

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

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended: September 30, 2019

**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 Office and Zip Code)

**+353-1-485-1200**  
(Registrant's telephone number, including area code)

**N/A**  
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

|   |                          |                           |                                     |
|---|--------------------------|---------------------------|-------------------------------------|
| Large accelerated filer                       | <input type="checkbox"/> | Accelerated filer         | <input checked="" type="checkbox"/> |
| Non-accelerated                               | <input type="checkbox"/> | Smaller reporting company | <input type="checkbox"/>            |
| (Do not check if a smaller reporting company) |                          | Emerging growth company   | <input type="checkbox"/>            |

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

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

At November 8, 2019, 37,450,300 ordinary shares, nominal value \$0.01 each, of the Company were outstanding.

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### Cautionary Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These include statements as to our future expectations, beliefs, plans, strategies, objectives, events, conditions, financial performance, prospects, or other events. In some cases, forward-looking statements can be identified by the use of words such as “will,” “may,” “believe,” “expect,” “anticipate,” “estimate,” “project” and similar expressions, and the negatives thereof.

Our forward-looking statements are based on estimates and assumptions that are made within the bounds of our knowledge of our business and operations and that we consider reasonable. However, our business and operations are subject to significant risks and as a result there can be no assurance that actual results of our research, development and commercialization activities and the results of our business and operations will not differ materially from the results contemplated in such forward-looking statements. Factors that could cause actual results to differ from expectations in our forward-looking statements include:

(a) risks relating to our recent net losses and restructuring plan, including risks relating to the following:

- due to a decrease in our available liquid assets, our business strategy has been refocused and is now substantially dependent upon a single product, FT218;
- our recent restructuring plan may not be as effective as we anticipate and may have unintended negative impacts;
- further restructuring actions, if needed, may require third-party consents (including consents under the indenture governing our convertible debt) and such consents may not be granted; and
- the Chapter 11 bankruptcy filing by our subsidiary Avadel Specialty Pharmaceuticals LLC may have unexpected adverse results.

(b) risks relating to the following:

- our three products Bloxiverz®, Vazculep® and Akovaz®, which are not patent protected, and have a small number of customers, currently produce substantially all of our revenues, and could face further competition resulting in a further loss of market share and/or forcing us to further reduce our prices for those products;
- our current “unapproved marketed drug” (UMD) product candidate, AV001, could fail to achieve FDA approval; or we could fail to develop future potential UMD product candidates, or competitors could develop such products and market such products with FDA approval before us;
- we could experience failure or further delay in completing the Phase III clinical trial for FT218, and if the FDA ultimately approves such product, the approval may not include any period of market exclusivity;
- we may not have sufficient cash or the ability to raise sufficient cash to service our \$143.75 million Exchangeable Senior Notes due 2023, including cash necessary to repay such Notes at maturity, to settle exchanges of such Notes in cash or to repurchase such Notes as required following a “fundamental change” event described in the indenture governing such Notes;
- we depend on one or a limited number of third parties to manufacture certain of our products and to provide certain raw materials used in our products;
- our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do;
- we face challenges in protecting intellectual property underlying our products and drug delivery technologies; and
- we depend on key personnel to execute our business plan.

(c) the other risks and uncertainties described in the “Risk Factors” section of Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018 which we filed with the Securities and Exchange Commission on March 15, 2019.

Forward-looking statements speak only as of the date they are made and are not guarantees of future performance. Accordingly, you should not place undue reliance on forward-looking statements. We do not undertake any obligation to publicly update or revise the forward-looking statements contained in this Quarterly Report.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

