# 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 2, 2017

# AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland
(State or Other Jurisdiction of Incorporation)

000-28508

(Commission File Number)

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

Block 10-1
Blanchardstown Corporate Park, Ballycoolin
Dublin 15, Ireland
(Address of Principal Executive Offices)

Not Applicable (Zip Code)

Registrant's telephone number, including area code: +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  $\square$ 

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 vised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

### Item 7.01 Regulation FD Disclosure.

On June 2, 2017, 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 December 1, 2015 (date of incorporation) through December 31, 2016, 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 12:00 Noon (Irish Standard Time) on Wednesday, June 28, 2017 at the offices of Arthur Cox, Ten Earlsfort Terrace, Dublin 2, D02 T380, Ireland. The Irish Statutory Accounts were sent to Holders in advance of the Company's Annual General Meeting, as required by Irish law, under cover of a letter, a copy of which is furnished as Exhibit 99.1 to this current report on Form 8-K and is incorporated herein by reference.

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; <u>provided</u>, <u>however</u>, that the Irish Statutory Accounts include disclosures and presentation formats required by the Republic of Ireland's Companies Act 2014 and which may not be required by US GAAP. A copy of the Irish Statutory Accounts is furnished as Exhibit 99.2 to this current report on Form 8-K and is incorporated herein by reference.

The Irish Statutory Accounts will also be available on the Company's website.

The information in this Item 7.01, including Exhibits 99.1 and 99.2, 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	Cover letter mailed with Irish Statutory Accounts for the Avadel Pharmaceuticals plc 2017 annushareholders.	ual general meeting of
99.2	Irish Statutory Accounts for the period beginning December 1, 2015 through December 31, 201	6.

### **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: <u>/s/ Phillandas T. Thompson</u>
Phillandas T. Thompson
Senior Vice President, General
Counsel and Corporate
Secretary

Date: June 2, 2017

# **Exhibit Index**

99.1	Cover letter mailed with Irish Statutory Accounts for the Avadel Pharmaceuticals plc 2017 annual general meeting of shareholders.
99.2	<u>Irish Statutory Accounts for the period beginning December 1, 2015 through December 31, 2016.</u>



June 2, 2017

### Avadel Pharmaceuticals plc Block 10-1, Blanchardstown Corporate Park Ballycoolin, Dublin 15, Ireland

### To our Shareholders:

We are forwarding herewith a copy of the Irish Statutory Financial Statements of Avadel Pharmaceuticals plc (the "Company") for the period beginning December 1, 2015 (the date of incorporation) through December 31, 2016, along with the related directors' and independent auditor's reports. These Irish Statutory Financial Statements may be considered to be part of the proxy materials which were furnished to you under cover of our letter dated May 26, 2017, namely, (a) the notice of the annual general meeting of shareholders (the "Meeting") of the Company to be held Wednesday, June 28, 2017 at 12:00 Noon (Irish Standard Time) at the offices of Arthur Cox, Ten Earlsfort Terrace, Dublin 2, D02 T380, Ireland, (b) the proxy statement relating to the matters to be considered at the Meeting and containing certain other information, (c) a proxy card (for use by holders of our ordinary shares) or a voting instruction card (for use by holders of our American Depositary Shares), as applicable, and (d) a copy of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

Additional copies of the materials described above may be obtained without charge by writing to the Corporate Secretary of Avadel Pharmaceuticals plc at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15, Ireland or downloaded from our website at www.Avadel.com.

Very truly yours,

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



### 2016 IRISH STATUTORY ACCOUNTS

# AVADEL PHARMACEUTICALS PLC

# **Directors' Report and Consolidated Financial Statements**

For the Year Ended 31 December, 2016

# AVADEL PHARMACEUTICALS PLC

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### **DIRECTORS' REPORT**

### For the Fiscal Year Ended 31 December, 2016

(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, 2016, which are set out on pages 36 to 71, and audited parent company financial statements for the financial period ended 31 December, 2016, which are set out on pages 72 to 88.

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 or of any regulations made thereunder.

The directors have elected to prepare the Avadel Pharmaceuticals plc parent company financial statements 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* (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 Company") 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 company.

### **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 TM or ® 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 company appearing in this Directors' Report is, to our knowledge, owned by such other company.

#### 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, 2016. We expressly disclaim any obligation to update these forward-looking statements other than as required by law.

### **Principal Activities**

Avadel is a specialty pharmaceutical company engaged in identifying, developing, and commercializing niche branded pharmaceutical products mainly in the U.S. Our business model consists of three distinct strategies:

- the development of differentiated, patent protected products through application of the Company's proprietary patented drug delivery platforms, Micropump® and LiquiTime®, that target high-value solid and liquid oral and alternative dosages forms through the U.S. Food and Drug Administration (FDA) 505(b)(2) approval process, which allows a sponsor to submit an application that doesn't depend on efficacy, safety, and toxicity data created by the sponsor. In addition to Micropump® and LiquiTime®, the Company has two other proprietary drug delivery platforms, Medusa<sup>TM</sup> (hydrogel depot technology for use with large molecules and peptides) and Trigger Lock<sup>TM</sup> (controlled release of opioid analgesics with potential abuse deterrent properties).
- the identification of Unapproved Marketed Drugs ("UMDs"), which are currently sold in the U.S., but unapproved by the FDA, and the pursuit of approval for these products via a 505(b)(2) New Drug Application (NDA). To date, the Company has received approvals through this "unapproved-to-approved" avenue for three products: Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection) and Akovaz® (ephedrine sulfate injection). As a potential source of near-term revenue growth, Avadel is working on the development of a fourth product for potential NDA submission by year-end 2017, and seeks to identify additional product candidates for development with this strategy.
- the acquisition of commercial and or late-stage products or businesses. The Company markets three branded pediatric-focused pharmaceutical products in the primary care space, and a 510(k) approved device that will launch in the second quarter of 2017, all of which were purchased through the acquisition of FSC Laboratories and FSC Pediatrics on February 5, 2016. We will consider further acquisitions, and the Company continues to look for assets that could fit strategically into its current or potential future commercial sales force.

### **Corporate Information**

The Company was incorporated on December 1, 2015 as an Irish private limited company, and re-registered as an Irish public limited company, or plc, on November 21, 2016. Its principal place of business is located at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15, Ireland. Its phone number is 00-353-1-485-1200, and its website is <a href="www.Avadel.com">www.Avadel.com</a>.

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 (the "Merger Agreement"). Immediately prior to the Merger, the Company was a wholly owned subsidiary of Flamel. 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 January 3, 2017 under the trading symbol "AVDL."

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

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

The Company currently has four direct wholly owned operating subsidiaries: Avadel US Holdings, Inc., Flamel Ireland Limited, trading under the name Avadel Ireland, Avadel Investment Company Limited and Avadel France Holding SAS. Avadel US Holdings, Inc. is a Delaware corporation, and is the holding entity of Avadel Pharmaceuticals (USA), Inc. (Formerly FSC Laboratories, Inc.), Avadel Legacy Pharmaceuticals, LLC (formerly Éclat Pharmaceuticals, LLC), Avadel Management Corporation, and Avadel Operations Company, Inc. Avadel Ireland is a corporation organized under the laws of Ireland and is where all intangible property was relocated on December 16, 2014. Avadel France Holding SAS is a société par actions simplifiée, organized under the laws of France and is the holding entity of Avadel Research SAS where the Company's research and development activities take place. A complete list of the Company's subsidiaries can be found in *Note 28*: *Subsidiary Undertakings* to the Notes to the consolidated financial statements.

### Dividends

No dividends have been paid in the current or preceding period. We currently do not anticipate paying any cash dividends for the foreseeable future, as we intend to retain earnings to finance R&D, acquisitions, the continued operation and expansion of our business and repurchase of shares. 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 Repurchase Program**

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

### Acquisitions

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

### **Consolidated Profit and Loss Accounts**

Loss after taxation of \$41,276 for fiscal 2016 and profit after taxation of \$41,798 for fiscal 2015 were debited and credited to reserves, respectively. No profits were distributed as dividends during fiscal 2016 and 2015. The following table presents the consolidated profit and loss accounts, with percentage of turnover:

							1	Increase / (	Decrease)
		Fiscal Year						2016 vs	. 2015
	_	2016	3		201	5		\$	%
Turnover	\$	150,246	100.0 %	\$	173,009	100%	\$	(22,763)	(13.2)%
Cost of sales		13,248	8.8		11,410	6.6		1,838	16.1 %
Gross profit		136,998	91.2		161,599	93.4		(24,601)	(15.2)%
Research and development cost		(34,611)	(23.0)		(25,608)	(14.8)		(9,003)	35.2 %
Distribution and administration expenses		(44,179)	(29.4)		(21,712)	(12.5)		(22,467)	103.5 %
Intangible asset amortization		(13,888)	(9.2)		(12,564)	(7.3)		(1,324)	10.5 %
Changes in fair value of related party contingent									
consideration		(49,285)	(32.8)		(30,957)	(17.9)		(18,328)	59.2 %
Operating (loss) profit		(4,965)	(3.3)		70,758	40.9		(75,723)	(107.0)%
Investment and other income		1,635	1.1		1,236	0.7		399	32.3 %
Interest expense		(963)	(0.6)		_	_		963	n/a
Other expense - changes in fair value of related									
party payable		(6,548)	(4.4)		(4,883)	(2.8)		1,665	34.1 %
Foreign exchange gain		1,123	0.7		10,594	6.1		(9,471)	(89.4)%
(Loss) profit before taxation		(9,718)	(6.5)		77,705	44.9		(87,423)	(112.5)%
Taxation (credit) charge		31,558	21.0		35,907	20.8		(4,349)	(12.1)%
(Loss) profit after taxation	\$	(41,276)	(27.5)	\$	41,798	24.2	\$	(83,074)	(198.8)%
			-7-						

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

							Increase /	(Decrease)
			Fisca	l Yea	ar		2016 v	/s. 2015
Turnover:	_	20	16		20	15	\$	<u>%</u>
Bloxiverz	\$	82,896	55.2%	\$	150,083	86.7%	\$ (67,187)	(44.8)%
Vazculep		39,796	26.5		20,151	11.6	19,645	97.5 %
Akovaz		16,831	11.2			_	16,831	n/a
Other		7,699	5.1		2,054	1.2	5,645	274.8 %
Sales and service turnover		147,222	98.0		172,288	99.6	(25,066)	(14.5)%
License and research turnover		3,024	2.0		721	0.4	2,303	319.4 %
Turnover	\$	150,246	100.0	\$	173,009	100.0	\$ (22,763)	(13.2)%

#### Turnover

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

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

### Gross profit

Gross profit for fiscal 2016 decreased \$24,601, or 15.2%, to \$136,998, compared with \$161,599 in fiscal 2015. The decrease in gross profit primarily resulted from the previously mentioned decreased turnover of Bloxiverz, partly offset by increased turnover of Vazculep in 2016, the launch of Akovaz in August 2016, and additional turnover from the acquisition of FSC in February 2016.

