding 1 August, 2022, a holder of the 2023 Notes may surrender all or any portion of its 2023 Notes for exchange at any time during any calendar quarter commencing after the calendar quarter ending on 30 June, 2018 (and only during such calendar quarter), if the last reported sale price of the ADSs for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the exchange price on each applicable trading day.

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- If the Company calls the 2023 Notes for redemption pursuant to Article 16 to the Indenture prior to the close of business on the business day immediately preceding 1 August, 2022, then a holder of the 2023 Notes may surrender all or any portion of its 2023 Notes for exchange at any time prior to the close of business on the second business day prior to the redemption date, even if the 2023 Notes are not otherwise exchangeable at such time. After that time, the right to exchange shall expire, unless the Company defaults in the payment of the redemption price, in which case a holder of the 2023 Notes may exchange its 2023 Notes until the redemption price has been paid or duly provided for.

The Company considered the guidance in ASC 815-15, Embedded Derivatives, to determine if this instrument contains an embedded feature that should be separately accounted for as a derivative. ASC 815 provides for an exception to this rule when convertible notes, as host instruments, are deemed to be conventional, as defined by ASC 815-40. The Company determined that this exception applies due, in part, to our ability to settle the 2023 Notes in cash, ADSs or a combination of cash and ADSs, at our option. The Company has therefore applied the guidance provided by ASC 470-20, Debt with Conversion and Other Options which requires that the 2023 Notes be separated into debt and equity components at issuance and a value be assigned to each. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the 2023 Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the 2023 Notes and the fair value of the liability of the 2023 Notes on its issuance date. The excess of the principal amount of the liability component over its carrying amount (the "Debt Discount") is amortized to interest expense using the effective interest method over the term of the 2023 Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

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

*Interest Expense*

Total interest expense related to the 2023 Notes for the year ended December 31, 2018 was \$10,491. The Group also incurred interest expense of \$131 and \$1,052 related to its \$15,000 related party payable with Deerfield during the years ended 31 December 2018 and 2017, respectively. This obligation was assumed by the buyer as part of the disposition of the pediatric products on 16 February, 2018. See *Note 16: Long-Term Related Party Payable* and *Note 26: Divestiture of the Pediatric Assets*.

*Other Debt*

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

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

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**NOTE 16: Long-Term Related Party Payable**

Long-term related party payable and related activity are reported at fair value and consist of the following at 31 December, 2018 and 2017, respectively:

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

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

Each of the above items is associated with related parties as further described in *Note 28: Related Party Transactions*.

- (a) As part of the consideration for the Group's acquisition of Éclat Pharmaceuticals, LLC on 13 March, 2012, the Group issued two warrants to a related party with a six-year term which allow for the

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purchase of a combined total of 3,300 ordinary shares of Avadel. One warrant was exercisable for 2,200 ordinary shares at an exercise price of \$7.44 per share, and the other warrant was exercisable for 1,100 ordinary shares at an exercise price of \$11.00 per share. On 23 February, 2018, the related party exercised in full the warrant for 2,200 ordinary shares. On 12 March, 2018, the remaining warrant for 1,100 ordinary shares expired worthless.

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

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

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

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

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

At the closing date of the 2012 Éclat acquisition and at 31 December, 2017, it was uncertain as to whether the Group would ultimately fulfill its obligation under these warrants using Group shares or cash. Accordingly, pursuant to the guidance of ASC 480, the Group determined that these warrants should be classified as a liability. This classification as a liability was further supported by the Group'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 Group's own ordinary shares, on the basis that the exercise price for the warrants is determined in U.S. dollars, although the functional currency of the Group at the closing date of the Éclat acquisition was the Euro.

- (b) In March 2012, the Group acquired all of the membership interests of Éclat from Breaking Stick Holdings, L.L.C. ("Breaking Stick", formerly Éclat Holdings), an affiliate of Deerfield. Breaking Stick is majority owned by Deerfield, with a minority interest owned by certain current and former employees. As part of the consideration, the Group 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.

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- (c) In February 2016, the Group acquired all of the membership interests of FSC from Deerfield. The consideration for this transaction in part included a commitment to pay quarterly a 15% royalty on the net sales of certain FSC products, up to \$12,500 for a period not exceeding ten years. This obligation was assumed by the buyer as part of the disposition of the pediatrics products on 16 February, 2018. See *Note 26: Divestiture of the Pediatric Assets*.
- (d) As part of a February 2013 debt financing transaction conducted with Deerfield, the Group received cash of \$2,600 in exchange for entering into a royalty agreement whereby the Group shall pay quarterly a 1.75% royalty on the net sales of certain Éclat products until 31 December, 2024.
- (e) As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund, a related party and current shareholder, the Group received cash of \$2,200 in exchange for entering into a royalty agreement whereby the Group shall pay quarterly a 0.834% royalty on the net sales of certain Éclat products until 31 December, 2024.
- (f) In February 2016, the Group acquired all of the membership interests of FSC from Deerfield. The consideration for this transaction in part consists of payments totaling \$1,050 annually for five years with a final payment in January 2021 of \$15,000. Substantially all of FSC's, and its subsidiaries, assets are pledged as collateral under this agreement. This obligation was assumed by the buyer as part of the disposition of the pediatrics products on 16 February, 2018. See *Note 26: Divestiture of the Pediatric Assets*.

At 31 December, 2018, the fair value of each related party payable listed in (b), (d) and (e) above was estimated using a discounted cash flow model based on estimated and projected annual net revenues or gross profit, as appropriate, of each of the specified Éclat products using an appropriate risk-adjusted discount rate of 15%. These fair value measurements are based on significant inputs not observable in the market and thus represent a level 3 measurement as defined in ASC 820. Subsequent changes in the fair value of the acquisition-related related party payables, resulting primarily from management's revision of key assumptions, will be recorded in the consolidated profit and loss account in the line items entitled "Changes in fair value of related party contingent consideration" for items noted in (b) above and in "Other expense — changes in fair value of related party payable" for items (d) and (e) above. See *Note 1: Summary of Significant Accounting Policies* under the caption Acquisition-related Contingent Consideration and Financing-related Royalty Agreements for more information on key assumptions used to determine the fair value of these liabilities.

The Group 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 sheet 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 profit and loss account.

**NOTE 17: Post-Retirement Benefit Plans**

***Post-Retirement Benefit Contributions to French Government Agencies***

The Group 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 Group in connection with these plans. (Income) expenses recognized for these plans were \$(69) in 2018, and \$123 in 2017. The 2018 and 2017 pension expense does not include the retirement indemnity curtailment gains of \$148 and \$717, respectively, which was associated with the reduction of certain defined benefit retirement plan liabilities due to the reduction in force.

***Retirement Indemnity Obligation — France***

French law requires the Group 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

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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 Group's consolidated profit and loss account 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 31 December:

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

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

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

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

The lump sum retirement indemnity is accrued on the Group's consolidated balance sheet within the provision for 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 31 December:

<b>Future Retirement Indemnity Benefit Obligation:</b>	<b>Balance</b>
2019	\$ —
2020	—
2021	—
2022	17
2023	—
Next five years	158
Total	<u>\$175</u>

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**NOTE 18: Called-up Share Capital and Reserves*****Called-up Share Capital***

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

	<u>2018</u>	<u>2017</u>
<b><u>Authorised:</u></b>		
25,000 deferred ordinary shares of €1.00 each at 31 December 2018 and 2017	\$ 26	\$ 26
500,000,000 ordinary shares of \$.01 each at 31 December 2018 and 2017	5,000	5,000
50,000,000 preferred shares of \$.01 each at 31 December 2018 and 2017	500	500
<b><u>Allotted, Called Up and Fully Paid:</u></b>		
25,000 deferred ordinary shares of €1.00 each at 31 December 2018 and 2017	\$ 26	\$ 26
42,720,249 and 41,462,699 ordinary shares of \$.01 each at 31 December 2018 and 2017, respectively	427	414
Called up share capital presented as equity	<u>\$ 453</u>	<u>\$ 440</u>

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.

In March 2017, the Board of Directors approved an authorization to repurchase up to \$25,000 of Avadel ordinary shares represented by American Depositary Receipts in the open market with an indefinite duration. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our shares, cash resources, alternative investment opportunities, corporate and regulatory requirements and market conditions. This share repurchase program may be modified, suspended or discontinued at any time without prior notice. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. Additionally, on 12 February, 2018, the Board of Directors approved an authorization to repurchase up to \$18,000 of Avadel ordinary shares represented by American Depositary Shares in connection with our Convertible Notes Offering completed on 16 February, 2018. See *Note 15: Long-Term Debt*. In March 2018, the Board of Directors approved an authorization to repurchase up to \$7,000 of Avadel ordinary shares represented by American Depositary Shares, bring the total authorization to \$50,000. As of 31 December, 2018, the Group had repurchased 5,407 ordinary shares for \$49,998, none of which have been cancelled. This amount has been recorded to the Profit and Loss Account.

***Share Premium Account***

In fiscal 2018, the share premium account increased due to the exercise of warrants of \$2,905 (See *Note 16: Long-Term Related Party Payable*), the exercise of stock options of \$534 and the employee share purchase plan issuance of \$127.

***Other Reserves***

In fiscal 2018, other reserves increased driven by the equity component of the 2023 notes (see *Note 15: Long-Term Debt*), share-based compensation and the expiration of warrants (see *Note 16: Long-Term Related Party Payable*).