|   | Three Months Ended September 30, |             | Nine Months Ended September 30, |             |
|---|----------------------------------|-------------|---------------------------------|-------------|
|   | 2019                             | 2018        | 2019                            | 2018        |
| <b>Revenues:</b>  |                                  |             |                                 |             |
| Product sales   | \$ 14,229                        | \$ 19,826   | \$ 48,220                       | \$ 82,103   |
| License revenue   | —                                | —           | —                               | 246         |
| Total revenues  | 14,229                           | 19,826      | 48,220                          | 82,349      |
| <b>Operating expenses:</b>  |                                  |             |                                 |             |
| Cost of products  | 2,823                            | 3,120       | 9,711                           | 13,224      |
| Research and development expenses                                       | 7,539                            | 11,402      | 25,160                          | 33,243      |
| Selling, general and administrative expenses                            | 5,316                            | 24,829      | 22,520                          | 77,159      |
| Intangible asset amortization   | 205                              | 1,620       | 610                             | 4,996       |
| Changes in fair value of related party contingent consideration         | 627                              | (7,115)     | 2,384                           | (17,036)    |
| Restructuring costs   | 1,866                            | 65          | 4,600                           | 268         |
| Total operating expenses  | 18,376                           | 33,921      | 64,985                          | 111,854     |
| Operating loss  | (4,147)                          | (14,095)    | (16,765)                        | (29,505)    |
| Investment and other income, net  | 781                              | 208         | 2,548                           | 845         |
| Interest expense  | (3,125)                          | (3,000)     | (9,293)                         | (7,577)     |
| Loss on deconsolidation of subsidiary                                   | —                                | —           | (2,840)                         | —           |
| Other (expense) income - changes in fair value of related party payable | (139)                            | 425         | (496)                           | 1,432       |
| Loss before income taxes  | (6,630)                          | (16,462)    | (26,846)                        | (34,805)    |
| Income tax provision (benefit)  | 2,234                            | (691)       | 3,641                           | (3,360)     |
| Net loss  | \$ (8,864)                       | \$ (15,771) | \$ (30,487)                     | \$ (31,445) |
| <b>Net loss per share:</b>  |                                  |             |                                 |             |
| Net loss per share - basic  | \$ (0.24)                        | \$ (0.43)   | \$ (0.82)                       | \$ (0.84)   |
| Net loss per share - diluted  | (0.24)                           | (0.43)      | (0.82)                          | (0.84)      |
| <b>Weighted average number of shares outstanding:</b>                   |                                  |             |                                 |             |
| Weighted average number of shares outstanding - basic                   | 37,436                           | 36,904      | 37,382                          | 37,410      |
| Weighted average number of shares outstanding - diluted                 | 37,436                           | 36,904      | 37,382                          | 37,410      |

See accompanying notes to unaudited condensed consolidated financial statements.

**AVADEL PHARMACEUTICALS PLC**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
*(In thousands)*  
*(Unaudited)*

|  | Three Months Ended September 30, |                    | Nine Months Ended September 30, |                    |
|--|----------------------------------|--------------------|---------------------------------|--------------------|
|  | 2019                             | 2018               | 2019                            | 2018               |
| Net loss   | \$ (8,864)                       | \$ (15,771)        | \$ (30,487)                     | \$ (31,445)        |
| Other comprehensive (loss) income, net of tax:   |                                  |                    |                                 |                    |
| Foreign currency translation gain (loss)   | (210)                            | (60)               | (309)                           | (293)              |
| Net other comprehensive income (loss), net of (\$5), (\$18), (\$46) and (\$88) tax, respectively | 86                               | 68                 | 753                             | (92)               |
| Total other comprehensive income (loss), net of tax  | (124)                            | 8                  | 444                             | (385)              |
| Total comprehensive loss   | <u>\$ (8,988)</u>                | <u>\$ (15,763)</u> | <u>\$ (30,043)</u>              | <u>\$ (31,830)</u> |

*See accompanying notes to unaudited condensed consolidated financial statements.*

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

|   | September 30, 2019 | December 31, 2018 |
|---|--------------------|-------------------|
|   | <i>(unaudited)</i> |                   |
| <b>ASSETS</b>   |                    |                   |
| Current assets:   |                    |                   |
| Cash and cash equivalents   | \$ 12,867          | \$ 9,325          |
| Marketable securities   | 59,587             | 90,590            |
| Accounts receivable   | 8,725              | 11,330            |
| Inventories   | 2,260              | 4,770             |
| Prepaid expenses and other current assets   | 5,163              | 8,836             |
| Total current assets  | 88,602             | 124,851           |
| Property and equipment, net   | 770                | 1,911             |
| Operating lease right-of-use assets   | 4,385              | —                 |
| Goodwill  | 18,491             | 18,491            |
| Intangible assets, net  | 1,019              | 1,629             |
| Research and development tax credit receivable  | 7,694              | 7,272             |
| Other non-current assets  | 34,927             | 36,146            |
| Total assets  | \$ 155,888         | \$ 190,300        |
| <b>LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY</b>   |                    |                   |
| Current liabilities:  |                    |                   |
| Current portion of long-term debt   | \$ 35              | \$ 106            |
| Current portion of long-term related party payable  | 7,588              | 9,439             |
| Current portion of operating lease liability  | 1,596              | —                 |
| Accounts payable  | 3,538              | 3,503             |
| Accrued expenses  | 17,017             | 21,695            |
| Other current liabilities   | 1,989              | 3,640             |
| Total current liabilities   | 31,763             | 38,383            |
| Long-term debt, less current portion  | 120,132            | 115,734           |
| Long-term related party payable, less current portion   | 14,118             | 19,401            |
| Long-term operating lease liability   | 2,866              | —                 |
| Other non-current liabilities   | 13,972             | 14,002            |
| Total liabilities   | 182,851            | 187,520           |
| Shareholders' (deficit) equity:   |                    |                   |
| Preferred shares, nominal value of \$0.01 per share; 50,000 shares authorized; none issued or outstanding at September 30, 2019 and December 31, 2018, respectively                                     | —                  | —                 |
| Ordinary shares, nominal value of \$0.01 per share; 500,000 shares authorized; 42,857 issued and 37,450 outstanding at September 30, 2019 and 42,720 issued and 37,313 outstanding at December 31, 2018 | 428                | 427               |
| Treasury shares, at cost, 5,407 shares held at September 30, 2019 and December 31, 2018, respectively   | (49,998)           | (49,998)          |
| Additional paid-in capital  | 434,055            | 433,756           |
| Accumulated deficit   | (388,476)          | (357,989)         |
| Accumulated other comprehensive loss  | (22,972)           | (23,416)          |
| Total shareholders' (deficit) equity  | (26,963)           | 2,780             |
| Total liabilities and shareholders' (deficit) equity  | \$ 155,888         | \$ 190,300        |