### Research and Development Cost

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

### Distribution and Administrative Expenses

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

#### *Intangible Asset Amortization*

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

### Changes in Fair Value of Related Party Contingent Consideration

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

### Interest Expense

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

### Other Expense - Changes in Fair Value of Related Party Payable

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

### Foreign Exchange Gains

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

#### **Taxation**

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

#### **Our Business Model and Strategy**

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

### Business Strengths and Strategies (future developments)

Our business strengths and strategies include:

- Continued Development of our Drug Delivery Technologies: Our versatile, proprietary drug delivery platforms (Micropump®, LiquiTime®, Trigger Lock™, Medusa™) allow us to select unique product development opportunities, representing either "life cycle" opportunities, whereby additional intellectual property (IP) can be added to a pharmaceutical to extend the commercial viability of a product, for marketed chemical and biological drugs (via 505(b)(2) approval), or innovative formulation opportunities for new chemical entities (NCE) or new biological entities (NBE) (via NDA regulatory path). Several products formulated using our proprietary drug delivery platforms are currently under various stages of development. These products will be marketed either by the Group and/or by partners via licensing/distribution agreements (see "- Other Products Under Development Proprietary pipeline to deliver several regulatory filings (US and/or EU) through 2018") in this Director's Report).
- Continued exploration and development of additional unapproved to approved drug products: Our unapproved to approved drug development process may provide us with near term revenue growth and provide cash flows that can be used to fund R&D and inorganic initiatives.
- Inorganic growth through Acquisitions and/or Partnerships: The Group maintains a strong balance sheet with substantial liquidity and no long term debt with fixed maturities. The Group intends to explore and pursue appropriate inorganic growth opportunities that complement its drug delivery platforms or to acquire proprietary products that enhance profitability and cash flow. This goal was evidenced in early 2016 with the acquisition of FSC Holdings, LLC and its subsidiaries, specialty pharmaceutical companies which focus on the commercialization of pediatric products and devices. The acquisition of the FSC companies adds to our marketing and licensing knowledge of commercial processes in the U.S, which we believe enhances our ability to identify potential product candidates for development, leverages new opportunities for the application of our drug delivery platforms, and establishes a commercial footprint to license and market products in the U.S.
- **Divestitures and out licensing:** We intend to narrow our focus to our two most developed drug delivery platforms, Micropump® and LiquiTime®, and plan to divest or out-license Trigger Lock<sup>TM</sup>, for abuse deterrence, and Medusa<sup>TM</sup>, for extended-release subcutaneous injection. We believe the Trigger Lock<sup>TM</sup> and Medusa<sup>TM</sup> platforms are robust and well protected from an IP standpoint; however, their development and FDA approval may require investments in clinical work and infrastructure which we are not currently prepared to support. In 2015, the Group entered into a transaction in which it granted Elan Pharma International Limited an exclusive U.S. license to use the Group's LiquiTime technology for Over-the-Counter ("OTC") products.

### Developments in 2016 and 2017

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

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

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

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

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

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

#### **Lead Products**

Bloxiverz® (neostigmine methylsulfate injection), Bloxiverz's NDA was filed on July 31, 2012. Bloxiverz, was approved by the FDA on May 31, 2013 and was launched in July 2013. Bloxiverz is a drug used intravenously in the operating room for the reversal of the effects of non-depolarizing neuromuscular blocking agents after surgery. Bloxiverz was the first FDA-approved version of neostigmine methylsulfate. Today, neostigmine is the most frequently used product for the reversal of the effects of other agents used for neuromuscular blocks. There are approximately four million vials sold annually in the U.S. On January 8, 2015 and December 28, 2015, the FDA approved the NDA submitted by Fresenius Kabi USA ("Fresenius") for neostigmine methylsulfate (for both 0.5 mg/1mL and 1 mg/1mL strengths) and an ANDA submitted by Eurohealth International, an affiliate of West-Ward Pharmaceuticals Corp., neostigmine methylsulfate (for both 0.5 mg/1mL and 1 mg/1mL strengths), respectively. In 2016, we recognized total revenues of \$82,896 for this product. (for more details, see "Consolidated Profit and Loss Accounts" in this Director's Report). In the future, turnover of Bloxiverz is dependent upon the competitive market dynamics between Avadel, Fresenius, West-Ward and any subsequent ANDA approvals that may occur. Additionally, an alternative product marketed by Merck, Bridion (sugammadex), was approved in early 2016 and has taken approximately 30% of the neostigmine market away through early February 2017.

**Vazculep®** (phenylephrine hydrochloride injection) On June 28, 2013, the Group filed an NDA for Vazculep (phenylephrine hydrochloride injection). The product was approved by the FDA on June 27, 2014 and is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. We started shipping Vazculep (in 1mL single use vials, and 5mL and 10mL pharmacy bulk package vials) to wholesalers in October 2014. There are approximately 7 million vials sold annually in the U.S. Vazculep is the only FDA-approved version of phenylephrine hydrochloride to be available in all three vial sizes. West-Ward Pharmaceuticals Corp. ("West Ward") commercializes the 1mL single-dose vial, as an approved product in the U.S. In 2016, we recognized total revenues of \$39,796 for this product. The volume of turnover of Vazculep is dependent upon the competitive landscape in the marketplace.

**Akovaz**<sup>®</sup> (**ephedrine sulfate injection**). On June 30, 2015, the Group announced its third NDA was accepted by the FDA, and was granted approval for Akovaz on April 29, 2016. On August 12, 2016, we launched Akovaz, into a market of approximately 7.5 million vials annually in the U.S. The Group was the first approved formulation of ephedrine sulfate, an alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. Avadel began shipping the product to wholesalers in August 2016 in cartons of twenty-five 50 mg/mL 1mL single use vials. During 2016 Akovaz was the only FDA approved version of ephedrine sulfate being commercially sold in the U.S. In 2016, we recognized total revenues of \$16,831 for this product. On January 27, 2017, Endo International plc's (NASDAQ: ENDP) subsidiary Par Pharmaceuticals, received NDA approval for ephedrine sulfate, packaged in cartons of twenty-five 50mg/mL, 1mL single use vials. On March 2, 2017, Akorn Pharmaceuticals (NASDAQ: AKRX) received FDA approval for its ampule presentation. We expect this market to remain a three player market.

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

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

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

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

### Other Products Under Development

FT218 is Avadel's Micropump-based formulation of sodium oxybate. Sodium oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid (GABA). It has been described as a therapeutic agent with high medical value; in Europe and the United States it is currently approved in a twice nightly formulation indicated for the treatment of cataplexy and excessive daytime sleepiness in patients with narcolepsy at doses up to 9g/night. In December 2016, the Group initiated patient enrollment and dosing for its REST-ON Phase III clinical trial to assess the safety and efficacy of its once nightly formulation of FT218 for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. The study is a randomized, double-blind, placebo controlled study of 264 patients being conducted in 50 - 60 clinical sites in the U.S., Canada and western Europe. The Group expects enrollment to be completed by year end 2017. In preparation for its REST-ON trial, Avadel sought and consequently reached an agreement with the FDA for the design and planned analysis of its study through a Special Protocol Assessment (SPA). An SPA is an acknowledgement by the FDA that the design and planned analysis of a pivotal clinical trial adequately addresses the objectives necessary to support a regulatory submission. Should the trial reach its primary endpoints of EDS and cataplexy, the Group believes an SPA agreement with the FDA should help to mitigate several risks associated with receiving approval, such as any questions surrounding statistical powering.

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

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

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

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

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

### Additional Unapproved Marketed Drug Products

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

### **Proprietary Product Pipeline**

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

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

continue development

### **Competition, Market Opportunities, and Proprietary Intellectual Property**

### Competition

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

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

In addition, the overall landscape of the Pharma/Biotech industry has changed, as consolidation has reduced our pool of potential partners and further accelerated the competition among drug delivery and specialty pharmaceutical companies. Over the past ten years, numerous standalone drug delivery companies have been acquired (partly or entirely) by pharmaceutical, biotech, generic or other drug delivery companies. By acquiring drug delivery platforms, those companies are internalizing their previously outsourced R&D efforts while potentially preventing competitors from accessing the acquired technologies. In the meantime, certain drug delivery companies have consolidated their existing positioning or have entered new markets via M&A transactions and/or restructuring.

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

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

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

<sup>\*</sup> From companies' web site and/or press releases.

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

### **Market Opportunities**

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

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

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

Market opportunities for proprietary pipeline products that Avadel intends to pursue independently are estimated by the Group to be worth at least several hundred million dollars each. For example, Xyrem® (sodium oxybate) recorded \$955 million in turnover in the U.S. for 2015 (source: Jazz press release Full Year and Fourth Quarter 2015 Financial Results, February 23, 2016) and is expected to generate between \$1.1 and \$1.125 billion in revenues in 2016; and the U.S. cough, cold, pain and allergy markets targeted by our LiquiTime-based products, is estimated between \$6 billion and \$8 billion annually (source: Nielsen Data Trend).

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

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

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

### **Proprietary Intellectual Property**

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

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

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

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

\* ROW: Rest of the World

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

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

Avadel's key patents include protection for the following:

- Micropump® platform is patented under multiple granted patents. Among them is Avadel's Micropump®-related key patent, WO 2003/030878, which discloses an efficacious coating formulation for providing delayed and sustained release of an active ingredient with absorption limited to the upper part of intestinal tract. It is granted in the U.S. as US Patent 8,101,209 and will expire on October 2025. Equivalent patents are granted in China, Hong Kong, Israel, India, Singapore, Japan, South Korea, Canada, South Africa, Mexico (expiry date: October 2022) and in France (expiry date: October 2021). Patent applications are pending in Brazil and Europe; and, would expire on October 2022.
- **LiquiTime**® **platform** is protected by Avadel's patent granted in the U.S. (US 7,906,145; expiry date: September 2025) and in South Korea, Canada, Israel, Japan, Australia, China, Austria, Belgium, Switzerland, Liechtenstein, Germany, Spain, France, United Kingdom, Italy, Ireland, Luxembourg, Netherlands, Portugal, Sweden, Turkey, India, Mexico, South Africa that expire in April 2023. A patent application is pending in Brazil and 3 continuation application are pending in the U.S.
- **Trigger Lock platform** is protected by 7 (seven) Avadel patent application families. Within these patent families, 12 (twelve) patents are granted in the U.S., Europe and Japan; and, 20 (twenty) patent applications are pending including other countries and will expire between November 2025 and December 2033.
- **Medusa platform** is patented under Avadel's key patent WO 2003/104303 granted in the U.S. and which will expire in July 2023. Equivalent patents to WO 2003/104303 are granted in China, Israel, Mexico, Australia, Japan, South Korea, Canada, Europe, India and South Africa. A patent application is pending in Brazil. These patents will expire in June 2023.
  - Medusa-based nanogels are protected by issued patents from WO 2005/051416' family in the U.S., Australia, China, Israel, Japan, South Korea, Mexico, South Africa, India, Canada and Europe expiring on November 2024. Corresponding patent application is pending in Brazil
  - Medusa-based microgels are protected by granted patents from WO 2007/141344' patents family in the U.S., Australia, Japan, Canada, China, Israel, South Korea, Mexico and South Africa. Patent applications are pending in Europe, India and Brazil. This patents family will expire on June 2027

### **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 Business and Industry

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

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

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

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

Our products may not gain market acceptance.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We may fail to effectively pursue our business strategy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The costs of compliance with privacy and security laws, including protecting electronically stored information from cyber-attacks, and potential liability associated with failure to do so could adversely affect our business, financial condition and results of operations. We are subject to various domestic and international privacy and security regulations, including but not limited to The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA.

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

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

We may not maintain an effective system of internal control over financial reporting, which could harm our business and financial results.

During its evaluation of the effectiveness of internal control over financial reporting as of 31 December, 2015, our management identified material weaknesses related to: lack of sufficient personnel, resulting in, among other things, a failure to implement a proper segregation of duties; ineffective controls over the revenue, income tax, and financial close processes; ineffective controls over information technology and key spreadsheets used in preparing financial statements; and ineffective monitoring of our internal control systems. While we have begun to implement measures that we believe are necessary and appropriate to address these material weaknesses, we cannot assure you that our efforts will prove wholly successful in remediating these material weaknesses. While we have not incurred and do not expect to incur material expenses specifically related to the remediation of these material weaknesses, actual expenses may exceed our current estimates and may be material. In addition, we cannot assure you that we have identified all existing material weaknesses, or that other material weaknesses will not arise in the future. If we are unable to successfully identify and remediate any material weakness that may exist in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements and applicable stock exchange listing requirements regarding timely filing of periodic reports, the market price of our ADSs may decline, and we could be subject to shareholder litigation.