***Profit and Loss Account***

In fiscal 2018, the profit and loss account activity was driven by 2018 net loss, the repurchase of ordinary shares of \$27,637 and the change in other comprehensive income.

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**NOTE 18.1: Equity Instruments and Stock Based Compensation**

Compensation expense included in the Group's consolidated profit and loss account for all stock-based compensation arrangements was as follows for the periods ended 31 December:

<b>Stock-based Compensation Expense:</b>	<b>2018</b>	<b>2017</b>
Research and development	\$ 880	\$ 672
Distribution and administrative	6,972	7,400
Total stock-based compensation expense	<u>\$7,852</u>	<u>\$8,072</u>

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

The excess tax benefit related to stock-based compensation recorded by the Group was \$0 for the years ended 31 December, 2018 and 2017.

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

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

***Determining the Fair Value of Stock Options and Warrants***

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

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

<b>Stock Option Assumptions:</b>	<b>2018</b>	<b>2017</b>
Stock option grants:		
Expected term (years)	6.25	6.25
Expected volatility	56.59%	58.82%
Risk-free interest rate	2.68%	2.20%
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 Group'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.



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

***Stock Options***

A summary of the combined stock option activity and other data for the Group's stock option plans for the year ended 31 December, 2018 is as follows:

<b>Stock Option Activity and Other Data:</b>	<b>Number of Stock Options</b>	<b>Weighted Average Exercise Price per Share</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Aggregate Intrinsic Value</b>
Stock options outstanding, 1 January, 2017	3,732	\$ 12.07		
Granted	1,477	9.24		
Exercised	(14)	4.99		
Forfeited	(46)	12.88		
Expired	(108)	13.47		
Stock options outstanding, 31 December, 2017	5,041	\$ 11.34	8.19 years	\$ 1,187
Granted	138	6.67		
Exercised	(82)	6.52		
Forfeited	(428)	10.04		
Expired	(68)	12.41		
Stock options outstanding, 31 December, 2018	4,601	\$ 11.39	7.25 years	\$ —
Stock options exercisable, 31 December, 2017	1,917	\$ 11.79	6.68 years	\$ 1,161
Stock options exercisable, 31 December, 2018	3,005	11.99	6.66 years	—

The aggregate intrinsic value of options exercised during the years ended 31 December, 2018, and 2017 was \$0, and \$1,161, respectively.

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

***Warrants***

A summary of the combined warrant activity and other data for the year ended 31 December, 2018 is as follows:

<b>Warrant Activity and Other Data:</b>	<b>Number of Warrants</b>	<b>Weighted Average Exercise Price per Share</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Aggregate Intrinsic Value</b>
Warrants outstanding, 1 January, 2017	959	\$ 16.05		
Exercised	(55)	6.14		
Expired	(10)	6.14		
Warrants outstanding, 31 December, 2017	894	16.77	1.51 years	\$ —
Exercised	—	—		
Expired	(298)	14.87		
Warrants outstanding, 31 December, 2018	596	\$ 17.72	1.03 years	\$ —
Warrants exercisable, 31 December, 2017	894	\$ 16.77	1.51 years	\$ —
Warrants exercisable, 31 December, 2018	596	17.72	1.03 years	—

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

At 1 January, 2018, an additional 3,300 warrants were outstanding and exercisable relative to consideration paid for the Group's acquisition of Éclat Pharmaceuticals, LLC on 13 March, 2012. These warrants are not considered stock-based compensation and are therefore excluded from the above tables, and instead are addressed within *Note 16: Long-Term Related Party Payable*. On February 23, 2018, the related party exercised in full the warrant to purchase 2,200 ordinary shares. On 12 March, 2018 the remaining warrants to purchase 1,100 ordinary shares expired.

***Restricted Share Awards***

Restricted share awards represent Group shares issued free of charge to employees of the Group as compensation for services rendered. The Group measures the total fair value of restricted share awards on the grant date using the Group's stock price at the time of the grant. Restricted share awards granted during and after 2017 vest over a three-year period; two-thirds (2/3) vesting on the second anniversary of the grant date and the remaining one-third (1/3) vesting on the third anniversary of the grant date. Employees, however, are not free to trade these awards until the end of a two-year holding period. Beginning in 2018, the Group issues restricted share awards to our Board of Directors vesting over a three-year period; one-third (1/3) vesting on each of the three anniversaries of the grant date. Compensation expense for such awards granted during and after 2017 is recognized over the applicable vesting period.

A summary of the Group's restricted share awards as of 31 December, 2018, and changes during the year then ended, is reflected in the table below.

<b>Restricted Share Activity and Other Data:</b>	<b>Number of Restricted Share Awards</b>	<b>Weighted Average Grant Date Fair Value</b>
Non-vested restricted share awards outstanding, 1 January, 2017	573	\$ 12.57
Granted	271	8.95
Vested	(23)	7.31
Forfeited	(2)	16.27
Non-vested restricted share awards outstanding, 31 December, 2017	819	\$ 11.51
Granted	279	5.87
Vested	(548)	12.78
Forfeited	(59)	8.95
Non-vested restricted shares awards outstanding, 31 December, 2018	491	\$ 7.20

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

***Employee Share Purchase Plan***

In 2017, the Board of Directors approved of the Avadel Pharmaceuticals plc 2017 Avadel Employee Share Purchase Plan ("ESPP"). The total number of Group ordinary shares, nominal value \$0.01 per share, or ADSs representing such ordinary shares (collectively, "Shares") which may be issued under the ESPP is 1,000. The purchase price at which a Share will be issued or sold for a given offering period will be established by the Compensation Committee of the Board ("Committee") (and may differ among participants, as determined by the Committee in its sole discretion) but will in no event be less than 85% of the lesser of: (a) the fair market value of a Share on the offering date; or (b) the fair market value of a Share on the purchase date. As of 31 December 2018, the Group has issued 25 ordinary shares to employees.

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**NOTE 19: Contingent Liabilities and Commitments**

***Litigation***

The Group is subject to potential liabilities generally incidental to our business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Group 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 31 December, 2018 and 31 December, 2017, there were no contingent liabilities with respect to any litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Group's consolidated financial position, results of operations, cash flows or liquidity.

***Litigation Related to Noctiva***

Specialty Pharma made a voluntary filing for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code on 6 February, 2019. On 26 April, 2019 this filing resulted in the bankruptcy court-approved sale of all of Specialty Pharma's intangible assets and inventory to an unaffiliated third party. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business. During the pendency of the bankruptcy case, all pending litigation against Specialty Pharma is automatically stayed and any new litigation against Specialty Pharma is precluded unless the bankruptcy court orders otherwise. Below are descriptions of a litigation to which Specialty Pharma is a party and a contract dispute involving Specialty Pharma, both of which matters are subject to the automatic stay during the bankruptcy case.

*Ferring Litigation.* Some of the patents covering the Noctiva<sup>TM</sup> product (the "Noctiva Patents") are the subject of litigation initiated by Ferring Pharmaceuticals Inc. and two of its foreign affiliates, who manufacture a competing product known as Nocdurna. Nocdurna was approved by the FDA in June 2018 and commercially launched in the U.S. in November 2018. In this litigation, Ferring seeks to invalidate and disputes the inventorship of the Noctiva Patents, seeks damages for various alleged breaches of contractual and common law duties, and seeks damages for alleged infringement by Noctiva<sup>TM</sup> of Ferring's "Nocdurna" trademark. Specialty Pharma and certain other parties including Serenity Pharmaceuticals, LLC ("Serenity") (the licensor of the Noctiva Patents) have defended this litigation, and have made counterclaims against Ferring, including for infringement of the Noctiva Patents and a declaratory judgment of noninfringement with respect to Ferring's "Nocdurna" trademark. The court dismissed Ferring's inventorship claim and its claims for alleged breaches of contractual and common law duties, although these dismissals may be appealed by Ferring. On 15 February, 2019, Specialty Pharma and its co-defendants moved to stay the litigation pending completion of the bankruptcy proceeding of Specialty Pharma. On 15 May 2019, that motion was denied due to an impending settlement of the litigation with respect to just Ferring and Specialty Pharma.

*Contract Dispute.* On 21 January, 2019, Serenity gave notice to Specialty Pharma of an alleged breach of the parties' Noctiva license agreement. Serenity alleges that Specialty Pharma breached its contractual obligation to devote commercially reasonable efforts to the commercialization of Noctiva and seeks unspecified damages. On 27 January, 2019, Specialty Pharma notified Serenity of a claim for \$1,700 in damages as a result of Serenity's breach of its contractual obligation to pay the costs of the Ferring Litigation. Serenity's notice to Specialty Pharma invoked the dispute resolution provisions of the Noctiva license agreement, which culminate in arbitration, but neither party has yet initiated an arbitration proceeding or filed suit.