*See accompanying notes to unaudited condensed consolidated financial statements.*

**AVADEL PHARMACEUTICALS PLC**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' (DEFICIT) EQUITY**  
*(In thousands)*  
*(Unaudited)*

**Nine Months Ended September 30, 2019**

|  | Ordinary shares |        | Additional<br>paid-in<br>capital | Accumulated<br>deficit | Accumulated<br>other<br>comprehensive<br>(loss) income | Treasury shares |             | Total<br>shareholders'<br>(deficit)<br>equity |
|--|-----------------|--------|----------------------------------|------------------------|--|-----------------|-------------|---|
|  | Shares          | Amount |                                  |                        |  | Shares          | Amount      |   |
| <b>Balance, December 31, 2018</b>              | 42,720          | \$ 427 | \$ 433,756                       | \$ (357,989)           | \$ (23,416)  | 5,407           | \$ (49,998) | \$ 2,780                                      |
| Net loss                                       | —               | —      | —                                | (13,018)               | —  | —               | —           | (13,018)                                      |
| Other comprehensive income                     | —               | —      | —                                | —                      | 213  | —               | —           | 213   |
| Vesting of restricted shares                   | 1               | —      | —                                | —                      | —  | —               | —           | —   |
| Employee share purchase plan<br>share issuance | 42              | —      | 92                               | —                      | —  | —               | —           | 92  |
| Stock-based compensation<br>expense            | —               | —      | 351                              | —                      | —  | —               | —           | 351   |
| <b>Balance, March 31, 2019</b>                 | 42,763          | \$ 427 | \$ 434,199                       | \$ (371,007)           | \$ (23,203)  | 5,407           | \$ (49,998) | \$ (9,582)                                    |
| Net loss                                       | —               | —      | —                                | (8,605)                | —  | —               | —           | (8,605)                                       |
| Other comprehensive income                     | —               | —      | —                                | —                      | 355  | —               | —           | 355   |
| Stock-based compensation<br>expense            | —               | —      | 55                               | —                      | —  | —               | —           | 55  |
| <b>Balance, June 30, 2019</b>                  | 42,763          | \$ 427 | \$ 434,254                       | \$ (379,612)           | \$ (22,848)  | 5,407           | \$ (49,998) | \$ (17,777)                                   |
| Net loss                                       | —               | —      | —                                | (8,864)                | —  | —               | —           | (8,864)                                       |
| Other comprehensive income                     | —               | —      | —                                | —                      | (124)  | —               | —           | (124)   |
| Stock-based compensation<br>expense            | —               | —      | (229)                            | —                      | —  | —               | —           | (229)   |
| Vesting of restricted shares                   | 82              | 1      | (1)                              | —                      | —  | —               | —           | —   |
| Employee share purchase plan<br>share issuance | 12              | —      | 31                               | —                      | —  | —               | —           | 31  |
| <b>Balance, September 30, 2019</b>             | 42,857          | \$ 428 | \$ 434,055                       | \$ (388,476)           | \$ (22,972)  | 5,407           | \$ (49,998) | \$ (26,963)                                   |

**AVADEL PHARMACEUTICALS PLC**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' (DEFICIT) EQUITY**  
*(In thousands)*  
*(Unaudited)*