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

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

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

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

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

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

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

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

### Risks Relating to Regulatory and Legal Matters

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### Risks Relating to Ownership of Our Securities

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

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

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

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

If we are unable to earn a profit in future periods, the market price of our stock may fall. The costs for R&D of our products and drug delivery platforms and general and administrative expenses have been the principal causes of our net losses in recent years. Our ability to operate profitably depends upon a number of factors, many of which are beyond our direct control. These factors include:

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

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

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

- the development and acquisition of new products and drug delivery platforms;
  - the progress of our research and product development programs;
- results of our partnership efforts with potential pharmaceutical and biotechnology company partners; and
- the timing of, and amounts received from, future product 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 we may choose to issue shares of preferred stock, in either case through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of such equity financings, may result in dilution to the holders of our ADSs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## Foreign Exchange Risk

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

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

### Liquidity and Risk Management

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

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

#### Accounting records

The directors are responsible for ensuring that the Company and Group keep adequate accounting records and appropriate accounting systems. The measures taken by the directors to ensure compliance with the Company's and Group'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 Company 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 Controller, 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 financial position of the company. The books of account 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 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. 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 Company'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.

Set forth below are the names of the individuals serving as statutory directors during fiscal 2016:

Nominee	Principal Occupation or Experience	Nationality	Committees
Michael S. Anderson	Chief Executive Officer of Avadel Pharmaceuticals plc	American	-
Guillaume Cerutti	Chairman and Chief Executive Officer of Sotheby's France	French	(2)(3)
Francis J.T. Fildes	Former senior executive in the pharmaceutical industry	British	(1)(2)
Christophe Navarre	Chief Executive Officer of Moët Hennessy	Belgian	(1)(3)
Craig R. Stapleton	Former U.S. Ambassador to France, Senior Advisor to Stone Point Capital, Director of Abercrombie & Fitch Co.	American	(1)(2)(3)(4)
Benoit Van Assche	Former senior executive in the chemical, pharmaceutical and healthcare industries	Belgian	(1)(2)(3)
Michael F. Kanan	Senior Vice President and Chief Financial Officer of Avadel Pharmaceuticals plc	American	(5)
Phillandas T. Thompson	General Counsel & Corporate Secretary of Avadel Pharmaceuticals plc	American	(5)
Dhiren D'Silva	Vice President of Irish and European Operations of Avadel Pharmaceuticals plc	American	(5)
Christopher McLaughlin	External lawyer	Irish	(6)
Fintan Clancy	External lawyer	Irish	(6)

- (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 2014
- (5) Member of the Board of Directors of Avadel Pharmaceuticals plc from inception until execution of the Merger on 31 December, 2016.
- (6) Member of the Board of Directors of Avadel Pharmaceuticals plc from inception to February 2016.

#### **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 28 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 company'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 company'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 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. The review of certain of those arrangements and structures was conducted in the financial year to which this report relates. The review of the other arrangements and structures was conducted after the end of such financial year. 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**

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

In March 2017, the Company announced a plan to reduce its workforce at its Lyon, France site by approximately 50%. This reduction is an effort to align the Company's cost structure with its ongoing and future planned projects. Subject to French regulatory requirements and the outcome of negotiations with the works council, the Company expects the reduction to be substantially complete by the end of the third quarter of 2017 and to incur employee severance, benefits and other costs of up to approximately \$4,000, which are likely to be recognized through 31 December, 2017.

In March 2017, the High Court of Ireland consented to the cancellation of \$317,254 of the Company's share premium to be treated as profits available for distribution as defined by section 117 of the Act. The Minute of the High Court confirming this cancellation was filed with the Irish Companies Registration Office on 6 March 2017, at which time the cancellation of the Company's share premium became effective. The reduction does not affect the Company's authorized share capital of 500,000,000 ordinary shares of \$0.01 each, 50,000,000 preferred shares of \$0.01 each and €25,000 deferred ordinary shares of €1.00 each, of which 41,370,804 fully-paid ordinary shares continue to be issued and outstanding. As a result of the reduction, the balance standing to the credit of the Company's share premium account is \$80,786.

#### **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, Chartered Accountants and statutory Audit Firm, who were appointed during the period, continue in office in accordance with Section 383(2) of the Companies Act 2014.

On behalf of the Directors

/s/ Michael S. Anderson Michael S. Anderson Director

May 30, 2017

/s/ Craig R. Stapleton Craig R. Stapleton Director

May 30, 2017

#### 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 Pharmacueticals 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 or of any regulations made thereunder.

The directors have elected to prepare the Avadel Pharmacueticals plc parent company financial statements 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* (Generally Accepted Accounting Practice in Ireland).

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.

#### **GROUP**

## INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF AVADEL PHARMACEUTICALS PLC

We have audited the group financial statements of Avadel Pharmaceuticals plc for the financial year ended 31 December 2016 which comprise the Consolidated Profit and Loss Account, the Consolidated Statement of Other Comprehensive Income, the Consolidated Balance Sheet, the Consolidated Statement of Cash Flows, the Consolidated Reconciliation of Changes in Shareholders Equity and the related notes 1 to 28. 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 any provision of Part 6 of the Companies Act ("relevant financial reporting framework").

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 auditors' 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.

#### Respective responsibilities of directors and auditors

As explained more fully in the Directors' Responsibilities Statement, the directors are responsible for the preparation of the group financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014. Our responsibility is to audit and express an opinion on the financial statements in accordance with the Companies Act 2014 and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

## Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the group's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the directors; and the overall presentation of the financial statements. In addition, we read all the financial and non-financial information in the Annual Report and Financial Statements to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

## Opinion

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 2016 and of the loss of the group for the financial 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.

#### Matters on which we are required to report by the Companies Act 2014

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the information given in the directors' report is consistent with the group financial statements.

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

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.

## Other Matter

We have reported separately on the company financial statements of Avadel Pharmaceuticals plc for the financial period ended 31 December 2016.

## /s/ Emer O'Shaughnessy

Emer O'Shaughnessy For and on behalf of Deloitte Chartered Accountants and Statutory Audit Firm Dublin

Date: 31 May 2017

# AVADEL PHARMACEUTICALS PLC CONSOLIDATED PROFIT AND LOSS ACCOUNT

(In thousands, except per share data)

		Fiscal Yea	ar
	Note	 2016	2015
Turnover	21	\$ 150,246 \$	173,009
Cost of sales		 13,248	11,410
Gross profit		 136,998	161,599
Research and development costs		(34,611)	(25,608)
Distribution and administrative expenses		(44,179)	(21,712)
Intangible asset amortization	11	(13,888)	(12,564)
Changes in fair value of related party contingent consideration	16	 (49,285)	(30,957)
Operating (loss) profit		 (4,965)	70,758
Investment and other income		1,635	1,236
Interest expense		(963)	
Other expense - changes in fair value of related party payable	16	(6,548)	(4,883)
Foreign exchange gain		 1,123	10,594
(Loss) profit on ordinary activities before taxation		 (9,718)	77,705
Taxation charge	5	31,558	35,907
(Loss) profit after taxation		\$ (41,276) \$	41,798
· · · · · ·		,	
Earnings (loss) per share - basic:		\$ (1.00) \$	1.03
Earnings (loss) per share - diluted:		\$ (1.00) \$	0.96

 $See\ accompanying\ notes\ to\ consolidated\ financial\ statements.$ 

# AVADEL PHARMACEUTICALS PLC CONSOLIDATED STATEMENT OF OTHER COMPREHENSIVE INCOME

(In thousands)

	Years ended Fiscal Year		
		2016	2015
(Loss) profit after taxation	\$	(41,276) \$	41,798
Other comprehensive profit (loss), net of taxation:			
Foreign currency translation loss		(1,024)	(15,087)
Net other comprehensive profit (loss) on marketable securities, net of \$16, and (\$20), tax, respectively		116	(147)
Total other comprehensive loss, net of taxation		(908)	(15,234)
Total comprehensive (loss) profit	\$	(42,184) \$	26,564

See accompanying notes to consolidated financial statements.

# AVADEL PHARMACEUTICALS PLC CONSOLIDATED BALANCE SHEET

(In thousands, except per share data)

			31 December,		
	Note		2016	2015	
Fixed Assets					
Intangible assets	11	\$	41,328 \$	34,316	
Tangible assets	10	•	3,320	2,616	
<u> </u>			44,648	36,932	
Current Assets					
Stocks	7		3,258	3,666	
Debtors	8		43,381	29,681	
Investments	9		114,980	79,738	
Cash at bank and in hand			39,215	65,064	
			200,834	178,149	
Creditors (amounts falling due within one year)	12		(28,244)	(20,044)	
Net Current Assets			172,590	158,105	
Total Assets Less Current Liabilities			217,238	195,037	
Creditors (amounts due after more than one year)	13		(16,826)	(749)	
Provision for Liabilities	14		(158,343)	(125,154)	
Net Assets		\$	42,069 \$	69,134	
Capital and Reserves					
Called-up share capital presented as equity	18	\$	440 \$	420	
Share premium account	18		398,040	398,040	
Other reserves	18		(13,046)	(28,145)	
Profit and loss account	18		(343,365)	(301,181)	
Shareholders' Funds		\$	42,069 \$	69,134	

Approved by the board of directors on 30 May 2017 and signed on its behalf by:

/s/ Michael S. Anderson

/s/ Craig R. Stapleton

	R. Stapleton		
AVADEL PHARMACEUTICAI CONSOLIDATED STATEMENT OF ( (In thousands)		S	
		Years ended 31 Decei 2016	mber, 2015
Cash flows from operating activities:			
(Loss) profit	\$	(41,276) \$	41,798
Adjustments to reconcile net profit (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization		14,489	13,132
Loss (gain) on disposal of tangible assets		110	_
Loss on sale of marketable securities		826	779
Unrealized foreign currency exchange gain		(349)	(8,969)
Gains on waiver of research and development grants and other		_	(1,498)
Remeasurement of related party acquisition-related contingent consideration		49,285	30,957
Remeasurement of related party financing-related royalty agreements		6,548	4,883
Change in deferred tax and income tax deferred charge		(4,000)	69
Stock-based compensation expense		14,679	7,741
Increase (decrease) in cash from:			
Trade debtors		(10,050)	(8,440)
Stocks		1,831	3,036
Prepaid expenses and other current assets		3,412	(684)
Research and development tax credit receivable		397	2,975
Trade creditors & other current liabilities		(434)	(8,533)
Deferred revenue		(2,923)	3,815
Accrued expenses		6,764	3,376
Accrued income taxes		1,778	(393)
Earn-out payments for related party contingent consideration in excess of acquisition	-date		
fair value		(20,252)	_
Royalty payments for related party payable in excess of original fair value		(2,469)	<del>-</del>
Other long-term assets and liabilities		535	249
Net cash provided by (used in) operating activities		18,901	84,293

Cash flows from investing activities:		
Purchases of tangible assets	(1,201)	(1,629)
Proceeds from disposal of tangible assets		<del></del>
Acquisitions of businesses, including cash acquired and other adjustments	628	_
Proceeds from turnover of marketable securities	71,546	48,308
Purchases of marketable securities	(107,603)	(78,409)
Net cash used in investing activities	(36,630)	(31,730)
Cash flows from financing activities:		
Reimbursement of loans	_	(4,911)
Reimbursement of conditional R&D grants	(277)	(747)
Principal payments on capital lease obligations	<del></del>	<u> </u>
Earn-out payments for related party contingent consideration	(6,892)	(24,526)
Royalty payments for related party payable	(1,225)	(3,371)
Excess tax benefit from stock-based compensation	<del>-</del>	2,814
Cash proceeds from issuance of ordinary shares and warrants	440	6,990
Net cash provided by (used in) financing activities	(7,954)	(23,751)
Effect of exchange rate changes on cash and cash equivalents	(166)	(3,508)
Net increase (decrease) in cash and cash equivalents	(25,849)	25,304
Cash and cash equivalents at January 1	65,064	39,760
Cash and cash equivalents at December 31	\$ 39,215	\$ 65,064
Supplemental disclosures of cash flow information:		
Income tax paid	\$ 27,180	\$ 42,121
Interest paid	788	4,738

See accompanying notes to consolidated financial statements.