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**Material Commitments**

At 31 December, 2018, the Group has various commitments to purchase finished product from customers. Commitments for these arrangements, at minimum quantities and at contractual prices over the remaining life of the contract, and excluding any waived commitments, are as follows for the year ended 31 December:

<b>Purchase Commitment:</b>	<b>Balance</b>
2019	\$ 7,194
2020	1,320
2021	1,320
2022	1,320
2023	220
Thereafter	—
<b>Total</b>	<b><u>\$11,374</u></b>

The Group also has a commitment with a contract manufacturer related to the construction and preparation of a production suite at the contract manufacturer's facility, which is substantially complete at 31 December, 2018. Subsequent to the initial build and preparation of the production suite, this commitment also includes annual production suite fees of approximately \$3,000 to \$4,000 which would commence at the time of FDA approval of the product and continue thereafter for five years. These amounts are not included in the table above, as the start date has not been determined.

The amounts in the Purchase Commitment table above, does not include any purchase commitments related to the Chapter 11 bankruptcy case of Specialty Pharma.

Of the \$11,374 of purchase commitments mentioned above, approximately \$4,875 is related to R&D, which has been committed to be paid during financial year 2019.

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

<b>Lease Commitment:</b>	<b>Balance</b>
2019	\$1,191
2020	1,208
2021	1,008
2022	767
2023	695
Thereafter	967
<b>Total</b>	<b><u>\$5,836</u></b>

Other than the above commitments, there were no other material commitments outside of the normal course of business. Material commitments in the normal course of business include long-term debt, long-term related party payable, and post-retirement benefit plan obligations which are disclosed in *Note 15: Long-Term Debt*, *Note 16: Long-Term Related Party Payable*, and *Note 17: Post-Retirement Benefit Plans*, respectively.

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**Contractual Obligations**

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

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 and interest	\$173,009	\$ 6,575	\$12,981	\$153,453	\$ —
Long-term related party payable (undiscounted)	51,284	9,439	8,713	7,250	25,882
Purchase commitments	11,374	7,194	2,640	1,540	—
Operating leases	5,836	1,191	2,217	1,461	967
Total contractual cash obligations	<u>\$241,503</u>	<u>\$24,399</u>	<u>\$26,551</u>	<u>\$163,704</u>	<u>\$ 26,849</u>

**NOTE 20: Fair Value Measurements**

The Group 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.

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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 sheet:

Fair Value Measurements:	As of 31 December, 2018			As of 31 December, 2017		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Investments (see Note 9)						
Equity securities	\$ 9,145	\$ —	\$ —	\$ 468	\$ —	\$ —
Money market funds	52,996	—	—	44,481	—	—
Corporate bonds	—	6,339	—	—	9,262	—
Government securities – U.S.	—	12,701	—	—	19,050	—
Other fixed-income securities	—	9,409	—	—	4,250	—
Total assets	<u>\$62,141</u>	<u>\$28,449</u>	<u>\$ —</u>	<u>\$44,949</u>	<u>\$32,562</u>	<u>\$ —</u>
Related party payable (see Note 16)	—	—	28,840	—	—	98,925
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$28,840</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$98,925</u>

A review of fair value hierarchy classifications is conducted on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification for certain investments or liabilities. During the fiscal year ended 31 December, 2018, there were no transfers in and out of Level 1, 2, or 3. During the twelve months ended 31 December, 2018, and 2017, we did not recognize any other-than-temporary impairment loss.

Some of the Group's financial instruments, such as cash and cash equivalents, trade debtors and creditors, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature. Additionally, the Group'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 21: Group Operations by Product, Customer and Geographic Area**

The Group has determined that it operates in one segment, the development and commercialization of pharmaceutical products, including controlled-release therapeutic products based on its proprietary polymer based technology. The Group's Chief Operating Decision Maker is the CEO. The CEO reviews profit and loss information on a consolidated basis to assess performance and make overall operating decisions as well as resource allocations. All products are included in one segment because the Group's products have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods and regulatory environment.

The following table presents a summary of total turnover by these products for the twelve months ended 31 December, 2018 and 2017:

Turnover by Product:	2018	2017
Bloxiverz	\$ 20,850	\$ 45,596
Vazculep	42,916	38,187
Akovaz	33,759	80,617
Noctiva	1,204	—
Other	2,694	8,441
Total product sales and services	101,423	172,841
License and research revenue	1,846	404
Total revenues	<u>\$103,269</u>	<u>\$173,245</u>

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Concentration of credit risk with respect to debtors is limited due to the high credit quality comprising a significant portion of 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 31 December, 2018 and 2017:

<b>Revenue by Significant Customer:</b>	<b>2018</b>	<b>2017</b>
Customer A	\$ 26,794	\$ 44,762
Customer B	25,413	37,965
Customer C	18,620	25,691
Customer D	9,653	53,342
Other	20,943	11,081
Total product sales	101,423	172,841
License revenue	1,846	404
Total revenues	<u>\$103,269</u>	<u>\$173,245</u>

As of 31 December, 2018, the Group had four customers each of which are substantial wholesale distributors, and accounted for 10% or more of the trade debtors balance. One customer accounted for 32%, or \$3,571, a second customer accounted for 24% or \$2,755, a third customer accounted for 24% or \$2,789 and a fourth customer accounted for 10% or \$1,174. As of 31 December, 2018 and 2017, the Group had no significant past due account receivable balances.

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

<b>Revenue by Geographic Region:</b>	<b>2018</b>	<b>2017</b>
United States	\$101,423	\$172,841
Ireland	1,846	404
Total	<u>\$103,269</u>	<u>\$173,245</u>

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

Non-monetary long-lived assets primarily consist of tangible assets, goodwill and intangible assets. The following table summarizes non-monetary long-lived assets by geographic region as of 31 December, 2018, and 2017:

<b>Long-lived Assets by Geographic Region:</b>	<b>2018</b>	<b>2017</b>
United States	\$27,761	\$116,536
France	1,365	2,257
Ireland	6,028	1,360
Total	<u>\$35,154</u>	<u>\$120,153</u>

The balances above include tangible and intangible assets, as well as the non-tax related portion of the other debtors (amounts receivable after one year).

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**NOTE 22: Loss Attributable to Avadel Pharmaceuticals plc**

In accordance with Section 304(2) of the Companies Act 2014, the Group is availing itself of the exemption from presenting and filing its parent company profit and loss account. Avadel Pharmaceuticals plc loss for the years ended 31 December, 2018 and 2017 as determined in accordance with Irish GAAP (FRS 102) was \$286,969 and \$878, respectively.

**NOTE 23: Key Management Compensation**

<u>Key Management Compensation</u>	<u>2018</u>	<u>2017</u>
Aggregate emoluments in respect to qualifying services	\$2,580	\$2,568
Aggregate amount of gains by the directors on the exercise of share options during the financial year	—	—
Aggregate amount of the money or value of other assets under long term incentive schemes in respect qualifying services	1,753	3,624
Aggregate contributions to a retirement benefit scheme in respect of directors' qualifying services – defined contributions schemes	—	—
Aggregate contributions to a retirement benefit scheme in respect of directors' qualifying services – defined benefit schemes	—	—
Compensation for loss of office	986	—
<b>Total</b>	<b><u>\$5,319</u></b>	<b><u>\$6,192</u></b>

See *Note 6* to the Company Financial Statements for directors remuneration.

**NOTE 24: Auditors' Remuneration**

Auditors' remuneration was as follows:

	<u>2018</u>	<u>2017</u>
Audit of individuals and group financial statements	\$171	\$178
Other assurance services	62	49
Taxation advisory services	—	—
Other non-audit services	—	—
<b>Total</b>	<b><u>\$233</u></b>	<b><u>\$227</u></b>

No amounts were incurred for other non-audit services. The Group incurred additional fees of \$1,348 and \$1,283 during fiscal 2018 and 2017, respectively, payable to affiliates of Deloitte Ireland LLP. These additional amounts reflect fees for all professional services rendered, including audit fees payable to Deloitte & Touche LLP in the United States for the audit of the Company's consolidated financial statements.

**NOTE 25: Employees**

The average number of persons, including executive directors, employed by the Group during the year was as follows:

<u>Average Number of Employees</u>	<u>2018</u>	<u>2017</u>
Research and development	50	69
General, administrative and sales	106	128
<b>Total</b>	<b><u>156</u></b>	<b><u>197</u></b>



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Employee costs consisted of the following:

<b>Employee Costs</b>	<b>2018</b>	<b>2017</b>
Wages and salaries	\$21,503	\$20,194
Social security costs and other tax	4,097	5,256
Pension and postretirement costs		
– Defined contribution (credit)/cost	(69)	123
Stock based compensation	7,852	8,072
Total	<u>\$33,383</u>	<u>\$33,645</u>

There were no employee costs capitalized during the years ended December 31, 2018 and 2017.

**NOTE 26: Divestiture of the Pediatric Assets**

On 12 February, 2018, the Group, together with its subsidiaries Avadel Pharmaceuticals (USA), Inc., Avadel Pediatrics, Inc., FSC Therapeutics, LLC (“FSC Therapeutics”), and Avadel US Holdings, Inc. (“Holdings”), as the “Sellers,” entered into an asset purchase agreement (the “Purchase Agreement”) with Cerecor, Inc. (“Cerecor”). The transaction closed on 16 February, 2018 wherein Cerecor purchased from the Sellers four pediatric commercial stage assets — Karbinal™ ER, Cefaclor, Flexichamber™ and AcipHex® Sprinkle™, together with certain associated business assets — which were held by FSC. The Group acquired FSC in February 2016 from Deerfield and certain of its affiliates. Pursuant to the Purchase Agreement, Cerecor assumed the Group’s remaining payment obligations to Deerfield under the Membership Interest Purchase Agreement, dated as of February 5, 2016, between Holdings, Flamel Technologies SA (the predecessor of the Group) and Deerfield and certain of its affiliates, which payment obligations consisted of the following (collectively, the “Assumed Obligations”): (i) a quarterly payment of \$263 beginning in July 2018 and ending in October 2020, amounting to an aggregate payment obligation of \$2,625; (ii) a payment in January 2021 of \$15,263; and (iii) a quarterly royalty payment of 15% on net sales of the FSC products through 5 February, 2026 (“FSC Product Royalties”), in an aggregate amount of up to approximately \$10,300. Cerecor also assumed certain contracts and other obligations related to the acquired assets, and in that connection Holdings agreed to pay Cerecor certain make-whole payments associated with obligations Cerecor is assuming related to a certain supply contract related to Karbinal™ ER.