**Nine Months Ended September 30, 2018**

|   | Ordinary shares |        | Additional<br>paid-in<br>capital | Accumulated<br>deficit | Accumulated<br>other<br>comprehensive<br>(loss) income | Treasury shares |             | Total<br>shareholders'<br>equity |
|---|-----------------|--------|----------------------------------|------------------------|--|-----------------|-------------|----------------------------------|
|   | Shares          | Amount |                                  |                        |  | Shares          | Amount      |                                  |
| <b>Balance, December 31, 2017</b>           | 41,463          | \$ 414 | \$ 393,478                       | \$ (262,685)           | \$ (23,266)  | 2,117           | \$ (22,361) | \$ 85,580                        |
| Net loss                                    | —               | —      | —                                | (12,236)               | —  | —               | —           | (12,236)                         |
| Other comprehensive loss                    | —               | —      | —                                | —                      | (404)  | —               | —           | (404)                            |
| Exercise of warrants                        | 603             | 6      | 2,905                            | —                      | —  | —               | —           | 2,911                            |
| Expiration of warrants                      | —               | —      | 2,167                            | —                      | —  | —               | —           | 2,167                            |
| Stock-based compensation expense            | —               | —      | 2,134                            | —                      | —  | —               | —           | 2,134                            |
| Equity component of 2023 Notes              | —               | —      | 26,699                           | —                      | —  | —               | —           | 26,699                           |
| Share repurchases                           | —               | —      | —                                | —                      | —  | 2,307           | (20,212)    | (20,212)                         |
| <b>Balance, March 31, 2018</b>              | 42,066          | \$ 420 | \$ 427,383                       | \$ (274,921)           | \$ (23,670)  | 4,424           | \$ (42,573) | \$ 86,639                        |
| Net loss                                    | —               | —      | —                                | (3,438)                | —  | —               | —           | (3,438)                          |
| Other comprehensive income                  | —               | —      | —                                | —                      | 11   | —               | —           | 11                               |
| Exercise of stock options                   | 82              | 1      | 534                              | —                      | —  | —               | —           | 535                              |
| Stock-based compensation expense            | —               | —      | 2,224                            | —                      | —  | —               | —           | 2,224                            |
| Share repurchases                           | —               | —      | —                                | —                      | —  | 983             | (7,425)     | (7,425)                          |
| <b>Balance, June 30, 2018</b>               | 42,148          | \$ 421 | \$ 430,141                       | \$ (278,359)           | \$ (23,659)  | 5,407           | \$ (49,998) | \$ 78,546                        |
| Net loss                                    | —               | —      | —                                | (15,771)               | —  | —               | —           | (15,771)                         |
| Other comprehensive income                  | —               | —      | —                                | —                      | 8  | —               | —           | 8                                |
| Stock-based compensation expense            | —               | —      | 2,832                            | —                      | —  | —               | —           | 2,832                            |
| Vesting of restricted shares                | 247             | 3      | (3)                              | —                      | —  | —               | —           | —                                |
| Employee share purchase plan share issuance | 24              | —      | 127                              | —                      | —  | —               | —           | 127                              |
| <b>Balance, September 30, 2018</b>          | 42,419          | \$ 424 | \$ 433,097                       | \$ (294,130)           | \$ (23,651)  | 5,407           | \$ (49,998) | \$ 65,742                        |



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

|   | Nine Months Ended September 30, |             |
|---|---------------------------------|-------------|
|   | 2019                            | 2018        |
| <b>Cash flows from operating activities:</b>  |                                 |             |
| Net loss  | \$ (30,487)                     | \$ (31,445) |
| Adjustments to reconcile net loss to net cash provided by operating activities:                       |                                 |             |
| Depreciation and amortization   | 1,690                           | 5,625       |
| Loss on disposal of property and equipment  | 478                             | —           |
| Amortization of premiums on marketable securities   | (275)                           | 2,889       |
| Remeasurement of related party acquisition-related contingent consideration                           | 2,384                           | (17,036)    |
| Remeasurement of related party financing-related contingent consideration                             | 496                             | (1,432)     |
| Amortization of debt discount and debt issuance costs   | 4,424                           | 3,402       |
| Change in deferred tax and income tax deferred charge   | 1,333                           | (4,675)     |
| Stock-based compensation expense  | 177                             | 7,190       |
| Loss on deconsolidation of subsidiary   | 1,750                           | —           |
| Other adjustments   | (392)                           | 117         |
| Net changes in assets and liabilities   |                                 |             |
| Accounts receivable   | 2,026                           | 5,059       |
| Inventories   | 2,465                           | (548)       |
| Prepaid expenses and other current assets   | (1,859)                         | 2,194       |
| Research and development tax credit receivable  | (749)                           | (1,350)     |
| Accounts payable & other current liabilities  | 259                             | 4,312       |
| Accrued expenses  | (2,379)                         | (11,660)    |
| Earn-out payments for related party contingent consideration in excess of acquisition-date fair value | (8,640)                         | (16,254)    |
| Royalty payments for related party payable in excess of original fair value                           | (1,374)                         | (2,362)     |
| Other assets and liabilities  | (1,399)                         | (2,216)     |
| Net cash used in operating activities   | (30,072)                        | (58,190)    |
| <b>Cash flows from investing activities:</b>  |                                 |             |
| Purchases of property and equipment   | (29)                            | (167)       |
| Proceeds from the disposal of property and equipment  | 154                             | —           |
| Purchase of intangible asset  | —                               | (20,000)    |
| Proceeds from sales of marketable securities  | 57,242                          | 308,015     |
| Purchases of marketable securities  | (23,814)                        | (341,036)   |
| Net cash provided by (used in) investing activities   | 33,553                          | (53,188)    |
| <b>Cash flows from financing activities:</b>  |                                 |             |
| Earn-out payments for related party contingent consideration  | —                               | (645)       |
| Proceeds from debt issuance   | —                               | 143,750     |
| Payments for debt issuance costs  | —                               | (6,190)     |
| Share repurchases   | —                               | (27,637)    |
| Proceeds from issuance of ordinary shares and warrants  | 123                             | 3,488       |
| Other financing activities, net   | (109)                           | (31)        |
| Net cash provided by financing activities   | 14                              | 112,735     |
| Effect of foreign currency exchange rate changes on cash and cash equivalents                         | 47                              | (84)        |
| Net change in cash and cash equivalents   | 3,542                           | 1,273       |
| Cash and cash equivalents at January 1,   | 9,325                           | 16,564      |
| Cash and cash equivalents at September 30,  | \$ 12,867                       | \$ 17,837   |
| <b>Supplemental disclosures of cash flow information:</b>   |                                 |             |
| Interest paid   | \$ 6,469                        | \$ 3,359    |
| Income taxes paid   | \$ 140                          | \$ 413      |