# AVADEL PHARMACEUTICALS PLC CONSOLIDATED RECONCILIATION OF CHANGES IN SHAREHOLDERS' EQUITY

(In thousands)

	Called-up Shar	re Capital	Share Premium		Profit and	
	Number	Amount		Other Reserves	Loss Account	Total
Balance, 31 December, 2014	40,216 \$	6,214 \$	_	\$ 346,556	\$ (327,745) \$	25,025
Net income		_		_	41,798	41,798
Other comprehensive loss	_	_	_	_	(15,234)	(15,234)
Subscription of warrants	_	_	_	601	_	601
Exercise of stock options or						
warrants	899	123	_	6,266	_	6,389
Vesting of free shares	151	20	_	(20)	_	_
Stock-based compensation expense	_	_	_	7,741	_	7,741
Excess tax benefit from stock-based						
compensation	_	_	_	2,814	_	2,814
Cross-border merger nominal value						
adjustment	_	(5,937)	_	5,937	<del>_</del>	
Share premium arising on cross						
border and domestic mergers in						
2016	<u> </u>		398,040	(398,040)	<u> </u>	_
Balance, 31 December, 2015	41,266 \$	420 \$	398,040	\$ (28,145)	\$ (301,181) \$	69,134
Net loss	_	_	_	_	(41,276)	(41,276)
Other comprehensive loss	_	_	_	_	(908)	(908)
Subscription of warrants	_	_		326	_	326
Exercise of stock options	15	2	_	112	_	114
Vesting of free shares	115	18		(18)	_	
Stock-based compensation expense	_	_	<del>-</del>	14,679	<del>_</del>	14,679
Balance, 31 December, 2016	41,396 \$	440 \$	398,040	\$ (13,046)	\$ (343,365) \$	42,069

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

- the development of differentiated, patent protected products through application of the Group's proprietary patented drug delivery platforms, Micropump® and LiquiTime®, that target high-value solid and liquid oral and alternative dosages forms through the U.S. Food and Drug Administration (FDA) 505(b)(2) approval process, which allows a sponsor to submit an application that doesn't depend on efficacy, safety, and toxicity data created by the sponsor. In addition to Micropump® and LiquiTime®, the Group has two other proprietary drug delivery platforms, Medusa<sup>TM</sup> (hydrogel depot technology for use with large molecules and peptides) and Trigger Lock<sup>TM</sup> (controlled release of opioid analgesics with potential abuse deterrent properties).
- the identification of Unapproved Marketed Drugs ("UMDs"), which are currently sold in the U.S., but unapproved by the FDA, and the pursuit of approval for these products via a 505(b)(2) New Drug Application (NDA). To date, the Group has received approvals through this "unapproved-to-approved" avenue for three products: Bloxiverz® (neostigmine methylsulfate injection), Vazculep® (phenylephrine hydrochloride injection) and Akovaz® (ephedrine sulfate injection). As a potential source of near-term revenue growth, Avadel is working on the development of a fourth product for potential NDA submission by year-end 2017, and seeks to identify additional product candidates for development with this strategy.
- the acquisition of commercial and or late-stage products or businesses. The Group markets three branded pediatric-focused pharmaceutical products in the primary care space, and a 510(k) approved device that will launch in the second quarter of 2017, all of which were purchased through the acquisition of FSC Laboratories and FSC Pediatrics on 5 February, 2016. We will consider further acquisitions, and the Group continues to look for assets that could fit strategically into its current or potential future commercial sales force.

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

The Company is an Irish public limited company, or plc, and is the successor to Flamel Technologies S.A., a French *société anonyme* ("Flamel"), as the result of the merger of Flamel with and into the Company which was completed at 11:59:59 p.m., Central Europe Time, on 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. As a result of the Merger Agreement:

- Flamel ceased to exist as a separate entity and the Company continued as the surviving entity and assumed all of the assets and liabilities of Flamel.
- a credit of \$398,040 was made to share based premium from other reserves for the value acquired through the Merger and domestic merger between the company and flamel Irish holdings limited in the prior financial period, fiscal 2015, reflecting the Share premium as determined under Irish company law at 31 December, 2016.
- our authorized share capital is \$5,500 divided into 500,000 ordinary shares with a nominal value of \$0.01 each and 50,000 preferred shares with a nominal value of \$0.01 each
  - all outstanding ordinary shares of Flamel, €0.122 nominal value per share, were canceled and exchanged on a one-for-one basis
    for newly issued ordinary shares of the Company, \$0.01 nominal value per share. This change in nominal value of our
    outstanding shares resulted in our reclassifying \$5,937 on our balance sheet from ordinary shares to other reserves in the prior
    financial period, fiscal 2015;

- 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-forone basis for ADSs representing ordinary shares of the Company.

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

References in these consolidated financial statements and the notes thereto to "Avadel," the "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 January 3, 2017 under the trading symbol "AVDL."

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 Company 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 the Company's share premium which can be treated as distributable reserves.

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

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 or of any regulations made thereunder.

The directors have elected to prepare the Avadel Pharmaceuticals plc parent company financial statements 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* (Generally Accepted Accounting Practice in Ireland) and the Companies Act 2014.

#### **NOTE 2: Summary of Significant Accounting Policies**

#### **Turnover Recognition**

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

#### **Product Sales and Services**

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

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

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

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

#### License and Research Revenue

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

#### **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 its obligation to repay the funds and as such the funds are recognized in the consolidated profit and loss accounts 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**

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

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

#### **Stock-based Compensation**

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

#### **Income Taxes**

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

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

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

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

#### 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.

#### **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*.

#### Stocks

Stocks consist of raw materials and finished products, which are stated at lower of cost or market 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.

#### **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

#### Goodwill

Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. Irish company law requires indefinite-lived intangible assets and goodwill to be amortized; however, the directors do not believe that this gives a true and fair view because not all goodwill and intangible assets decline in value. In addition, goodwill that does decline in value rarely declines on a straight-line basis, as such straightline amortization of goodwill over an arbitrary period does not reflect the economic reality. Therefore, to present a true and fair view of the economic reality, under U.S. GAAP, goodwill and certain other intangible assets are considered indefinite-lived and are not amortized. The Group has determined that it operates in a single segment and has a single reporting unit associated with the development and commercialization of pharmaceutical products. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then, in the second step, the loss is measured as the excess of recorded goodwill over the implied fair value of the goodwill. Implied fair value of goodwill is the excess of the fair value of the reporting unit as a whole over the fair value of all separately identified assets and liabilities within the reporting unit. The Group tests goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. The Group uses projections of future discounted cash flows and takes into account assumptions regarding the evolution of the market and the Group's ability to successfully develop and commercialize its products. Changes in market conditions could have a major impact on the valuation of these assets and could result in potential associated impairment. During the fourth quarter of 2016, we performed our required annual impairment test

#### Fixed Assets

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

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. 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 has determined that no indications of impairment existed at 31 December, 2016 or 2015.

#### Acquisition-related Contingent Consideration

The acquisition-related contingent consideration payables arising from the acquisition of Éclat Pharmaceuticals (i.e., our Avadel Legacy Pharmaceutical products business) and FSC are accounted for at fair-value (see *Note 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 accounts, balance sheet and statements of cash flows. Changes in fair value of these liabilities are recorded in the consolidated profit and loss accounts 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 accounts, balance sheet and statements of cash flows. Changes in the fair value of this liability are recorded in the consolidated profit and loss accounts as other expense - changes in fair value of related party payable.

#### **Foreign Currency Translation**

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

#### **Use of Estimates**

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

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

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2017-04, "Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment." This update eliminates step 2 from the goodwill impairment test, and requires the goodwill impairment test to be performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. This guidance is effective for the Group in the first quarter of fiscal 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 January, 2017, the FASB issued ASU 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business." This update provides a screen to determine whether or not a set of assets is a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set of assets is not a business. If the screen is not met, the amendments in this update (1) require that to be considered a business, a set of assets must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. This guidance is effective for the Group in the first quarter of fiscal 2018. Early adoption is permitted for transactions not previously reported in the Group's consolidated financial statements. The Group will assess the timing of adoption and impact of this guidance on further transactions.

In October 2016, the FASB issued ASU 2016-16, "*Income Taxes (Topic 740), Intra-Entity Transfers of Assets Other Than Inventory*," which requires companies to recognize the income tax consequences of an intra-entity transfer of an asset other than stock when the transfer occurs. ASU 2016-16 is effective for annual reporting periods, and interim periods therein, beginning after 15 December, 2017. The Group is currently in the process of evaluating the impact of ASU 2016-16 on its consolidated financial statements. In 2017, the Group plans to adopt the provisions of ASU 2016-16, related to Intra-Entity Transfers of Assets Other Than Inventory. Adoption of ASU 2016-16 will eliminate the \$11,156 income tax deferred charge recorded within the consolidated balance sheet as of 31 December, 2016.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments." ASU 2016-15 identifies how certain cash receipts and cash payments are presented and classified in the Statement of Cash Flows under Topic 230. ASU 2016-15 is effective for the 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 does not believe this standard will materially impact its consolidated financial statements.

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

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

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

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

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

## **NOTE 4: Acquisitions**

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

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

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

These items are reported in separate notes within the Group's consolidated balance sheet, and are further disclosed in Note 16: Long-Term Related Party Payable.

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

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

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

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

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

Pro Forma Net Turnover and Income (Losses):		2016	
Net turnover	¢	150,721 \$	170 104
	\$		178,104
(Loss) profit		(42,290)	30,965
_52_			

## **NOTE 5: Taxation**

Taxation (credit) charge

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

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

(Loss) Profit on Ordinary Activities Before Taxation	 2016	2015	
Ireland	\$ (22,866) \$	(29,469)	
United States	32,786	100,552	
France	 (19,638)	6,622	
Total profit (loss) before taxation The taxation (credit) charge for the years ended 31 December, is as follows:	\$ (9,718) \$	77,705	
Taxation (Credit) Charge	 2016	2015	
Current:			
United States - Federal	\$ 30,738 \$	33,289	
United States - State	1,081	970	
France	5,267	1,657	
Total current	37,086	35,916	
Deferred:			
United States - Federal	(6,443)	504	
United States - State	(23)	1,234	
France	938	(1,747)	
Total deferred	(5,528)	(9)	

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

31,558 \$

35,907

Reconciliation to Effective Income Tax Rate:	 2016		2015
Statutory tax rate (1)	12.5 %		33.3 %
Non-deductible changes in fair value of contingent consideration	(165.0)%	)	11.9 %
Change in valuation allowance	11.8 %	)	(9.6)%
Income tax deferred charge	(9.7)%	)	1.3 %
International tax rates differential	(31.9)%	•	11.0 %
Nondeductible stock based compensation	(14.8)%	)	1.3 %
Cross-border merger	(100.6)%	)	— %
Unrecognized tax benefit	(15.2)%	)	0.4 %
State and local taxes (net of federal)	(9.6)%	)	1.5 %
Other	(2.3)%	)	(4.9)%
Effective income tax rate	 (324.8)%		46.2 %
Taxation (credit) charge - at statutory tax rate	\$ (1,215)	\$	25,876
Non-deductible changes in fair value of contingent consideration	16,036		9,249
Change in valuation allowance	(1,143)		(7,425)
Income tax deferred charge	938		980
International tax rates differential	3,097		8,547
Nondeductible stock based compensation	1,436		1,004
Cross-border merger	9,773		_
Unrecognized tax benefit	1,475		290
State and local taxes (net of federal)	934		1,170
Other	 227		(3,784)
Taxation (credit) charge - at effective income tax rate	\$ 31,558	\$	35,907

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

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

#### **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, US Federal, and state and local examinations for years before 2012. The Internal Revenue Service (IRS) commenced an examination of the Group's US income tax return for 2015 in the 4th quarter of 2016 that is anticipated to be completed by the end of 2017.