In conjunction with the divestiture, the Group also entered into the following arrangements:

*License and Development Agreement*

Also, in connection with the closing under the Purchase Agreement, Flamel Ireland Limited, an Irish limited company operating under the trade name of Avadel Ireland (“Avadel Ireland”) and a wholly-owned subsidiary of the Group, and Cerecor entered into a license and development agreement (the “License and Development Agreement”) pursuant to which, among other things:

- Avadel Ireland will provide Cerecor with four product formulations utilizing Avadel Ireland’s LiquiTime™ technology, and will complete pilot bioequivalence studies for such product formulations within 18 months;
- Cerecor will reimburse Avadel Ireland for development costs of the four LiquiTime™ products in excess of \$1,000 in the aggregate;
- Upon transfer of the four product formulations, Cerecor will assume all remaining development costs and responsibilities for the product development, clinical studies, NDA applications and associated filing fees; and
- Upon regulatory approval and commercial launch of any LiquiTime™ products, Cerecor will pay Avadel Ireland quarterly royalties based on a percentage of net sales of any such products in the mid-single digit range.

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*Deerfield Guarantee*

In connection with the closing under the Purchase Agreement, the Group and Holdings provided their guarantee (the “Deerfield Guarantee”) in favor of Deerfield. Under the Deerfield Guarantee, the Group and Holdings guaranteed to Deerfield the payment by Cerecor of the Assumed Obligations under the Membership Interest Purchase Agreement between the Group and Deerfield dated 5 February, 2016. The Assumed Obligations include (i) a quarterly payment of \$263 beginning in July 2018 and ending in October 2020, amounting to an aggregate payment obligation of \$2,625; (ii) a payment in January 2021 of \$15,263; and (iii) a quarterly royalty payment of 15% on net sales of the FSC products through 6 February, 2026 (“FSC Product Royalties”), in an aggregate amount of up to approximately \$10,300. In addition, under the Deerfield Guarantee, the Group and Holdings guaranteed that Deerfield would receive certain minimum annual FSC Product Royalties through 6 February, 2026 (the “Minimum Royalties”). Given the Group’s explicit guarantee to Deerfield, the Group recorded the guarantee in accordance with ASC 460. A valuation was performed, which was based largely on an analysis of the potential timing of each possible cash outflow described above and the likelihood of Cerecor’s default on such payments assuming an S&P credit rating of CCC+. The result of this valuation identified a guarantee liability of \$6,643. This liability is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield. At 31 December, 2018, the carrying value of this liability was \$6,253. See *Note 14: Provisions for Liabilities*.

*Armistice Guarantee*

In connection with the closing under the Purchase Agreement, Armistice Capital Master Fund, Ltd., the majority shareholder of Cerecor, guaranteed to Holdings the payment by Cerecor of the Assumed Obligations, including the Minimum Royalties. A valuation of the guarantee asset was performed in accordance with ASC 460 “Guarantees” and a guarantee asset of \$6,620 was recorded. This asset is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield noted above. At 31 December, 2018, the carrying value of this asset was \$6,231. See *Note 8: Debtors*.

The fair values of the Avadel guarantee to Deerfield and the guarantee received by Avadel from Armistice largely offset and when combined are not material.

Based on management’s review of ASU 2014-08, “Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity”, the disposition of our pediatric assets and related liabilities did not qualify for discontinued operations reporting. Our results of operations for the period 1 January, 2018 through February 16, 2018 and for the year ended 31 December, 2017 include the results of FSC, prior to its 16 February, 2018 disposition date.

The net impact of this transaction was not material to the consolidated profit and loss account.

**NOTE 27: Post Balance Sheet Events**

*Corporate Restructuring.* In February 2019, Avadel announced a corporate restructuring in order to focus efforts and resources on the clinical development of FT218. In conjunction with the restructuring, Avadel will reduce its workforce by more than 50%. The reduction in workforce is primarily a result of the exit of Noctiva during the first quarter of 2019 (see *Specialty Pharma Bankruptcy and Deconsolidation* section below), as well as an effort to better align the Company’s remaining cost structure at our U.S. and Ireland locations with our ongoing and future planned projects. The reduction in workforce is projected to be substantially complete by the end of the fiscal year 2019, and to result in employee severance, benefits and other costs of up to approximately \$3,000, which are likely to be recognized through December 31, 2019. 2019 Corporate Restructuring charges of \$1,398 were recognized during the three months ended March 31, 2019.

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*Specialty Pharma Bankruptcy and Deconsolidation.* Specialty Pharma made a voluntary filing for bankruptcy protection under Chapter 11 of the U.S. Bankruptcy Code on February 6, 2019. As noted above, Specialty Pharma is a special-purpose entity and wholly-owned subsidiary responsible solely for the sales, marketing and distribution of Noctiva. As a result of Specialty Pharma's bankruptcy filing, Avadel has ceded authority for managing the business to the Bankruptcy Court, and Avadel management cannot carry on Specialty Pharma's activities in the ordinary course of business without Bankruptcy Court approval. Avadel manages the day-to-day operations of Specialty Pharma, but does not have discretion to make significant capital or operating budgetary changes or decisions and purchase or sell significant assets, as Specialty Pharma's material decisions are subject to review by the Bankruptcy Court. For these reasons, we have concluded that Avadel has lost control of Specialty Pharma, and no longer has significant influence over Specialty Pharma during the pendency of the bankruptcy. Therefore, we deconsolidated Specialty Pharma effective with the filing of the Chapter 11 bankruptcy in February 2019.

In order to deconsolidate Specialty Pharma, the carrying values of the assets and certain liabilities of Specialty Pharma were removed from our unaudited condensed consolidated balance sheet as of 5 February, 2019, and we recorded our investment in Specialty Pharma at its estimated fair value of \$0. As the estimated fair value of our investment in Specialty Pharma was lower than its net book value immediately prior to the deconsolidation, we recorded a non-cash charge of approximately \$2,673 associated with the deconsolidation of Specialty Pharma. Subsequent to the deconsolidation of Specialty Pharma, we are accounting for our investment in Specialty Pharma using the cost method of accounting because Avadel does not exercise significant influence over the operations of Specialty Pharma due to the Chapter 11 filing.

On 26 April, 2019, Specialty Pharma sold its intangible assets and remaining inventory to an unaffiliated third party in exchange for aggregate cash proceeds of approximately \$250, pursuant to an order approving such sale which was issued by the Bankruptcy Court on 15 April, 2019. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business.

*2019 French Restructuring.* In May 2019, the Group initiated a plan to reduce substantially all of its workforce at its Vénissieux, France site. This reduction is an effort to align the Group's cost structure with our ongoing and future planned projects. The reduction in workforce is projected to be substantially complete by the end of the fiscal year 2019, and to result in employee severance, benefits and other costs of up to approximately \$3,000, which are likely to be recognized through December 31, 2019.

**NOTE 28: Related Party Disclosures**

In March 2012, the Group 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 Group. At December 31, 2018, the remaining consideration obligation for this transaction consisted of commitments to make earnout payments to Breaking Stick of 20% of any gross profit generated by certain Éclat products (the "Products"). Breaking Stick is majority owned by Deerfield, with a minority interest owned by certain current and former employees. The Group entered into a Security Agreement dated March 13, 2012 with Breaking Stick, whereby Breaking Stick was granted a security interest in various tangible and intangible assets related to the Products to secure the obligations of Éclat and Avadel US Holdings, Inc., including the full and prompt payment of royalties to Breaking Stick under the Royalty Agreement.

As part of a February 2013 debt financing transaction conducted with Deerfield Management, Éclat entered into a Royalty Agreement with Horizon Santé FLML, Sarl and Deerfield Private Design Fund II, L.P., both affiliates of the Deerfield Entities (together, "Deerfield PDF/Horizon"). The Royalty Agreement provides for the Group to pay Deerfield PDF/Horizon 1.75% of the net sales of the Products sold by the Group and any of our affiliates until December 31, 2024, with royalty payments paid in arrears for each calendar quarter during the term of the Royalty Agreement. The Group has also entered into a Security

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Agreement dated February 4, 2013 with Deerfield PDF/Horizon, whereby Deerfield PDF/Horizon was granted a security interest in the various tangible and intangible assets related to the Products to secure the obligations of Éclat and Avadel US Holdings, Inc., including the full and prompt payment of royalties to Deerfield PDF/Horizon under the Royalty Agreement.