See accompanying notes to unaudited condensed consolidated financial statements.

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

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

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

Avadel is developing FT218, an investigational once-nightly formulation of sodium oxybate based on its propriety Micropump® drug delivery technology, for the treatment of EDS and cataplexy in patients suffering from narcolepsy. FT218 is currently being evaluated in a Phase 3 clinical trial called REST-ON. In addition, the Company submitted a new drug application (“NDA”) in March 2019 on a fourth sterile injectable drug which we refer to as AV001, for use in the hospital setting. AV001, if approved, could contribute revenues to Avadel starting in 2020. In May 2019, the FDA accepted the NDA for AV001, with a Prescription Drug User Fee Act (PDUFA) target action date of December 15, 2019.

Our current marketed products include:

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

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

The Company was incorporated on December 1, 2015 as an Irish private limited company, and re-registered as an Irish public limited company, or plc, on November 21, 2016. Our principal place of business is located at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15, Ireland. Avadel’s phone number is 011-353-1-485-1200. Our website is [www.avadel.com](http://www.avadel.com), where we make available free of charge our reports (and any amendments thereto) on Forms 10-K, 10-Q and 8-K as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission (“SEC”). These filings are also available to the public at [www.sec.gov](http://www.sec.gov).

The Company is the successor to Flamel Technologies S.A., a French *société anonyme* (“Flamel”), as the result of the France-to-Ireland redomestication merger of Flamel with and into the Company completed on December 31, 2016 (the “Merger”). In the Merger, we changed our company name to Avadel Pharmaceuticals plc and our jurisdiction of organization to Ireland; we assumed all the assets and liabilities of Flamel; and we issued one Avadel ordinary share (either directly or in the form of an American Depositary Share (ADS)) in exchange for each formerly outstanding share of Flamel, all of which were canceled. Thus, an Avadel ordinary share held (either directly or represented by an ADS) immediately after the Merger continued to represent the same proportional interest in our equity owned by the holder of a share of Flamel immediately prior to the Merger. References in this Annual Report on Form 10-K to “Avadel,” the “Company,” “we,” “our,” “us,” and similar terms shall be deemed to be references to Flamel prior to the completion of the Merger, unless the context otherwise requires. Additional details about the Merger are set forth in Item 1 under the caption “The Reincorporation Merger” of the Company’s Annual Report on Form 10-K filed with the SEC on March 15, 2019.

The Company currently has five direct wholly-owned subsidiaries: (a) Avadel US Holdings, Inc., (b) Flamel Ireland Limited, which conducts business under the name Avadel Ireland, (c) Avadel Investment Company Limited, (d) Avadel Finance Ireland Designated Activity Company and (e) Avadel France Holding SAS. Avadel US Holdings, Inc., a Delaware corporation, is the holding entity of (i) Avadel Specialty Pharmaceuticals, LLC (currently the subject of a voluntary Chapter 11 bankruptcy proceeding as noted in *Note 3: Subsidiary Bankruptcy and Deconsolidation*), (ii) Avadel Legacy Pharmaceuticals, LLC, (iii) Avadel

Management Corporation, (iv) FSC Holding Company and (v) Avadel Operations Company, Inc. Avadel Finance Ireland Designated Activity Company is the holding entity of Avadel Finance Cayman Limited. Flamel Ireland Limited (operating under the trade name Avadel Ireland) is an Irish corporation which, since December 16, 2014, has been the owner of substantially all of Avadel's intellectual property. Avadel France Holding SAS, a French *société par actions simplifiée*, is the holding entity of Avadel Research SAS through which Avadel conducts substantially all of its R&D activities.