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

Unrecognized Tax Benefit Activity	2	016	2015
Balance at January 1:	\$	291 \$	_
Additions based on tax positions related to the current year		1,614	291
Additions (reductions) for tax positions of prior years		(340)	_
Balance at December 31:	\$	1,565 \$	291

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

At 31 December, 2016, and 2015, there are \$1,565, and \$291, 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, 2016, and 2015, the Group recognized approximately \$26, and \$0 in interest and penalties. The Group had approximately \$27, and \$0 for the payment of interest and penalties accrued at 31 December, 2016, and 2015 respectively.

## **Deferred Tax Assets (Liabilities)**

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

2016		2015
\$	11,566 \$	44,587
	5,012	1,767
	3,386	2,435
	2,152	1,348
	583	1,037
	22,699	51,174
	(7,599)	(45,516)
	15,100	5,658
	(4,349)	(5,649)
	(3,319)	_
	(7,668)	(5,649)
\$	7,432 \$	9
<u> </u>		
	\$	\$ 11,566 \$ 5,012 3,386 2,152 583 22,699 (7,599) 15,100 (4,349) (3,319) (7,668) \$ 7,432 \$

At 31 December, 2016, the Group had \$45,907 of net operating losses in Ireland that do not have an expiration date, and thus paid no taxes on its Irish operations during the year. Additionally, at 31 December, 2016, the Group had \$14,920 of net operating losses in the United States that expire 2033 through 2035. The US net operating losses were acquired as part of the acquisition of FSC. A valuation allowance is recorded if, based on the weight of available evidence, it is more likely than not that a deferred tax asset will not be realized. This assessment is based on an evaluation of the level of historical taxable income and projections for future taxable income. For the year ended 31 December, 2016, the Group recorded \$5,738 of valuation allowances related to Irish net operating losses and \$1,272 of valuation allowance on U.S. net operating losses. The U.S. net operating losses are subject to an annual limitation as a result of the acquisition of FSC under internal revenue code section 382 and will not be fully utilized before they expire. In 2016, the Group removed all French net operating losses and the corresponding valuation allowances from the stock of deferred tax assets as a result of the cross-border merger. For the year ended 31 December, 2015, the Group recorded \$40,959 and \$3,628 of valuation allowances related to French and Irish net operating losses, respectively. The Group believes that it will generate sufficient future taxable income to realize the tax benefits related to the remaining net deferred tax assets.

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

At 31 December, 2016, the Group has no unremitted earnings outside of Ireland as measured on a US GAAP basis. Whereas the measure of earnings for purposes of taxation of a distribution may differ for tax purposes, these earnings, which are considered to be invested indefinitely, would become subject to income tax if they were remitted as dividends or if the 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 government provides tax credits to companies for spending on innovative R&D. These credits are recorded as an offset of R&D expenses and are credited against income taxes payable in each of the four years after being incurred or, if not so utilized, are recoverable in cash. As of 31 December, 2016, the Group's net Research tax credit receivable amounts to \$1,775 and represents a gross research tax credit of \$3,376, partially offset by current income tax payable of \$1,601. The Group utilized \$4,001 of research tax credits in 2016 to offset the tax cost of the cross-border merger. As of 31 December, 2015, the Group's net Research tax credit receivable amounts to \$2,382 and represents a gross research tax credit of \$3,720, partially offset by current income tax payable of \$1,338.

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

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

## Cross-Border Merger

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

On March 8, 2017 the European Court of Justice issued a ruling on case C-14/16, related to the treatment of cross-border mergers amongst entities that operate within Member States of the EU. Based on our initial assessment of the ruling, the Group may not have been required to apply for an advanced ruling from the French Tax Authority in order to defer a portion of the tax cost of the cross-border merger. The impact of this ruling could potentially generate an income tax benefit in 2017 of \$3,848 by restoring \$2,582 of French research and development tax credits and releasing \$1,266 of unrecognized tax benefits originally recognized as part of the cross-border merger. The Group is in the process of assessing the administrative and legal options to potentially secure recovery of these benefits.

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

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

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

Basic and Diluted Earnings (Loss) Per Share:	 2016	2015
Earnings (loss) per share numerator:		
Profit (loss) from ordinary operations attributable to common shareholders		
before allocation of earnings to participating securities	\$ (41,276)	\$ 41,798
Less: earnings allocated to participating securities	_	<u> </u>
Profit (loss) attributable to common shareholders, after allocation of earnings to		
participating securities	\$ (41,276)	\$ 41,798
Earnings (loss) per share denominator:		
Weighted-average shares outstanding - basic	\$ 41,248	\$ 40,580
Impact of dilutive securities	_	3,039
Weighted-average shares outstanding - dilute	\$ 41,248	\$ 43,619
Basic earnings (loss) per share attributable to common shareholders:	\$ (1.00)	\$ 1.03
Diluted earnings (loss) per share attributable to common shareholders:	\$ (1.00)	\$ 0.96

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

#### **NOTE 7: Stocks**

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

Stocks:	2016		2015
Finished goods	\$ 2.	29 \$	2,545
Raw materials		29	1,121
Total stocks	\$ 3,2	58 \$	3,666
			_

# **NOTE 8 : Debtors**

At the end of fiscal 2016 and 2015, debtors were comprised of:

	2016	 2015
Debtors (amounts receivable within one year):		
Valued-added tax recoverable	\$ 736	\$ 1,099
Prepaid expenses	3,442	2,921
Advance to suppliers and other current assets	1,265	518
Income tax receivable	451	3,526
Trade debtors	17,839	7,487
Research and development tax credit receivable	_	2,382
Total	\$ 23,733	\$ 17,933
Debtors (amounts receivable after one year):		
Deferred tax assets	\$ 7,432	\$ 9
Research and development tax credit receivable	1,775	_
Income tax deferred charge	10,342	11,581
Other	99	158
Total	\$ 19,648	\$ 11,748
Total	\$ 43,381	\$ 29,681

#### **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 income (loss) in shareholders' equity, net of income tax effects.

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, 2016 and 2015, respectively:

			20	16		
			Unrealized		Unrealized	
Marketable Securities:	Adj	usted Cost	 Gains		Losses	Fair Value
					(a=)	
Equity securities	\$	3,689	\$ 409	\$	(65) \$	4,033
Corporate bonds		57,871	89		(612)	57,348
Government securities - U.S.		43,049	515		(750)	42,814
Government securities - Non-U.S.		247			(14)	233
Other fixed-income securities		10,281	221		(31)	10,471
Other securities		81				81
Total	\$	115,218	\$ 1,234	\$	(1,472) \$	114,980

			20	15		
Marketable Securities:	Adjı	ısted Cost	 Unrealized Gains		Unrealized Losses	Fair Value
Equity securities	\$	3,510	\$ 29	\$	(14) \$	3,525
Time deposits		13,641	_		<u>`</u>	13,641
Corporate bonds		42,129	1,520		(1,510)	42,139
Government securities - U.S.		13,822	4		(88)	13,738
Government securities - Non-U.S.		1,112	8		(57)	1,063
Other fixed-income securities		4,008	_		(16)	3,992
Other securities		1,663	 <u> </u>		(23)	1,640
Total	\$	79,885	\$ 1,561	\$	(1,708) \$	79,738

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

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, 2016:

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

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

# **NOTE 10 : Tangible Assets**

Tangible asset activity for fiscal year 2016 and 2015 was as follows:

	Laboratory Equipment			ffice and Computer Equipment	 Furniture, Fixtures, and Fittings	Total Tangible Assets		
Cost:								
At 31 December, 2014	\$	9,801	\$	3,288	\$ 4,544	\$ 17,633		
Additions		1,101		256	273	1,630		
Disposals		_		(20)	_	(20)		
Transfers		214		(212)	(2)	_		
Currency translation and other		(1,153)		(344)	(500)	(1,997)		
At 31 December, 2015	\$	9,963	\$	2,968	\$ 4,315	\$ 17,246		
Additions		433		595	174	\$ 1,202		
Acquisitions		236		_	24	260		
Disposals		(1,357)		(965)	(119)	(2,441)		
Currency translation and other		(256)		(79)	(155)	(490)		
At 31 December, 2016	\$	9,019	\$	2,519	\$ 4,239	 15,777		
Depreciation:								
At 31 December, 2014	\$	(8,965)	\$	(2,779)	\$ (4,113)	\$ (15,857)		
Depreciation expense		(342)		(98)	(128)	(568)		
Currency translation and other		1,023		325	447	1,795		
At 31 December, 2015	\$	(8,284)	\$	(2,552)	\$ (3,794)	\$ (14,630)		
Depreciation expense		(322)		(172)	(107)	(601)		
Disposal of tangible assets		1,247		965	119	2,331		
Currency translation and other		228		62	153	443		
At 31 December, 2016	\$	(7,131)	\$	(1,697)	\$ (3,629)	\$ (12,457)		
Net Book Value								
At 31 December, 2015	\$	1,679	\$	416	\$ 521	\$ 2,616		
At 31 December, 2016	\$	1,888	\$	822	\$ 610	\$ 3,320		

Gain or loss on disposal of tangible assets was immaterial in both fiscal 2016 and 2015.

# **NOTE 11 : Goodwill and Intangible Assets**

Intangible asset activity for fiscal 2016 and 2015 was as follows:

	 Goodwill	A	cquired IPR&D	quired Product arketing Rights	Acquired Developed Technology	 Total Tangible Assets
Cost:						
At 31 December, 2014	\$ 18,491	\$	47,309	\$ <u> </u>	\$ _	\$ 65,800
Additions	_		_		_	_
Currency translation and other	_				_	_
At 31 December, 2015	\$ 18,491	\$	47,309	\$ <u> </u>	\$ 	\$ 65,800
Additions	 _		_	16,600	4,300	 20,900
Currency translation and other	_		_	_	_	_
At 31 December, 2016	\$ 18,491	\$	47,309	\$ 16,600	\$ 4,300	\$ 86,700
Amortization:						
At 31 December, 2014	\$ _	\$	(18,920)	\$ _	\$ _	\$ (18,920)
Amortization expense	_		(12,564)	_	_	(12,564)
Currency translation and other	_		<u> </u>		_	_
At 31 December, 2015	 <u> </u>	\$	(31,484)	\$ 	\$ <u> </u>	\$ (31,484)
Amortization expense	 _		(12,565)	(1,019)	(304)	(13,888)
Currency translation and other	_		_	<del></del>		_
At 31 December, 2016	\$ 	\$	(44,049)	\$ (1,019)	\$ (304)	\$ (45,372)
Net Book Value						
At 31 December, 2015	\$ 18,491	\$	15,825	\$ 	\$ _	\$ 34,316
At 31 December, 2016	\$ 18,491	\$	3,260	\$ 15,581	\$ 3,996	\$ 41,328

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

Estimated Amortization Expense:		<u></u>	Balance
Fiscal 2017		\$	2,258
Fiscal 2018			2,258
Fiscal 2019			2,258
Fiscal 2020			2,258
Fiscal 2021			1,443
	CO		

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

At the end of fiscal 2016 and 2015, creditors (amounts falling due within one year) were comprised of:

Creditors (amounts falling due within one year):		2016		2015
	ф	200	<b>.</b>	12.1
Debt	\$	268	\$	434
Trade creditors		7,105		5,048
Deferred revenue		2,223		5,121
Accrued compensation		3,291		1,888
Accrued social charges		794		1,710
Customer allowances		7,981		5,710
Income taxes		1,200		
Accrued contract research organization		1,764		_
Other		3,618		133
Total	\$	28,244	\$	20,044

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

At the end of fiscal 2016 and 2015, creditors (amounts falling due after more than a year) were comprised of:

Creditors (amounts falling after more than a year):		2016		
Debt (Note 15)	¢	547	\$	684
Long-term liability - FSC (Note 16)	Ψ	15,000	Ψ	—
Customer allowances		905		_
Other		374		65
Total	\$	16,826	\$	749