As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund (“Broadfin”), the Group also entered into a Royalty Agreement with Broadfin, a significant shareholder of the Group, dated as of December 3, 2013 (the “Broadfin Royalty Agreement”). Pursuant to the Broadfin Royalty Agreement, the Group is required to pay a royalty of 0.834% on the net sales of certain products sold by the Group and any of our affiliates until December 31, 2024 with royalty payments paid in arrears for each calendar quarter during the term of the Royalty Agreement. The Group has also entered into a Security Agreement dated December 3, 2013 with Broadfin, whereby Broadfin was granted a security interest in the various tangible and intangible assets related to the Products to secure the obligations of Éclat and Avadel US Holdings, Inc., including the full and prompt payment of royalties to Broadfin under the Royalty Agreement.

The Group entered into an agreement dated February 5, 2016 to acquire FSC Holdings, LLC (“FSC”), a specialty pharmaceutical company dedicated to providing innovative solutions to unmet medical needs for pediatric patients, from Deerfield CSF, LLC, a Deerfield Management company (“Deerfield”), a related party. Under the terms of the acquisition, which was completed on February 8, 2016, the Group was to pay \$1,050 annually for five years with a final payment in January 2021 of \$15,000 for a total of \$20,250 to Deerfield for all of the equity interests in FSC. The Group will also pay Deerfield a 15% royalty per annum on net sales of the current FSC products, up to \$12,500 for a period not exceeding ten years. These obligations were assumed by Cerecor in connection with the divestiture of the Group’s pediatric products on February 16, 2018. In connection with the divestiture, the Group provided their guarantee in favor of Deerfield and in return, Armistice Capital Master Fund, Inc., the majority shareholder of Cerecor, guaranteed to the Company the payment by Cerecor of the Assumed Obligations mentioned in *Note 26: Divestiture of the Pediatric Assets*.

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**NOTE 29: Subsidiary Undertakings**

As of 31 December, 2018, the Company had 100% interest in the equity of the following subsidiaries:

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

The Group does not have any interest in any other subsidiaries, other than the ones mentioned above.

**AVADEL PHARMACEUTICALS PLC**

**Company Financial Statements**

**For the year ended 31 December, 2018**

## **Independent auditor’s report to the members of Avadel Pharmaceuticals Public Limited Company**

### **Report on the audit of the financial statements**

#### **Opinion on the financial statements of Avadel Pharmaceuticals Public Limited Company (the ‘company’)**

In our opinion the parent company financial statements:

- give a true and fair view of the assets, liabilities and financial position of the parent company as at 31 December 2018; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

The parent company financial statements we have audited comprise:

- the Balance Sheet;
- the Statement of Changes in Equity; and
- the related notes 1 to 16, including a summary of significant accounting policies as set out in note 1.

The relevant financial reporting framework that has been applied in the preparation of the financial statements is the Companies Act 2014 and FRS 102 “The Financial Reporting Standard applicable in the UK and Republic of Ireland” (“the relevant financial reporting framework”).

#### **Basis for opinion**

We conducted our audit in accordance with International Standards on Auditing (Ireland) (ISAs (Ireland)) and applicable law. Our responsibilities under those standards are further described in the “*Auditor’s responsibilities for the audit of the financial statements*” section of our report.

We are independent of the company in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority, as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### **Conclusions relating to going concern**

We have nothing to report in respect of the following matters in relation to which ISAs (Ireland) require us to report to you where:

- the directors’ use of the going concern basis of accounting in preparation of the financial statements is not appropriate; or
- the directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the company’s ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

#### **Key Audit Matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current financial period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

<u>Key Audit Matter Description</u>	<u>How the scope of our audit responded to the key audit matter</u>
<p><b>Carrying Value of Financial Assets</b> <b>\$52m</b></p> <p>There is a risk that an impairment in the Company's investment in its subsidiaries is not appropriately recorded in the financial statements.</p> <p>Refer also to Note 1 (accounting policy for Investments in Subsidiary) and Note 7 Financial Assets.</p>	<p>We considered the appropriateness of the Directors' approach to impairment review which considers the valuation of the Company's subsidiaries and net assets against other indicators of value, such as the overall market capitalisation of the Avadel Pharmaceutical Group and carrying value of net assets in the consolidated financial statements.</p> <p>An impairment charge of \$226m was recorded such that the overall net assets of the company does not exceed the fair value of the Group at the balance sheet date.</p> <p>We assessed the adequacy of related disclosures.</p>
<p>Our audit procedures relating to this matter were designed in the context of our audit of the financial statements as a whole, and not to express an opinion on individual accounts or disclosures. Our opinion on the financial statements is not modified with respect to any of the risks described above, and we do not express an opinion on these individual matters.</p>	
<p><b>Our application of materiality</b></p> <p>We define materiality as the magnitude of misstatement that makes it probable that the economic decisions of a reasonably knowledgeable person, relying on the financial statements, would be changed or influenced. We use materiality both in planning the scope of our audit work and in evaluating the results of our work.</p> <p>We determined planning materiality for the Company to be \$1.4 million which is 80% of group materiality. We have considered net assets to be the critical component for determining materiality because we determined net assets to be of most importance to the principal external users of these financial statements, as this is the key balance in this legal entity and holding this investment is the purpose of the entity.</p> <p>We agreed with the Audit Committee that we would report to the Audit Committee any audit differences in excess of \$0.07 million or 5% of materiality, as well as differences below that threshold that, in our view, warranted reporting on qualitative grounds. We also report to the Audit Committee on disclosure matters that we identified when assessing the overall presentation of the financial statements.</p>	
<p><b>An overview of the scope of our audit</b></p> <p>Our audit is a risk-based approach taking into account the structure of the Company, our knowledge of the Group and industry in which the company operates and the accounting processes and controls in place.</p>	
<p><b>Other information</b></p> <p>The directors are responsible for the other information. The other information comprises the information included in the Directors' Report and Consolidated Financial Statements, other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.</p> <p>In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.</p> <p>We have nothing to report in this regard.</p>	



### **Responsibilities of directors**

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the company or to cease operations, or have no realistic alternative but to do so.

### **Auditor's responsibilities for the audit of the financial statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs (Ireland), we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or conditions may cause the entity to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that the auditor identifies during the audit.

For listed entities and public interest entities, the auditor also provides those charged with governance with a statement that the auditor has complied with relevant ethical requirements regarding independence, including the Ethical Standard for Auditors (Ireland) 2016, and communicates with them all relationships and other matters that may reasonably be thought to bear on the auditor's independence, and where applicable, related safeguards.

Where the auditor is required to report on key audit matters, from the matters communicated with those charged with governance, the auditor determines those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. The auditor describes these matters in the auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, the auditor determines that a matter should not be communicated in the auditor's report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

This report is made solely to the company's members, as a body, in accordance with Section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

#### **Opinion on other matters prescribed by the Companies Act 2014**

Based solely on the work undertaken in the course of the audit, we report that:

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the company were sufficient to permit the financial statements to be readily and properly audited.
- The company balance sheet is in agreement with the accounting records.
- In our opinion the information given in the directors' report is consistent with the financial statements and the directors' report has been prepared in accordance with the Companies Act 2014.

#### **Other Matters**

We have reported separately on the consolidated financial statements of Avadel Pharmaceuticals Plc for the year ended 31 December 2018.

#### **Matters on which we are required to report by exception**

Based on the knowledge and understanding of the company and its environment obtained in the course of the audit, we have not identified material misstatements in the directors' report that have been specified for our review.

We have nothing to report in respect of the provisions in the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

/s/ Cathal Treacy

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Cathal Treacy  
For and on behalf of Deloitte Ireland LLP  
Chartered Accountants and Statutory Audit Firm  
Deloitte & Touche House  
Earlsfort Terrace  
Dublin 2  
Date: 13 June, 2019

**AVADEL PHARMACEUTICALS PLC**

**COMPANY BALANCE SHEET  
AT 31 DECEMBER 2018  
(Amounts in \$ thousands)**

	Note	2018	2017
<b>FIXED ASSETS</b>			
Financial assets	7	\$ 51,845	\$271,701
		51,845	271,701
<b>CURRENT ASSETS</b>			
Debtors			
– Due within one year	8	672	694
– Due after one year	8	19,837	104,815
Cash at bank and in hand		644	3,461
		21,153	108,970
<b>CURRENT LIABILITIES</b>			
<b>Creditors (amounts falling due within one year)</b>	9	(676)	(5,061)
<b>NET CURRENT ASSETS</b>		20,477	103,909
<b>Total assets less current liabilities</b>		72,322	375,610
Creditors (amounts falling due after more than one year)	9	(1,266)	(1,373)
<b>NET ASSETS</b>		<u>\$ 71,056</u>	<u>\$374,237</u>
<b>CAPITAL AND RESERVES</b>			
Called up share capital presented as equity	10	\$ 453	\$ 440
Share premium	11	84,748	81,182
Other reserves	11	15,914	8,062
Profit and loss account		(30,059)	284,553
<b>SHAREHOLDERS' FUNDS</b>		<u>\$ 71,056</u>	<u>\$374,237</u>

The Company recorded a loss of \$286,969 for the financial year (2017: \$878).