**Basis of Presentation.** The unaudited condensed consolidated balance sheet as of September 30, 2019, which is derived from the prior year 2018 audited consolidated financial statements, and the interim unaudited condensed consolidated financial statements presented herein, have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP), the requirements of Form 10-Q and Article 10 of Regulation S-X and, consequently, do not include all information or footnotes required by U.S. GAAP for complete financial statements or all the disclosures normally made in an annual report on Form 10-K. Accordingly, the unaudited condensed consolidated financial statements included herein should be read in conjunction with the audited consolidated financial statements and footnotes included in the Company's 2018 Annual Report on Form 10-K filed with the SEC on March 15, 2019.

The unaudited condensed consolidated financial statements include the accounts of the Company and subsidiaries, and reflect all adjustments (consisting only of normal recurring adjustments) that are, in the opinion of management, necessary for a fair presentation of the Company's financial position, results of operations and cash flows for the dates and periods presented. All material intercompany accounts and transactions have been eliminated. Results for interim periods are not necessarily indicative of the results to be expected during the remainder of the current year or for any future period.

On February 6, 2019, the Company's indirect wholly-owned subsidiary, Avadel Specialty Pharmaceuticals, LLC ("Specialty Pharma"), filed a voluntary petition for reorganization under Chapter 11 of the United States ("U.S.") Code (the "Bankruptcy Code") in the U.S. District Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"), Case No. 19-10248. Specialty Pharma is operating and managing its business as "debtors-in-possession" under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code and order of the Bankruptcy Court. As a result of Specialty Pharma's voluntary bankruptcy filing on February 6, 2019, we no longer controlled the operations of Specialty Pharma; therefore, we deconsolidated Specialty Pharma effective with the bankruptcy filing and the Company recorded its investment in Specialty Pharma under the cost method. See *Note 3: Subsidiary Bankruptcy and Deconsolidation*. Our results of operations for the period January 1, 2019 through February 6, 2019 include the results of Specialty Pharma prior to its February 6, 2019 voluntary petition for reorganization under Chapter 11 of the U.S. Bankruptcy Code.

Our results of operations for the period January 1, 2018 through February 16, 2018 include the results of FSC Therapeutics and FSC Laboratories, Inc., (collectively "FSC"), prior to its February 16, 2018 disposition date. See *Note 14: Divestiture of the Pediatric Assets*, for additional information. All intercompany accounts and transactions have been eliminated.

**Revenue.** Revenue includes sales of pharmaceutical products, licensing fees, and, if any, milestone payments for research and development ("R&D") achievements.

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

#### *Product Sales and Services*

The Company sells products primarily through wholesalers and considers these wholesalers to be its customers. Under ASC 606, revenue from product sales is recognized when the customer obtains control of the Company's product, which occurs typically upon receipt by the customer. As is customary in the pharmaceutical industry, the Company's gross product sales are subject to a variety of price adjustments in arriving at reported net product sales. These adjustments include estimates of product returns,

chargebacks, payment discounts, rebates, and other sales allowances and are estimated based on analysis of historical data for the product or comparable products, future expectations for such products and other judgments and analysis.

#### *License Revenue*

The Company from time to time may enter into out-licensing agreements which are within the scope of ASC 606 under which it licenses to third parties certain rights to its products or intellectual property. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; development, regulatory, and commercial milestone payments; and sales-based royalty payments. Each of these payments results in license revenue.

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

#### **NOTE 2: Newly Issued Accounting Standards**

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

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

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

In June 2016, the FASB issued ASU No. 2016-13, “*Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”)*.” This standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 will be effective for the Company for fiscal years beginning on or after January 1, 2020, including interim periods within those annual reporting periods and early adoption is permitted. We are currently evaluating the impact of our adoption of ASU 2016-13 on our condensed consolidated financial statements.