## **NOTE 14: Provisions for Liabilities**

	P	Related arty Payable (Note 16)	Un	recognized Tax Benefits (Note 5)	_	Provision for Retirement Indemnity (Note 17)	 Provision for Liabilities
At 31 December, 2014	\$	114,750	\$	_	\$	2,350	\$ 117,100
Additions during the year		<u> </u>		291		137	428
Amounts charged against the provision		(27,897)		_		(46)	(27,943)
Changes in the fair value		35,840		_		(27)	35,813
Exchange adjustment		_		_		(244)	(244)
At 31 December, 2015	\$	122,693	\$	291	\$	2,170	\$ 125,154
Additions during the year		6,659		1,274		152	8,085
Amounts charged against the provision		(30,838)		_		_	(30,838)
Changes in the fair value		55,833		_		203	56,036
Exchange adjustment		_		_		(94)	(94)
At 31 December, 2016	\$	154,347	\$	1,565	\$	2,431	\$ 158,343
		-61-					

## **NOTE 15: Long-Term Debt**

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

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

## **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, 2016 and 2015, respectively:

Activity during the Twelve Months Ended 21 December

	Activity during the Twelve Months Ended 31 December,										
	2016										
							Changes in 1				
							Related Pa	rty	Payable		
		Balance,			P	ayments to					Balance,
	31	December,				Related	Operating		Other	31	December,
		2015		Additions		Parties	Expense		Expense		2016
Acquisition-related:											
Warrants - Éclat Pharmaceuticals <sup>(a)</sup>	\$	20,617	\$		\$		\$ (9,400)	\$		\$	11,217
Earn-out payments - Éclat Pharmaceuticals (b)		90,468		_		(26,700)	57,609		_		121,377
Royalty agreement - FSC (c)				6,659		(444)	1,076				7,291
Financing-related:											
Royalty agreement - Deerfield (d)		7,862				(2,501)	_		4,433		9,794
Royalty agreement - Broadfin <sup>(e)</sup>		3,746		_		(1,193)	_		2,115		4,668
Long-term liability - FSC (f)		_		15,000				_			15,000
Total related party payable	\$	122,693	\$	21,659	\$	(30,838)	\$ 49,285	\$	6,548	\$	169,347

Each of the above items is associated with related parties as further described in *Note 27: Related Party Transactions*.

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

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

Warrant Assumptions:		2016	2015
717 1 1 1	ф	0.63 <b>.</b> #	0.63
Weighted average exercise price per share	\$	8.63 \$	8.63
Expected term (years)		1.25	2.25
Expected volatility		54.20%	64.54%
Risk-free interest rate		0.94%	0.93%
Expected dividend yield		_	_
-62-			

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 for a period approximating the expected term.

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

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

At the closing date of the 2012 Éclat acquisition and at 31 December, 2016, 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 long-term liability. This classification as a long-term 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 stock, 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 Mr. Michael Anderson, the Group's CEO, and certain other 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.
- (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.
- (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.

At 31 December, 2016, the fair value of each related party payable listed in (b) through (e) above was estimated using a discounted cash flow model based on probability-adjusted annual net revenues or gross profit, as appropriate, of each of the specified Éclat and FSC products using an appropriate risk-adjusted discount rate ranging from 15% to 22%. These fair value measurements are based on significant inputs not observable in the market and thus represent a level 3 measurement as defined in ASC 820. Subsequent changes in the fair value of the acquisition-related related party payables, resulting primarily from management's revision of key assumptions, will be recorded in the consolidated profit and loss accounts in the line items entitled "Changes in fair value of related party contingent consideration" for items noted in (b) and (c) above and in "Other expense - changes in fair value of related party payable" for items (d) and (e) above. See Note 2: 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 accounts.

#### **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. Expenses recognized for these plans were \$348 in 2016, and \$573 in 2015.

#### 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 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 accounts 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:

Retirement Benefit Obligation Assumptions:	2016 20	)15			
Compensation rate increase	3.00%	3.00%			
Discount rate	1.31%	2.03%			
Employee turn-over	Actuarial standard and average of the last 5	years			
Average age of retirement	60 to 65 years actuarial standard based on age and pro	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:

Retirement Benefit Obligation Activity:		2016	2015
Detings and in describe here fit ablications he give in a few and	ф	2.170 f	2.250
Retirement indemnity benefit obligation, beginning of year	Ф	2,170 \$	2,350
Service cost		123	117
Interest cost		29	20
Benefits paid		_	(46)
Actuarial loss (gain)		203	(27)
Exchange rate changes		(94)	(244)
Retirement indemnity benefit obligation, end of year	\$	2,431 \$	2,170

The lump sum retirement indemnity is accrued on the 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:

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

#### **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.

		2016
Authorised:	_	
25,000 deferred ordinary shares of €1.00 each	\$	26
500,000,000 ordinary shares of \$.01 each		5,000
50,000,000 preferred shares of \$.01 each		500
Allotted, Called Up and Fully Paid:		
25,000 deferred ordinary shares of €1.00 each	\$	26
41,370,804 ordinary shares of \$.01 each		414
Called up share capital presented as equity	\$	440

In March of 2016, there was a domestic merger between the company and Flamel Irish Holdings Limited, where 100 ordinary shares were issued to Flamel Technologies SA following the merger at a premium of \$80,000. On 11 November 2016, the Company acquired and canceled 100 ordinary shares for Nil consideration.

In November of 2016, Flamel US Holdings Inc. subscribed to 25,000 ordinary deferred shares at par in order for Avadel Pharmaceuticals plc to meet minimum capital requirements set out by Irish law. These minimum capital requirements were necessary for Avadel Pharmaceuticals plc to become a public limited company. These are accounted for as treasury shares within shareholder funds.

In December of 2016, all outstanding American Depository Shares ("ADS") representing ordinary shares of Flamel Technologies SA were canceled and exchanged on a one-for-one basis for ADSs representing 41,370,804 ordinary shares of Avadel Pharmaceuticals plc as part of a cross-border merger resulting in a credit of \$318,040 to share premium account, representing the fair value of shares issued in excess of book value of assets and liabilities transferred.

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.

#### **Share Premium Account**

In fiscal 2016 and 2015, the share premium account activity resulted from the value acquired through the cross-border merger.

#### Other Reserves

The balance as of 31 December, 2016 was primarily comprised of the initial additional paid in capital balance under US GAAP, adjusted for the value acquired through the cross-border merger and domestic merger of \$398,040 and accumulated share-based compensation.

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

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

Stock-based Compensation Expense:	2016			2015
Research and development	\$	3,523	\$	1,587
Distribution and administrative		11,156		6,154
Total stock-based compensation expense	\$	14,679	\$	7,741

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

The excess tax benefit related to stock-based compensation recorded by the Group was \$65 and \$1,767, for the years ended 31 December, 2016 and 2015.

## Determining the Fair Value of Stock Options and Warrants

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

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

Stock Option and Warrant Assumptions:	2016	2015
Stock option grants:		
Expected term (years)	6.25	6.25
Expected volatility	58.39%	58.59%
Risk-free interest rate	2.04%	1.89%
Expected dividend yield	<del>-</del>	
Warrant grants:		
Expected term (years)	2.50	2.50
Expected volatility	60.57%	55.00%
Risk-free interest rate	0.82%	0.89%
Expected dividend yield	_	_

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

*Expected volatility*: The expected volatility is calculated based on an average of the historical volatility of the 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.

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

#### Stock Options

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

Stock Option Activity and Other Data:	Number of Stock Options	Weighted Average Exercise Price per Share	xercise Price per Remaining		Aggregate trinsic Value
Stock options outstanding, 1 January, 2015	2,498	\$ 11.45			
Granted	934	16.71			
Exercised	(708)	8.75			
Forfeited	(398)	14.59			
Stock options outstanding, 31 December, 2015	2,326	13.84	8.26 years	\$	6,426
Granted	1,505	10.68	J		•
Exercised	(15)	6.50			
Forfeited	(6)	14.35			
Expired	(78)	31.70			
Stock options outstanding, 31 December, 2016	3,732	\$ 12.07	8.48 years	\$	3,681
Stock options exercisable, 31 December, 2015	798	\$ 10.80	8.26 years	\$	4,880
Stock options exercisable, 31 December, 2016	1,161	10.49	6.76 years		3,035

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

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

At 31 December, 2016 and 2015, there were 94 and 97 shares authorized for stock option grants in subsequent periods, respectively.

## Warrants

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

Warrant Activity and Other Data:	Number of Warrants	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life	Aggregate I	
Warrants outstanding, 1 January, 2015	553	\$ 10.47			
Granted	305	21.67			
Exercised	(190)	5.57			
Warrants outstanding, 31 December, 2015	668	16.97	2.90 years	\$	687
Granted	291	13.59	·		
Warrants outstanding, 31 December, 2016	959	\$ 16.05	2.47 years	\$	276
Warrants exercisable, 31 December, 2015	363	\$ 13.04	2.41 years	\$	687
Warrants exercisable, 31 December, 2016	668	17.12	1.97 years		276

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

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

At 31 December, 2016, 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*.

At 31 December, 2016 and 2015, there were 59 and 45 shares authorized for warrant grants in subsequent periods, respectively.

#### Free Share Awards

Free 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 free share awards on the grant date using the Group's stock price at the time of the grant. Free share awards granted prior to 2016 generally cliff vest at the end of a four-year vesting period, and are expensed over a two or four-year service period. Free share awards granted during 2016 were fully expensed at the date of grant as they contain no service requirement. Employees, however, are not free to trade these awards until the end of a two-year holding period.

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

Free Share Activity and Other Data:	Number of Free Share Awards	Weighted Average Grant Date Fair Value
Non-vested free share awards outstanding, 1 January, 2015	402 \$	11.29
Vested	(151)	7.36
Forfeited	(25)	10.95
Non-vested free share awards outstanding, 31 December, 2015	226	13.95
Granted	463	12.11
Vested	(115)	13.44
Forfeited	(1)	16.27
Non-vested free shares awards outstanding, 31 December, 2016	573	12.57

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

At 31 December, 2016 and 2015, there were 290 and 250 shares authorized for free share award grants in subsequent periods, respectively.

#### **NOTE 19: Contingent Liabilities and Commitments**

## Litigation

The Group is subject to potential liabilities generally incidental to its business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The 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, 2016 and 2015, there were no contingent liabilities with respect to any threat of litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Group's consolidated balance sheet, profit and loss accounts, cash flows or liquidity.

#### **Material Commitments**

The Group has commitments to purchase services from Recipharm Pessac for a total of \$22,500 for a five-year period commencing 1 January, 2015, included in the purchase commitments in the table below.

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

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

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

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

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

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

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

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

#### **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.

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:

	As of 31 December, 2016			As of 31 December, 2015							
Fair Value Measurements:		Level 1		Level 2	 Level 3	Level	1	Lev	el 2	]	Level 3
Investments (see Note 9)											
Equity securities	\$	4,033	\$		\$ _ 5	3	,525	\$		\$	_
Time deposits		_		_			_		13,641		_
Corporate bonds		_		57,348	<del></del>		_	4	42,139		_
Government securities - U.S.		_		42,814	_		_		13,738		_
Government securities - Non-U.S.		_		233	<del></del>		_		1,063		_
Other fixed-income securities		_		10,471	_		_		3,992		_
Other securities		_		81	_		_		1,640		_
Total assets	\$	4,033	\$	110,947	\$ 	3	,525	\$	76,213	\$	_
Related party payable (see Note 16)		_		_	169,347		—		_		122,693
Total liabilities	\$		\$		\$ 169,347	\$		\$		\$	122,693

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

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

Some of the 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 drug delivery technologies. The Group's Chief Operating Decision Maker is the CEO. The CEO and the Group's Board of Directors review profit and loss information on a consolidated basis to assess performance and make overall operating decisions as well as resource allocations.