The financial statements were approved by the board on 13 June, 2019 and signed on its behalf by:

/s/ Geoffrey M. Glass

Geoffrey M. Glass  
Director

/s/ Gregory J. Divis

Gregory J. Divis  
Director

**AVADEL PHARMACEUTICALS PLC**  
**STATEMENT OF CHANGES IN EQUITY**  
**FOR THE YEAR ENDED 31 DECEMBER 2018**  
**(Amounts in \$ Thousands)**

	<u>Share Capital</u>	<u>Share Premium</u>	<u>Other Reserves</u>	<u>Profit and Loss Account</u>	<u>Total Equity</u>
At 1 December 2016	\$440	\$ 398,040	\$ (9,462)	\$ —	\$ 389,018
Result for the Period	—	—	—	(878)	(878)
Contribution of Assets to Avadel Research SAS	—	—	9,462	(9,462)	—
Exercise of stock options	—	396	—	—	396
Stock-based compensation expense	—	—	8,062	—	8,062
Repurchase of ordinary shares	—	—	—	(22,361)	(22,361)
Transfer to profit and loss account	—	(317,254)	—	317,254	—
At 31 December 2017	<u>\$440</u>	<u>\$ 81,182</u>	<u>\$ 8,062</u>	<u>\$ 284,553</u>	<u>\$ 374,237</u>
Result for the Period	\$ —	\$ —	\$ —	\$ (286,969)	\$(286,969)
Exercise of stock options	1	534	—	—	535
Exercise of warrants	6	2,905	—	—	2,911
Vesting of restricted shares	6	—	—	(6)	—
Stock-based compensation expense	—	—	7,852	—	7,852
Employee share purchase plan issuance	—	127	—	—	127
Repurchase of ordinary shares	—	—	—	(27,637)	(27,637)
At 31 December 2018	<u>\$453</u>	<u>\$ 84,748</u>	<u>\$15,914</u>	<u>\$ (30,059)</u>	<u>\$ 71,056</u>

**Share premium**

This reserve records the excess of the fair value of the consideration receivable for issued shares above the nominal value of shares issued. On 6 March 2017, following approval from the High Court, \$317,254 of the Company's share premium can be treated as distributable reserves. This amount was transferred to the Profit and Loss Account.

In fiscal 2018, the share premium account increased due to the exercise of warrants of \$2,905 (See *Note 16* to the Group's Notes to Consolidated Financial Statements), the exercise of stock options of \$534 and the employee share purchase plan issuance of \$127.

**Other reserves**

On 1 January 2017, the Company contributed certain assets and liabilities to Avadel Research SAS. The merger reserves on the related assets and liabilities were transferred to the profit and loss account at that same date.

The balance as of 31 December, 2017 and 31 December, 2018 was comprised of accumulated share-based compensation.

## AVADEL PHARMACEUTICALS PLC

NOTES TO THE FINANCIAL STATEMENTS  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018

## NOTE 1: ACCOUNTING POLICIES

**Statement of compliance**

Avadel Pharmaceuticals plc was incorporated on December 1, 2015 as an Irish private limited company under the Companies Act 2014, 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 website is www.Avadel.com. The Company registration number is 572535.

The company financial statements have been prepared on a going concern basis and comply with FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* in accordance with the Companies Act 2014.

**Basis of preparation**

The financial statements have been prepared in accordance with applicable accounting standards issued by the Financial Reporting Council and promulgated by the Institute of Chartered Accountants in Ireland, including FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* and the Companies Act 2014. The financial statements are prepared for the year ended 31 December 2018 with comparatives presented for the year ended 31 December 2017.

The principal accounting policies are summarised below. They have all been applied consistently throughout the financial year.

In accordance with section 304 of the Companies Act 2014, the company is availing of the exemption from presenting the individual statement of comprehensive income.

**General Information and Basis of Accounting**

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 31 December, 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. Immediately prior to the merger, the Company was a wholly owned subsidiary of Flamel. In accordance with 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. These assets and liabilities were valued using the book value of the assets and liabilities at the time of the merger.

On January 1, 2017, Avadel Pharmaceuticals plc contributed all the assets and liabilities associated with the research and development services business performed in France to Avadel Research SAS, which is a wholly owned subsidiary of Avadel France Holding SAS, in exchange for stock in Avadel Research SAS.

The functional currency of the Company is considered to be US dollar because that is the currency of the primary economic environment in which the company operates.

**Going Concern**

The company’s business activities, together with the factors likely to affect its future development, performance and position are set out in the Business Review which forms part of the directors’ report. The directors’ report also describes the financial position of the company, the company’s objectives, policies and processes for managing its capital, its financial risk management objectives and details of its financial instruments and its exposure to credit risk and liquidity risk.

## AVADEL PHARMACEUTICALS PLC

NOTES TO THE FINANCIAL STATEMENTS  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018

The directors have a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Thus, they continue to adopt the going concern basis of accounting in preparing the financial statements. See *Note 2* of the Group financial statements.

**Investments in Subsidiaries**

The company's investment in subsidiaries are initially recorded at fair value of consideration given plus any directly attributable costs (at cost). The investments are carried at cost and tested for impairment if circumstances or indicators suggest that impairment may exist.

**Financial instruments*****Financial Assets & Liabilities (including Investment in Subsidiary Undertakings)***

All financial assets and liabilities are initially measured at transaction price (including transaction costs), except for those financial assets classified as at fair value through profit or loss, which are initially measured at fair value (which is normally the transaction price excluding transaction costs), unless the arrangement constitutes a financing transaction. If an arrangement constitutes a finance transaction, the financial asset or financial liability is measured at the present value of the future payments discounted at a market rate of interest for a similar debt instrument.

Non-current debt instruments which meet the following conditions are subsequently measured at amortised cost using the effective interest method:

- a. Returns to the holder are (i) a fixed amount; or (ii) a fixed rate of return over the life of the instrument; or (iii) a variable return that, throughout the life of the instrument, is equal to a single referenced quoted or observable interest rate; or (iv) some combination of such fixed rate and variable rates, providing that both rates are positive.
- b. There is no contractual provision that could, by its terms, result in the holder losing the principal amount or any interest attributable to the current period or prior periods.
- c. Contractual provisions that permit the issuer to prepay a debt instrument or permit the holder to put it back to the issuer before maturity are not contingent on future events, other than to protect the holder against the credit deterioration of the issuer or a change in control of the issuer, or to protect the holder or issuer against changes in relevant taxation or law.
- d. There are no conditional returns or repayment provisions except for the variable rate return described in (a) and prepayment provisions described in (c).

Debt instruments that are classified as payable or receivable within one year and which meet the above conditions are measured at the undiscounted amount of the cash or other consideration expected to be paid or received, net of impairment.

Other debt instruments not meeting these conditions are measured at fair value through profit or loss.

Financial assets are derecognised when and only when:

- a. The contractual rights to the cash flows from the financial asset expire or are settled,
- b. The Company transfers to another party substantially all of the risks and rewards of ownership of the financial asset, or
- c. The Company, despite having retained some significant risks and rewards of ownership, has transferred control of the asset to another party and the other party has the practical ability to sell the asset in its entirety to an unrelated third party and is able to exercise that ability unilaterally and without needing to impose additional restrictions on the transfer.

## AVADEL PHARMACEUTICALS PLC

NOTES TO THE FINANCIAL STATEMENTS  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**Impairment of Assets**

Assets, other than those measured at fair value, are assessed for indicators of impairment at each balance sheet date. If there is objective evidence of impairment, an impairment loss is recognised in profit or loss as described below.

***Financial assets***

For financial assets carried at amortised cost, the amount of an impairment is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the financial asset's original effective interest rate.

For financial assets carried at cost less impairment, the impairment loss is the difference between the asset's carrying amount and the best estimate of the amount that would be received for the asset if it were to be sold at the reporting date.

Where indicators exist for a decrease in impairment loss, and the decrease can be related objectively to an event occurring after the impairment was recognised, the prior impairment loss is tested to determine reversal. An impairment loss is reversed on an individual impaired financial asset to the extent that the revised recoverable value does not lead to a revised carrying amount higher than the carrying value had no impairment been recognised.

**Taxation**

Current tax, including Irish corporation tax and foreign tax, is provided at amounts expected to be paid (or recovered) using the tax rates and laws that have been enacted or substantively enacted by the statement of financial position date.

Deferred tax is recognised in respect of all timing differences that have originated but not reversed at the balance sheet date where transactions or events that result in an obligation to pay more tax in the future or a right to pay less tax in the future have occurred at the balance sheet date. Timing differences are differences between the company's taxable profits and its results as stated in the financial statements that arise from the inclusion of gains and losses in tax assessments in periods different from those in which they are recognised in the financial statements.

Unrelieved tax losses and other deferred tax assets are recognised only to the extent that, on the basis of all available evidence, it can be regarded as more likely than not that there will be suitable taxable profits from which the future reversal of the underlying timing differences can be deducted.

When the amount that can be deducted for tax for an asset (other than goodwill) that is recognised in a business combination is less (more) than the value at which it is recognised, a deferred tax liability (asset) is recognised for the additional tax that will be paid (avoided) in respect of that difference. Similarly, a deferred tax asset (liability) is recognised for the additional tax that will be avoided (paid) because of a difference between the value at which a liability is recognised and the amount that will be assessed for tax. The amount attributed to goodwill is adjusted by the amount of deferred tax recognised.

Deferred tax liabilities are recognised for timing differences arising from investments in subsidiaries and associates, except where the company is able to control the reversal of the timing difference and it is probable that it will not reverse in the foreseeable future.