#### **NOTE 3: Subsidiary Bankruptcy and Deconsolidation**

##### ***Bankruptcy Filing and Deconsolidation***

As a result of Specialty Pharma’s bankruptcy filing on February 6, 2019, Avadel has ceded authority for managing the business to the Bankruptcy Court, and Avadel management cannot carry on Specialty Pharma’s activities in the ordinary course of business without Bankruptcy Court approval. Avadel manages the day-to-day operations of Specialty Pharma, but does not have discretion to make significant capital or operating budgetary changes or decisions and purchase or sell significant assets, as Specialty Pharma’s material decisions are subject to review by the Bankruptcy Court. For these reasons, we have concluded that Avadel has lost control of Specialty Pharma, and no longer has significant influence over Specialty Pharma during the pendency of the bankruptcy. Therefore, we deconsolidated Specialty Pharma effective with the filing of the Chapter 11 bankruptcy in February 2019.

In order to deconsolidate Specialty Pharma, the carrying values of the assets and certain liabilities of Specialty Pharma were removed from our unaudited condensed consolidated balance sheet as of February 5, 2019, and we recorded our investment in Specialty Pharma at its estimated fair value of \$0. As the estimated fair value of our investment in Specialty Pharma was lower than its net book value immediately prior to the deconsolidation, we recorded a non-cash charge of approximately \$2,840 for the nine months ended September 30, 2019 associated with the deconsolidation of Specialty Pharma. Subsequent to the deconsolidation of Specialty Pharma, we are accounting for our investment in Specialty Pharma using the cost method of accounting because Avadel does not exercise significant influence over the operations of Specialty Pharma due to the Chapter 11 filing.

On April 26, 2019, Specialty Pharma sold its intangible assets and remaining inventory to an unaffiliated third party in exchange for aggregate cash proceeds of approximately \$250, pursuant to an order approving such sale which was issued by the Bankruptcy

Court on April 15, 2019. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business.

On July 2, 2019, Specialty Pharma was made aware of a \$50,695 claim made by the Internal Revenue Service (IRS) as part of the bankruptcy claims process against Specialty Pharma. On October 2, 2019 the IRS amended the original claim filed in July, reducing the claim to \$9,302. Specialty Pharma files its U.S. federal tax return as a member of the Company's consolidated U.S. tax group. As such, the IRS claim was filed against Specialty Pharma in the bankruptcy proceedings due to IRS tax law requirements for joint and several liability of all members in a consolidated U.S. tax group. Both Specialty Pharma and the Company disagree with the merits of the amended IRS claim and intend to defend their positions vigorously.

#### *DIP Financing – Related Party Relationship*

In connection with the bankruptcy filing, Specialty Pharma entered into a Debtor in Possession Credit and Security Agreement with Avadel US Holdings ("DIP Credit Agreement") dated as of February 8, 2019, in an aggregate amount of up to \$2,700, of which the funds are to be used by Specialty Pharma solely to fund operations through February 6, 2020. As of September 30, 2019, the Company had funded \$407 under the DIP Credit Agreement. As the Company has assessed that it is unlikely that Specialty Pharma will pay back the loan to Avadel, the \$407 has been recorded as part of the loss on deconsolidation of subsidiary within the unaudited condensed consolidated statements of loss. At September 30, 2019 the fair value of the remaining commitment under the DIP Credit Agreement is not material.

#### **NOTE 4: Revenue Recognition**

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

#### *Product Sales and Services*

Effective January 1, 2018, the Company implemented ASC 606, "Revenue From Contracts With Customers". The Company sells products primarily through wholesalers and considers these wholesalers to be its customers. Under ASC 606, revenue from product sales is recognized when the customer obtains control of the Company's product and the Company's performance obligations are met, which occurs typically upon receipt of delivery to the customer. As is customary in the pharmaceutical industry, the Company's gross product sales are subject to a variety of price adjustments in arriving at reported net product sales. These adjustments include estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated when the product is delivered based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

#### *Reserves to Reduce Gross Revenues to Net Revenues*

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

#### *Product Returns*

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

### *Chargebacks, Discounts and Rebates*

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

### **Revenue from licensing arrangements**

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

### *License of Intellectual Property*

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

### **Disaggregation of revenue**

The Company's primary source of revenue is from the sale of pharmaceutical products, which are equally affected by the same economic factors as it relates to the nature, amount, timing, and uncertainty of revenue and cash flows. For further detail about the Company's revenues by product, see *Note 18: Company Operations by Product*.

### **Contract Balances**

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

A receivable is recognized in the period the Company sells its products and when the Company's right to consideration is unconditional.

There were no material deferred contract costs at September 30, 2019.

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

For product sales, the Company generally satisfies its performance obligations within the same period the product is delivered. Product sales recognized in 2019 from performance obligations satisfied (or partially satisfied) in previous periods were immaterial.

For certain licenses of intellectual property, specifically those with performance obligations satisfied over time, the Company allocates a portion of the transaction price to that performance obligation and recognizes revenue using an appropriate measure of progress towards development of the product.