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

Turnover by Product:	2016			2015		
Bloxiverz	\$	82,896	\$	150,083		
Vazculep		39,796		20,151		
Akovaz		16,831		_		
Other		7,699		2,054		
Total product sales and services		147,222		172,288		
License and research revenue		3,024		721		
Total revenues	\$	150,246	\$	173,009		

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

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

Revenue by Significant Customer:	2016	2015		
Customer A	\$ 51,648	\$	53,988	
Customer B	39,359		60,420	
Customer C	30,916		43,434	
Customer D	17,728		_	
Other	 7,571		14,446	
Total product sales and services	147,222		172,288	
License and research revenue	 3,024		721	
Total revenues	\$ 150,246	\$	173,009	

As of 31 December, 2016, the Group had three customers each of which accounted for 10% or more of the trade debtors balance. One customer accounted for 42%, or \$7,472, a second customer accounted for 24% or \$4,307, and a third customer accounted for 24% or \$4,291. As of 31 December, 2016, 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, 2016 and 2015:

Revenue by Geographic Region:	 2016	2015		
United States	\$ 147,283 \$	172,179		
France	<del>_</del>	89		
Ireland	2,963	741		
Total	\$ 150,246 \$	173,009		

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

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

Long-lived Assets by Geographic Region:	2016	2015
United States	\$ 42,021 \$	34,515
France	2,524	2,317
Ireland	202	258
Total	\$ 44,747 \$	37,090

## **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. The Company did not trade during the financial periods presented and received no income and incurred no expenditure during such time. Consequently, during the fiscal period ended 2016 and 2015, the company made neither a profit nor a loss as determined in accordance with Irish GAAP FRS 102.

#### **NOTE 23: Directors' Remuneration**

Directors' Remuneration	 2016	2015
Aggregate emoluments in respect to qualifying services	\$ 2,528	\$ 1,673
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	5,496	5,837
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	_	_
Total	\$ 8,024	\$ 7,510

#### **NOTE 24: Auditors' Remuneration**

Auditors' remuneration was as follows (in thousands):

	2016		2015
Audit of individuals and group financial statements	\$	171 \$	_
Other assurance services		120	_
Taxation advisory services		_	—
Other non-audit services		<del></del>	_
Total	\$	291 \$	

No amounts were incurred for other non-audit services. The Group incurred additional fees of \$1,689 and \$1,041 during fiscal 2016 and 2015, respectively, payable to affiliates of Deloitte & Touche, Ireland, and our predecessor auditor Pricewaterhouse Coopers. These additional amounts reflect fees for all professional services rendered, including audit fees payable to Deloitte & Touche LLP and Pricewaterhouse Coopers 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:

Average Number of Employees	2016	2015
Research and development	88	84
General, administrative and sales	102	34
Total	190	118

Employee costs consisted of the following:

Employee Costs	 2016	2015
Wages and salaries	\$ 18,164 \$	10,414
Social security costs and other tax	5,079	3,221
Pension and postretirement costs		
-Defined contribution	348	573
Stock based compensation	14,679	7,741
Total	\$ 38,270 \$	21,949

#### **NOTE 26 : Post Balance Sheet Events**

In preparing these consolidated financial statements, subsequent events were evaluated through the time the financial statements were issued. Financial statements are considered issued when they are approved in accordance with Irish law.

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

In March 2017, the Company announced a plan to reduce its workforce at its Lyon, France site by approximately 50%. This reduction is an effort to align the Company's cost structure with its ongoing and future planned projects. Subject to French regulatory requirements and the outcome of negotiations with the works council, the Company expects the reduction to be substantially complete by the end of the third quarter of 2017 and to incur employee severance, benefits and other costs of up to approximately \$4,000, which are likely to be recognized through 31 December, 2017.

In March 2017, the High Court of Ireland consented to the cancellation of \$317,254 of the Company's share premium to be treated as profits available for distribution as defined by section 117 of the Act. The Minute of the High Court confirming this cancellation was filed with the Irish Companies Registration Office on 6 March 2017, at which time the cancellation of the Company's share premium became effective. The reduction does not affect the Company's authorized share capital of 500,000,000 ordinary shares of \$0.01 each, 50,000,000 preferred shares of \$0.01 each and €25,000 deferred ordinary shares of €1.00 each, of which 41,370,804 fully-paid ordinary shares continue to be issued and outstanding. As a result of the reduction, the balance standing to the credit of the Company's share premium account is \$80,786.

#### **NOTE 27: 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. As of 31 December, 2016 and 2015, the remaining consideration obligations for this transaction consisted of two warrants to purchase a total of 3,300 shares of Avadel and commitments to make earnout payments to Breaking Stick of 20% of any gross profit generated by certain Éclat products (the "Products"). Breaking Stick is majority owned by Deerfield, with a minority interest owned by Mr. Michael Anderson, the Group's CEO, and certain other current and former employees. The original consideration for the acquisition of Éclat also included a \$12 million senior note payable to the majority owners of Breaking Stick, which was fully repaid in March 2014 using the net proceeds from the Group's public offering of ADS's.

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

As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund ("Broadfin"), the Group entered into a Royalty Agreement with Broadfin, a significant shareholder of the Group, dated as of 3 December, 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 its affiliates until December 31, 2024. This original Broadfin debt financing transaction also included a \$5 million facility agreement which was repaid in full in March 2014 using the net proceeds from the Group's public offering of ADS's.

On 8 February, 2016, the Group entered into an agreement to acquire FSC Holdings, LLC ("FSC"), a Charlotte, NC-based specialty pharmaceutical company dedicated to providing innovative solutions to unmet medical needs for pediatric patients, from Deerfield CSF, LLC, a Deerfield Management company ("Deerfield"), a related party. Under the terms of the acquisition, which was completed on 8 February, 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. 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.

# NOTE 28 : Subsidiary Undertakings

As of 31 December, 2016, the Group had the following fully owned subsidiary undertakings:

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

# AVADEL PHARMACEUTICALS PLC

Company Financial Statements
For the Period From 1 December 2015 (date of Incorporation)
to 31 December 2016

#### **COMPANY**

#### INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF AVADEL PHARMACEUTICALS PLC

We have audited the company financial statements of Avadel Pharmaceuticals plc for the financial period from 1 December 2015 (date of incorporation) to 31 December 2016 which comprise the company Balance Sheet, company Statement of Cash Flows, the Statement of changes in Equity and the related notes 1 to 18. The relevant financial reporting framework that has been applied in the preparation of the company financial statements is the Companies Act 2014 and FRS 102 The Financial Reporting Standard applicable in the UK and Republic of Ireland ("relevant financial reporting framework").

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 auditors' 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.

#### Respective responsibilities of directors and auditors

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. Our responsibility is to audit and express an opinion on the financial statements in accordance with the Companies Act 2014 and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

## Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the company's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the directors; and the overall presentation of the financial statements. In addition, we read all the financial and non-financial information in the company Financial Statements to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

#### **Opinion on financial statements**

In our opinion the company financial statements:

- give a true and fair view of the assets, liabilities and financial position of the company as at 31 December 2016; and
- have been properly prepared in accordance with the relevant financial reporting framework and, in particular, with the requirements of the Companies Act 2014.

#### Matters on which we are required to report by the Companies Act 2014

- 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's 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.

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

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.

## Other Matter

We have reported separately on the group financial statements of Avadel Pharmaceuticals plc for the financial year ended 31 December 2016.

/s/ Emer O'Shaughnessy

Emer O'Shaughnessy

For and on behalf of Deloitte

Chartered Accountants and Statutory Audit Firm

Dublin

Date: 31 May 2017

# COMPANY BALANCE SHEET AT 31 DECEMBER 2016

(Amounts in \$ thousands)

		Fiscal Year	
	Note		2016
FIXED ASSETS			
Tangible assets	6	\$	2,425
Financial assets	7		225,333
			227,758
CURRENT ASSETS			
Debtors			
Due within one year	9		21,148
-Due after one year	9		33,121
-Investments	8		104,946
Cash at bank and in hand			11,856
			171,071
CURRENT LIABILITIES			
Creditors (amounts falling due within one year)	10		(5,302)
NET CURRENT ASSETS			165,769
Total assets less current liabilities			393,527
Creditors (amounts falling due after more than one year)	10		(2,078)
Provision for liabilities and charges			
Defined benefit pension scheme liability	14		(2,431)
NET ASSETS		\$	389,018
CAPITAL AND RESERVES			
Called up share capital presented as equity	11	\$	440
Share premium	11	<del>-</del>	398,040
Other reserves	12		(9,462)
SHAREHOLDERS' FUNDS		\$	389,018

The financial statements were approved by the board on 30 May, 2017 and signed on its behalf by:

/s/ Michael S. Anderson Director /s/ Craig R. Stapleton Director

## COMPANY STATEMENT OF CASH FLOWS FOR THE FINANCIAL PERIOD FROM 1 DECEMBER 2015 (DATE OF INCORPORATION) **TO 31 DECEMBER 2016**

## (Amounts in \$ thousands)

-	Note	 2016 \$'000
NET CASH FLOWS FROM OPERATING ACTIVITIES		\$ _
CASH FLOWS FROM INVESTING ACTIVITIES		
Cash received as part of cross border merger		11,831
NET CASH FLOWS FROM INVESTING ACTIVITIES		11,831
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds on issue of shares		25
NET CASH FLOWS FROM FINANCING ACTIVITIES		25
NET INCREASE IN CASH AND CASH EQUIVALENTS		11,856
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD		_
Effect of foreign exchange rate changes		 
CASH AND CASH EQUIVALENTS AT END OF PERIOD		\$ 11,856
RECONCILIATION TO CASH AT BANK AND IN HAND:		
Cash at bank and in hand at end of period		\$ 11,856
Cash equivalents		_
Cash and cash equivalents at end of period		\$ 11,856
-79-		

## STATEMENT OF CHANGES IN EQUITY

# FOR THE FINANCIAL PERIOD FROM 1 DECEMBER 2015 (DATE OF INCORPORATION) TO 31 DECEMBER 2016 (Amounts in \$ Thousands)

	Sl	hare Capital	Share Premium	Other Reserves	<b>Total Equity</b>
At 1 December 2015	\$	_	\$ —	\$ —	\$ —
Result for the period		_	_	_	_
Allotment of 100 ordinary shares		<del></del>	80,000	_	80,000
Allotment of 25,000 ordinary deferred shares		26	_	_	26
Share issued as part of cross-border merger		414	318,040	(9,462)	308,992
At 31 December 2016	\$	440	\$ 398,040	\$ (9,462)	\$ 389,018

## **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.

## Other reserves

These reserves comprise the merger reserves arising on cross border merger

#### **AVADEL PHARMACEUTICALS PLC**

# NOTES TO THE FINANCIAL STATEMENTS FOR THE FINANCIAL PERIOD FROM 1 DECEMBER 2015 (DATE OF INCORPORATION) TO 31 DECEMBER 2016

#### **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 reregistered 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 <a href="https://www.Avadel.com">www.Avadel.com</a>.

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* (Generally Accepted Accounting Practice in Ireland) and 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* (Generally Accepted Accounting Practice in Ireland) and the Companies Act 2014.

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

In accordance with section 304 of the Companies Act 2014, the company is availing of the exemption from presenting the individual profit and loss account. The company had no trading activity in the period ended 31 December 2016 and therefore had neither a profit or loss to report.

## **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.

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.

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 period financial statements.

#### Tangible assets

Tangible fixed assets are stated at cost or valuation, net of depreciation and any provision for impairment. Depreciation is provided on all tangible fixed assets, other than investment properties and freehold land, at rates calculated to write off the cost or valuation, less estimated residual value, of each asset on a straight-line basis over its expected useful life, as follows:

Asset: Useful life

## Property and equipment

3-10 years

Residual value represents the estimated amount which would currently be obtained from disposal of an asset, after deducting estimated costs of disposal, if the asset were already of the age and in the condition expected at the end of its useful life.

#### **Investments in Subsidiary**

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 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.