Deferred tax is measured using the tax rates and laws that have been enacted or substantively enacted by the balance sheet date that are expected to apply to the reversal of the timing difference. Deferred tax relating to tangible assets measured using the revaluation model and investment property is measured using the tax rates and allowances that apply to sale of the asset.

## AVADEL PHARMACEUTICALS PLC

NOTES TO THE FINANCIAL STATEMENTS  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018

The tax expense or income is presented in the same component of comprehensive income or equity as the transaction or other event that resulted in the tax expense or income.

Current tax assets and liabilities are offset only when there is a legally enforceable right to set off the amounts and the company intends either to settle on a net basis or to realise the asset and settle the liability simultaneously.

Deferred tax assets and liabilities are offset only if: a) the company has a legally enforceable right to set off current tax assets against current tax liabilities; and b) the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

**Financial Guarantees**

At the time the Company issues a guarantee, the Company recognizes an initial liability for the fair value of the obligation which the Company assumes under that guarantee.

**Foreign currency**

Transactions in foreign currencies are recorded at the rate of exchange at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are reported at the rates of exchange prevailing at that date.

Exchange differences arising on translation of the opening net assets are reported in other comprehensive income and accumulated in equity. Other exchange differences are recognised in profit or loss in the period in which they arise except for exchange differences arising on gains or losses on non-monetary items which are recognized in other comprehensive income.

**Cash and cash equivalents**

Cash and cash equivalents in the Balance Sheet comprise cash at banks and in hand and short term deposits readily convertible to known amounts of cash with an original maturity date of three months or less.

**Leases**

Assets held under finance leases, hire purchase contracts and other similar arrangements, which confer rights and obligations similar to those attached to owned assets, are capitalised as tangible fixed assets at the fair value of the leased asset (or, if lower, the present value of the minimum lease payments as determined at the inception of the lease) and are depreciated over the shorter of the lease terms and their useful lives. The capital elements of future lease obligations are recorded as liabilities, while the interest elements are charged to the profit and loss account over the period of the leases to produce a constant periodic rate of interest on the remaining balance of the liability.

Rentals under operating leases are charged on a straight-line basis over the lease term, even if the payments are not made on such a basis. Benefits received and receivable as an incentive to sign an operating lease are similarly spread on a straight-line basis over the lease term.

**Share-based payment**

The Company issues equity-settled share options and equity-settled share appreciation rights to certain employees within the Group. Equity-settled share based payment transactions are measured at fair value of the equity instruments (excluding the effect of non market-based vesting conditions) at the date of grant.



## AVADEL PHARMACEUTICALS PLC

NOTES TO THE FINANCIAL STATEMENTS  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018

The fair value determined at the grant date of the equity-settled share based payments is expensed on a straight-line basis over the vesting period, based on the Group's estimate of shares that will eventually vest and adjusted for the effect of non market-based vesting conditions.

Fair value is measured by use of the Black Scholes pricing model which is considered by management to be the most appropriate method of valuation. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of nontransferability, exercise restrictions, and behavioural considerations.

Avadel Pharmaceuticals plc accounts for share-based payments available to members within the Group as a deemed equity contribution and increases the value of their investment in subsidiary undertakings by the value associated with the share-based payment.

**Cash flow Statement exemption and other disclosure exemptions under FRS 102**

The Company meets the definition of a qualifying entity under FRS 102 and has therefore taken advantage of the disclosure exemptions available to it in respect of its separate financial statements, which are presented alongside the consolidated financial statements. Exemptions have been taken in relation to share-based payments, financial instruments, presentation of a cash flow statement and remuneration of key management personnel. Please refer to *Note 18.1* Equity Instruments and Stock Based Compensation, *Note 20* Fair Value Measurements, Consolidated Statement of Cash Flows and *Note 23* Key Management Compensation in the consolidated financial statements.

**NOTE 2: CRITICAL ACCOUNTING JUDGEMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY**

In the application of the company's accounting policies, which are described in *Note 1*, the directors are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

The following are the critical judgements, apart from those involving estimations (which are dealt with separately below), that the directors have made in the process of applying the company's accounting policies and that have the most significant effect on the amounts recognised in the financial statements.

***Going concern***

The directors have considered the applicability of the going concern basis in the preparation of these financial statements; refer to *Note 1*.

***Impairment of Financial assets***

Where there are indicators of impairment of financial assets, the Company performs impairment tests based on the valuation of the Company's subsidiaries and net assets against other indicators of value, such as the overall market capitalisation of the Avadel Pharmaceutical Group and carrying value of net assets in the consolidated financial statements. The overall market capitalisation calculation used an average stock price of Avadel Pharmaceutical plc from the period February to May 2019, increased by a control premium based on available data from similar, observable market transactions. Additional, publicly-available analysis from unrelated parties is also used to verify market capitalisation assumptions for the analysis.

**AVADEL PHARMACEUTICALS PLC**

**NOTES TO THE FINANCIAL STATEMENTS  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

**NOTE 3: TURNOVER**

The Company did not have any turnover for the year ended 31 December, 2018 (2017: \$nil).

**NOTE 4: LOSS ATTRIBUTABLE TO AVADEL PHARMACEUTICALS PLC**

In accordance with Section 304(2) of the Companies Act 2014, Avadel Pharmaceuticals plc is availing itself of the exemption from presenting and filing its individual profit and loss account. Avadel Pharmaceuticals plc loss for the year ended 31 December, 2018 as determined in accordance with Irish GAAP (FRS 102) was \$286,969. Avadel Pharmaceuticals plc loss for the period ended 31 December, 2017 was \$878.

**NOTE 5: AUDITOR'S REMUNERATION**

The analysis of the auditor's remuneration is as follows:

Auditor's remuneration for work carried out for the company in respect of the financial period is as follows (Amounts are in \$ thousands):	31 December 2018	31 December 2017
Audit of Company accounts	\$ 18	\$ 18
Other assurance services – initial accounts	—	—
Tax advisory services	—	—
Other non-audit services	—	—

No amounts were incurred for tax advisory services or other non-audit services. *Note 24* to the consolidated Group financial statements provides additional details of fees paid by the Group.

**NOTE 6: DIRECTORS' REMUNERATION (Amounts in \$ thousands)**

Directors' Remuneration	2018	2017
Aggregate emoluments in respect to qualifying services	\$ 833	\$1,248
Aggregate amount of gains by the directors on the exercise of share options during the financial year	—	—
Aggregate amount of the money or value of other assets under long term incentive schemes in respect qualifying services	1,554	2,031
Aggregate contributions to a retirement benefit scheme in respect of directors' qualifying services – defined contributions schemes	—	—
Aggregate contributions to a retirement benefit scheme in respect of directors' qualifying services – defined benefit schemes	—	—
Compensation for loss of office	986	—
<b>Total</b>	<b>\$3,373</b>	<b>\$3,279</b>

The Company had no other employees apart from the directors during the financial year.

See *Note 23* to the Group's Notes to Consolidated Financial Statements for key management compensation.

**AVADEL PHARMACEUTICALS PLC**  
**NOTES TO THE FINANCIAL STATEMENTS**  
**FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

**NOTE 7: FINANCIAL ASSETS (Amounts in \$ thousands)****Principal Company Investments — Subsidiary Undertakings**

	<b>Financial Assets</b>
<b>At 1 December 2016</b>	<b>\$ 225,333</b>
Contribution of French assets and liabilities to Avadel Research SAS	5,802
Subscription in Flamel Ireland Ltd	33,121
Deemed contributions of stock based compensation	7,445
<b>At 31 December 2017</b>	<b>271,701</b>
Deemed contributions of stock based compensation	6,296
Impairment of financial assets	(226,152)
<b>At 31 December 2018</b>	<b><u>\$ 51,845</u></b>

Avadel Pharmaceuticals plc has investments in the following subsidiary undertakings.

<b>Direct Subsidiary Undertakings:</b>	<b>Country</b>	<b>Principal Activity</b>	<b>%</b>
Avadel US Holdings Inc	USA	Marketing Services	100
Avadel France Holding SAS	France	Holding Company	100
Flamel Ireland Ltd	Ireland	Research & Development	100
Avadel Investment Company Limited	Cayman Islands	Investment Services	100
Avadel Finance Designated Activity Company	Ireland	Finance Services	100

Refer to *Note 29* of the consolidated Group financial statements for the full list of subsidiary undertakings for the Group.

On January 1, 2017, Avadel Pharmaceuticals plc contributed all the assets and liabilities associated with the research and development services business performed in France to Avadel Research SAS, which is a wholly owned subsidiary of Avadel France Holding SAS, in exchange for stock in Avadel Research SAS. The value of the net assets was \$5,802.

On January 2, 2017 Avadel Pharmaceuticals plc contributed the stock in Avadel Research SAS to Avadel France Holding SAS.

On January 2, 2017 Avadel Pharmaceuticals plc subscribed to 1 share of Flamel Ireland Ltd for \$33,121 by releasing the intercompany loan between Avadel Pharmaceuticals plc and Flamel Ireland Ltd.

Avadel Pharmaceuticals plc accounts for share-based payments available to members within the Group as a deemed equity contribution and increases the value of their investment in subsidiary undertakings by the value associated with the share-based payment. In 2018 and 2017, the value associated with share-based payments provided to employees in subsidiary undertakings was \$6,296 and \$7,445, respectively.