#### Fair value measurement

The best evidence of fair value is a quoted price for an identical asset in an active market. When quoted prices are unavailable, the price of a recent transaction for an identical asset provides evidence of fair value as long as there has not been a significant change in economic circumstances or a significant lapse of time since the transaction took place. If the market is not active and recent transactions of an identical asset on their own are not a good estimate of fair value, an entity estimates the fair value by using a valuation technique.

#### **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 statement of financial position 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 statement of financial position 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 statement of financial position 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.

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 signi cant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

#### **Retirement benefits**

For defined benefit schemes the amounts charged to operating profit are the costs arising from employee services rendered during the period and the cost of plan introductions, benefit changes, settlements and curtailments. They are included as part of staff costs. The net interest cost on the net defined benefit liability is charged to profit or loss and included within finance costs. Remeasurement comprising actuarial gains and losses and the return on scheme assets (excluding amounts included in net interest on the net defined benefit liability) are recognised immediately in other comprehensive income.

Defined benefit schemes are funded, with the assets of the scheme held separately from those of the Company, in separate trustee administered funds. Pension scheme assets are measured at fair value and liabilities are measured on an actuarial basis using the projected unit credit method. The actuarial valuations are obtained at least annually and are updated at the statement of financial position date.

For defined contribution schemes the amount charged to the profit and loss account in respect of pension costs and other post-retirement benefits is the contributions payable in the year. Differences between contributions payable in the year and contributions actually paid are shown as either accruals or prepayments in the statement of financial position.

Other long-term employee benefits are measured at the present value of the benefit obligation at the reporting date.

#### 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 statement of financial position 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 statement of financial position comprise cash at banks and in hand and short term deposits readily convertible 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.

#### 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.

#### Tangible assets

The Company establishes a reliable estimate of the useful life oftangible assets. This estimate is based on a variety of factors such as the expected use of the assets, any legal, regulatory or contractual provisions that can limit useful life and assumptions.

## Impairment of Intangible assets

Where there are indicators of impairment of individual assets, the Company performs impairment tests based on fair value less costs to sell or a value in use calculation. The fair value less costs to sell calculation is based on available data from binding sales transactions in an arm's length transaction on similar assets or observable market prices less incremental costs for disposing of the asset. The value in use calculation is based on a discounted cash flow model. The cash flows are derived from the budget for the next five years and do not include restructuring activities that the Company is not yet committed to or significant future investments that will enhance the asset's performance of the cash generating unit being tested. The recoverable amount is most sensitive to the expected probability of launches of developed products and discount rate used for the discounted cash flow model as well as the expected future cash flows and the growth rate used for extrapolation purposes.

## **NOTE 3: TURNOVER**

Other non-audit services

The Company did not have any turnover for the period ended 31 December, 2016.

## NOTE 4: PROFIT ON ORDINARY ACTIVITIES BEFORE TAXATION

The Company did not have any profit or loss on ordinary activities before taxation for the period ended 31 December, 2016.

The analysis of the auditors' remuneration is as follows:

Auditors' remuneration for work carried out for the company in respect of the financial period is as follows	
(Amounts are in \$ thousands):	 Period Ended 2016
Audit of Company accounts	\$ 17
Other assurance services - initial accounts	231
Tax advisory 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 5: DIRECTORS REMUNERATION AND KEY MANAGEMENT COMPENSATION

Directors remuneration is displayed on Note 23 to the Group financial statements. Key management did not receive any compensation from the Company during the financial period.

The Company had no employees during the financial period.

## **NOTE 6: TANGIBLE ASSETS (Amounts in \$ thousands)**

	<b>Property</b>	& Equipment	Total
Cost:			
At 1 December 2015	\$	— \$	_
Additions		2,425	2,425
At 31 December 2016	\$	2,425 \$	2,425
Depreciation			
At 1 December 2015	\$	— \$	_
Charge for the year			
At 31 December 2016	\$	<u> </u>	_
Net Book Value:			
At 31 December 2016	\$	2,425 \$	2,425

The Company recorded \$2,425 of tangible assets related to the completion of the cross-border merger on 31 December, 2016.

## **NOTE 7: FINANCIAL ASSETS (Amounts in \$ thousands)**

#### **Principal Company Investments**

The parent Company has investments in the following subsidiary undertakings.

Cost and Net Book Value:	<u></u>	
At 1 December 2015	\$	_
Additions		225,333
At 31 December 2016	\$	225,333

**Subsidiary Undertakings** 

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

Refer to Note 28 of the consolidated Group financial statements for the full list of subsidiary undertakings for the Group.

On 14 March 2016, there was a domestic merger between the company and Flamel Irish Holdings Limited, under which all the assets and liabilities of Flamel Irish Holdings Limited, comprising \$80,000 investment in Avadel Ireland Limited (formerly Flamel Ireland Limited) transferred by operation of law to the company and Flamel Irish Holdings Limited was subsequently dissolved. The fair value of the consideration was \$80,000.

On 30 December 2016, the company acquired a direct interest in Flamel US Holdings Inc. for \$145,333.

On 31 December 2016, there was a cross border merger between the company and Flamel Technologies SA (France), under which all the remaining assets and liabilities of Flamel Technologies SA transferred by operation of law to the company and Flamel Technologies SA was dissolved.

### **NOTE 8: OTHER INVESTMENTS (Amounts in \$ thousands)**

Fair Value and Net Book Value		2016
The live of the state of the st	¢.	
Listed investments - at fair value	\$	_
Unlisted investments - at cost less impairment		104,946
	\$	104,946

The fair values of unlisted investments are determined with reference to 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.

	 2016	
Amounts Falling Due Within One Year:		
Trade debtors	\$ 201	
Amounts owed by group undertakings	17,272	
Other debtors	1,775	
Prepayments and accrued income	1,900	
	\$ 21,148	
Amounts Falling Due After One Year:		
Amounts owed by group undertakings	\$ 33,121	
	\$ 33,121	

In April of 2016, Flamel Technologies SA entered into a loan agreement with Avadel Ireland, Ltd, where Flamel agreed to provide a €60,000 loan to Avadel Ireland Ltd. Interest on the loan is receivable by Flamel Technologies SA and is accrued at a rate of EURIBOR plus 300 basis points. The term of the loan is three years. All rights to this loan were transferred to Avadel Pharmaceuticals plc as part of the cross-border merger in December 2016.

## **NOTE 10: CREDITORS (Amounts in \$ thousands)**

	 2016	
Amounts Falling Due Within One Year:		
Trade creditors	\$ 807	
Amounts owed to group undertakings	1,390	
Accruals and other creditors	2,837	
Other creditors	268	
	\$ 5,302	
Amounts Falling Due After One Year:		
Other creditors	\$ 1,531	
Other loans	547	
	\$ 2,078	

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.

	2016	
	-	
Authorised:		
25,000 deferred ordinary shares of €1.00 each	\$	26
500,000,000 ordinary shares of \$.01 each		5,000
50,000,000 preferred shares of \$.01 each		500
Allotted, Called Up and Fully Paid:		
25,000 deferred ordinary shares of €1.00 each	\$	26
41,370,804 ordinary shares of \$.01 each		414
Called up share capital presented as equity	\$	440

In March of 2016, there was a domestic merger between the company and Flamel Irish Holdings Limited, where 100 ordinary shares were issued to Flamel Technologies SA following the merger at a premium of \$80,000. On 11 November 2016, the Company acquired and canceled 100 ordinary shares for Nil consideration.

In November of 2016, Flamel US Holdings Inc. subscribed to 25,000 ordinary deferred shares at par in order for Avadel Pharmaceuticals plc to meet minimum capital requirements set out by Irish law. These minimum capital requirements were necessary for Avadel Pharmaceuticals plc to become a public limited company.

In December of 2016, all outstanding American Depository Shares ("ADS") representing ordinary shares of Flamel Technologies SA were canceled and exchanged on a one-for-one basis for ADSs representing 41,370,804 ordinary shares of Avadel Pharmaceuticals plc as part of a cross-border merger resulting in a credit of \$318,040 to share premium account, representing the fair value of shares issued in excess of book value of assets and liabilities transferred.

#### **NOTE 12: OTHER RESERVES (Amounts in \$ thousands)**

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

#### **NOTE 13: LEASE COMMITMENTS**

**Operating leases** 

Future minimum lease payments under non-cancellable operating leases are as follows:

re Minimum Lease Payments		2016	
Not leter then one year	¢	332	
Not later than one year  Later than one year and not later than five years	Ф	332	
Later than five years  Later than five years		_	
Total	\$	332	

The Company enters into operating lease arrangements for the hire of buildings as these arrangements are a cost-efficient way of obtaining the short-term benefits of these assets. There are no other material off-balance sheet arrangements.

Other than those noted above, there are no other commitments or contingent liabilities at the end of the financial period.

## **NOTE 14: RETIREMENT BENEFIT SCHEMES (Amounts in \$ thousands)**

The Company is required by French law to deduct specific monthly payroll amounts to support post-retirement benefit programs sponsored by the relevant government agencies in France. As the ultimate obligation is maintained by the French government agencies, there is no additional liability recorded by the Company in connection with these plans. Expenses recognized for these plans were \$0 during the period.

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

Key assumptions used:	2016
Compensation rate increase	3.00%
Discount rate	1.31%
Employee turnover	Actuarial Standard
Average age of retirement	60 to 65 years

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:

Retirement Benefit Obligation Activity:	2016	
Retirement indemnity benefit obligation, beginning of period	\$	—
Service cost		
Interest cost		_
Benefits paid		
Actuarial loss (gain)		_
Exchange rate changes		_
Transfer in due to cross-border merger		2,431
Retirement indemnity benefit obligation, end of year	\$	2,431

The lump sum retirement indemnity is accrued on the company's statement of financial position within non-current other liabilities, excluding the current portion. As these are not funded benefit plans, there are no respective assets recorded.

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

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

## **NOTE 15 : GUARANTEES (Amounts in \$ thousands)**

At 31 December, 2016, 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 Eclat 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 Eclat 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 Eclat 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.

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.

Avadel Pharmaceuticals plc has assessed the fair value of these guarantees and determined them to be insignificant.

## **NOTE 16: POST BALANCE SHEET EVENTS (Amounts in \$ thousands)**

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 1, 2017 Avadel Investment Company Ltd. drew down \$115,534 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 \$115,534 held in various Morgan Stanley accounts from Avadel Pharmaceuticals, plc in exchange for cash.

On January 2, 2017 Avadel Pharmaceuticals plc subscribed to 1 share of Avadel Ireland Ltd for \$33,069 by releasing the intercompany loan between Avadel Pharmaceuticals plc and Avadel Ireland Ltd.

On February 15, 2017, the company filed a petition with the High Court of Ireland seeking the court's confirmation of a reduction of the Company's share premium so that it can be treated as distributable reserves for the purposes of Irish law.

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

In March 2017, the Company announced a plan to reduce its workforce at its Lyon, France site by approximately 50%. This reduction is an effort to align the Company's cost structure with its ongoing and future planned projects. Subject to French regulatory requirements and the outcome of negotiations with the works council, the Company expects the reduction to be substantially complete by the end of the third quarter of 2017 and to incur employee severance, benefits and other costs of up to approximately \$4,000, which are likely to be recognized through 31 December, 2017.

In March 2017, the High Court of Ireland consented to the cancellation of \$317,254 of the Company's share premium to be treated as profits available for distribution as defined by section 117 of the Act. The Minute of the High Court confirming this cancellation was filed with the Irish Companies Registration Office on 6 March 2017, at which time the cancellation of the Company's share premium became effective. The reduction does not affect the Company's authorized share capital of 500,000,000 ordinary shares of \$0.01 each, 50,000,000 preferred shares of \$0.01 each and €25,000 deferred ordinary shares of €1.00 each, of which 41,370,804 fully-paid ordinary shares continue to be issued and outstanding. As a result of the reduction, the balance standing to the credit of the Company's share premium account is \$80,786.

## NOTE 17: 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 18: APPROVAL OF THE FINANCIAL STATEMENTS

The financial statements were approved and authorised for issue on 30 May, 2017.