In 2018, Avadel Pharmaceuticals plc recorded a \$226,152 impairment on its investment in financial assets of the Avadel Pharmaceutical Group based on the overall market capitalization of Avadel Pharmaceuticals plc such that the overall net assets of the Company did not exceed the fair value of the group at the balance sheet date.

**AVADEL PHARMACEUTICALS PLC**  
**NOTES TO THE FINANCIAL STATEMENTS**  
**FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

**NOTE 8: DEBTORS (Amounts in \$ thousands)**

	<u>2018</u>	<u>2017</u>
<b><u>Amounts Falling Due Within One Year:</u></b>		
Prepayments and accrued income	\$ 672	\$ 694
	<u>\$ 672</u>	<u>\$ 694</u>
<b><u>Amounts Falling Due After One Year:</u></b>		
Amounts owed by group undertakings	\$19,837	\$104,815
	<u>\$19,837</u>	<u>\$104,815</u>

On January 1, 2017 Avadel Investment Company Ltd. drew down \$109,224 of cash from Avadel Pharmaceuticals plc using the intercompany revolving credit facility set up between both entities. Following the draw down, Avadel Investment Company Ltd. purchased cash and investments of \$109,224 held in various third-party accounts from Avadel Pharmaceuticals, plc.

On January 1, 2017, Avadel Pharmaceuticals plc contributed all the assets and liabilities associated with the research and development services business performed in France to Avadel Research SAS, which is a wholly owned subsidiary of Avadel France Holding SAS, in exchange for stock in Avadel Research SAS.

On January 2, 2017 Avadel Pharmaceuticals plc subscribed to 1 share of Flamel Ireland Ltd for \$33,121 by releasing the intercompany loan between Avadel Pharmaceuticals plc and Flamel Ireland Ltd.

During 2017, Avadel Investment Company Ltd. made several cash payments in partial repayment of the intercompany revolving credit facility set up on January 1, 2017 between Avadel Investment Company Ltd. and Avadel Pharmaceuticals plc. On November 2, 2017 Avadel Investment Company Ltd repaid the remaining outstanding balance on the intercompany revolving credit facility by transferring a note receivable from Avadel US Holdings, Inc. for \$104,815 to Avadel Pharmaceuticals plc.

During 2018, the decrease was due to approximately \$53,400 of intercompany loans with Avadel US Holdings being written-off, and a partial repayment of loan principal and interest of approximately \$51,400 from Flamel Ireland Ltd, partially offset by an additional \$19,800 of loans to Flamel Ireland Ltd.

**NOTE 9: CREDITORS (Amounts in \$ thousands)**

	<u>2018</u>	<u>2017</u>
<b><u>Amounts Falling Due Within One Year:</u></b>		
Trade creditors	\$ 69	\$ 83
Amounts owed to group undertakings	—	4,546
Accruals and other creditors	607	432
	<u>\$ 676</u>	<u>\$5,061</u>
<b><u>Amounts Falling Due After One Year:</u></b>		
Other creditors	\$ —	\$ 107
Deferred income taxes	1,266	1,266
	<u>\$1,266</u>	<u>\$1,373</u>

Trade creditors are repayable within 30 to 60 days of the amount owing.

The amounts owed to group undertakings are not interest bearing and are repayable on demand.

**AVADEL PHARMACEUTICALS PLC**

**NOTES TO THE FINANCIAL STATEMENTS  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

**NOTE 10: CALLED UP SHARE CAPITAL (Amounts in \$ thousands)**

	<u>2018</u>	<u>2017</u>
<b>Authorised:</b>		
25,000 deferred ordinary shares of €1.00 each at 31 December 2018 and 2017	\$ 26	\$ 26
500,000,000 ordinary shares of \$.01 each at 31 December 2018 and 2017	5,000	5,000
50,000,000 preferred shares of \$.01 each at 31 December 2018 and 2017	500	500
<b>Allotted, Called Up and Fully Paid:</b>		
25,000 deferred ordinary shares of €1.00 each at 31 December 2018 and 2017	\$ 26	\$ 26
42,720,249 and 41,462,699 ordinary shares of \$.01 each at 31 December 2018 and 2017, respectively	427	414
Called up share capital presented as equity	<u>\$ 453</u>	<u>\$ 440</u>

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.

In March 2017, the Board of Directors approved an authorization to repurchase up to \$25,000 of Avadel ordinary shares represented by American Depositary Receipts in the open market with an indefinite duration. The timing and amount of repurchases, if any, will depend on a variety of factors, including the price of our shares, cash resources, alternative investment opportunities, corporate and regulatory requirements and market conditions. This share repurchase program may be modified, suspended or discontinued at any time without prior notice. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. Additionally, on 12 February, 2018, the Board of Directors approved an authorization to repurchase up to \$18,000 of Avadel ordinary shares represented by American Depositary Shares in connection with our Convertible Notes Offering completed on 16 February, 2018. See *Note 15* Group's Notes to Consolidated Financial Statements. In March 2018, the Board of Directors approved an authorization to repurchase up to \$7,000 of Avadel ordinary shares represented by American Depositary Shares, bring the total authorization to \$50,000. As of 31 December, 2018, the Group had repurchased 5,407 ordinary shares for \$49,998, none of which have been cancelled. This amount has been recorded to the Profit and Loss Account.

**NOTE 11: OTHER RESERVES (Amounts in \$ thousands)**

**Share premium**

This reserve records the excess of the fair value of the consideration receivable for issued shares above the nominal value of shares issued. On 6 March 2017, following approval from the High Court, \$317,254 of the Company's share premium can be treated as distributable reserves. This amount was transferred to the Profit and Loss Account.

In fiscal 2018, the share premium account increased due to the exercise of warrants of \$2,905 (See *Note 16* to the Group's Notes to Consolidated Financial Statements), the exercise of stock options of \$534 and the employee share purchase plan issuance of \$127.

**Other reserves**

The Company recorded \$9,462 of Merger Reserves related to the completion of the cross-border merger on 31 December, 2016.

## AVADEL PHARMACEUTICALS PLC

NOTES TO THE FINANCIAL STATEMENTS  
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On 1 January 2017, the Company contributed certain assets and liabilities to Avadel Research SAS. The merger reserves on the related assets and liabilities were transferred to the profit and loss account at that same date.

The balance as of 31 December 2018 was comprised of accumulated share-based compensation.

**NOTE 12: LEASE COMMITMENTS**

There are no commitments or contingent liabilities, including operating leases, at the end of the financial period.

**NOTE 13: GUARANTEES (Amounts in \$ thousands)**

At 31 December, 2017, Avadel Pharmaceuticals plc has provided guarantees to several financing and leasing agreements of certain of its subsidiaries. Material guarantees are as follows:

Avadel Pharmaceuticals plc is the guarantor of an agreement entered into in March 2012, related to the acquisition of all of the membership interests of Éclat from Breaking Stick Holdings, L.L.C., an affiliate of Deerfield Capital L.P. In the agreement Avadel US Holdings Inc is required to make earnout payments to Breaking Stick of 20% of any gross profit generated by certain Éclat products.

Avadel Pharmaceuticals plc is the guarantor of a debt financing agreement entered into in February 2013 with Deerfield Management. In this transaction, 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 Éclat 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.

Avadel Pharmaceuticals plc is the guarantor of a December 2013 debt financing agreement conducted with Broadfin Healthcare Master Fund ("Broadfin"). Pursuant to the Broadfin Royalty Agreement, Avadel US Holdings Inc 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.

As set out in *Note 15* to the Group's Notes to Consolidated Financial Statements, Avadel Pharmaceuticals plc is a guarantor to \$143,750 of convertible Loan notes issued by its subsidiary, Avadel Cayman Limited. At the balance sheet date the company assessed the likelihood being called upon to honor the guarantee as unlikely and accordingly no provision was made.

Avadel Pharmaceuticals plc is a guarantor of an agreement where, on February 8, 2016, Avadel US Holdings Inc entered into an agreement to acquire FSC Holdings, LLC ("FSC"), a Charlotte, NC-based specialty pharmaceutical company, 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 Group 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. Avadel US Holdings Inc 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.

Avadel Pharmaceuticals plc is the guarantor of a lease agreement in Ireland where Avadel Ireland Ltd leases office space in Dublin, Ireland.

Avadel Pharmaceuticals plc is the guarantor of a lease agreement in the United States where Avadel Ireland Ltd leases office space in Chesterfield, Missouri.

**NOTE 14: POST BALANCE SHEET EVENTS**

*Note 27* to the Group's Notes to Consolidated Financial Statements provides details of post balance sheet events. Avadel Pharmaceuticals plc was a party (along with other entities in the Group) to each of the listed transactions.

**AVADEL PHARMACEUTICALS PLC**

**NOTES TO THE FINANCIAL STATEMENTS  
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2018**

**NOTE 15: RELATED PARTY DISCLOSURES**

The company has availed of the exemption provided in FRS 102 Section 33 “Related Party Disclosures” for wholly owned subsidiary undertakings whose voting rights are controlled within the group, from the requirements to give details of transactions with entities that are part of the group or investees of the group qualifying as related parties.

**NOTE 16: APPROVAL OF THE FINANCIAL STATEMENTS**

The financial statements were approved and authorised for issue on 13 June, 2019