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

### **NOTE 5: Fair Value Measurement**

The Company is required to measure certain assets and liabilities at fair value, either upon initial recognition or for subsequent accounting or reporting. For example, we use fair value extensively when accounting for and reporting certain financial instruments, when measuring certain contingent consideration liabilities and in the initial recognition of net assets acquired in a business

combination. Fair value is estimated by applying the hierarchy described below, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement.

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

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

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

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

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

| Fair Value Measurements:            | As of September 30, 2019 |                  |                  | As of December 31, 2018 |                  |                  |
|-------------------------------------|--------------------------|------------------|------------------|-------------------------|------------------|------------------|
|                                     | Level 1                  | Level 2          | Level 3          | Level 1                 | Level 2          | Level 3          |
| Marketable securities (see Note 6)  |                          |                  |                  |                         |                  |                  |
| Equity securities                   | \$ 4,176                 | \$ —             | \$ —             | \$ 9,145                | \$ —             | \$ —             |
| Money market and mutual funds       | 44,091                   | —                | —                | 52,996                  | —                | —                |
| Corporate bonds                     | —                        | 4,258            | —                | —                       | 6,339            | —                |
| Government securities - U.S.        | —                        | 5,344            | —                | —                       | 12,701           | —                |
| Other fixed-income securities       | —                        | 1,718            | —                | —                       | 9,409            | —                |
| Total assets                        | <u>\$ 48,267</u>         | <u>\$ 11,320</u> | <u>\$ —</u>      | <u>\$ 62,141</u>        | <u>\$ 28,449</u> | <u>\$ —</u>      |
| Related party payable (see Note 10) | \$ —                     | \$ —             | \$ 21,706        | \$ —                    | \$ —             | \$ 28,840        |
| Total liabilities                   | <u>\$ —</u>              | <u>\$ —</u>      | <u>\$ 21,706</u> | <u>\$ —</u>             | <u>\$ —</u>      | <u>\$ 28,840</u> |

A review of fair value hierarchy classifications is conducted on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification for certain financial assets or liabilities. During the periods ended September 30, 2019 and December 31, 2018, respectively, there were no transfers in and out of Level 1, 2, or 3. During the three month periods ended September 30, 2019 and 2018, respectively, we did not recognize any other-than-temporary impairment loss.

Some of the Company’s financial instruments, such as cash and cash equivalents, accounts receivable and accounts payable, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

## Debt

We estimate the fair value of our \$143,750 aggregate principal amount of 4.50% exchangeable senior notes due 2023 (the “2023 Notes”), a Level 2 input, based on interest rates that would be currently available to the Company for issuance of similar types of debt instruments with similar terms and remaining maturities or recent trading prices obtained from brokers. The estimated fair value of the 2023 Notes at September 30, 2019 is \$76,425 compared to a book value of \$120,132.

Additionally, the Company’s other debt is reflected in the balance sheet at carrying value. The fair value of these loans is impracticable to estimate as these represent non-interest bearing grants from the French government and are repayable only if the

research project is technically or commercially successful.

See *Note 11: Long-Term Debt* for additional information regarding our debt obligations.

#### NOTE 6: Marketable Securities

The Company has investments in equity and available-for-sale debt securities which are recorded at fair market value. The change in the fair value of equity investments is recognized in our unaudited condensed consolidated statements of loss and the change in the fair value of available-for-sale debt investments is recorded as other comprehensive income (loss) in shareholders' (deficit) equity, net of income tax effects.

The following tables show the Company's available-for-sale securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category as of September 30, 2019 and December 31, 2018, respectively:

| Marketable Securities:        | September 30, 2019 |                  |                   |                  |
|-------------------------------|--------------------|------------------|-------------------|------------------|
|                               | Adjusted Cost      | Unrealized Gains | Unrealized Losses | Fair Value       |
| Equity securities             | \$ 4,200           | \$ —             | \$ (24)           | \$ 4,176         |
| Money market and mutual funds | 43,306             | 785              | —                 | 44,091           |
| Corporate bonds               | 4,190              | 69               | (1)               | 4,258            |
| Government securities - U.S.  | 5,217              | 129              | (2)               | 5,344            |
| Other fixed-income securities | 1,693              | 26               | (1)               | 1,718            |
| Total                         | <u>\$ 58,606</u>   | <u>\$ 1,009</u>  | <u>\$ (28)</u>    | <u>\$ 59,587</u> |

| Marketable Securities:        | December 31, 2018 |                  |                   |                  |
|-------------------------------|-------------------|------------------|-------------------|------------------|
|                               | Adjusted Cost     | Unrealized Gains | Unrealized Losses | Fair Value       |
| Equity securities             | \$ 10,101         | \$ —             | \$ (956)          | \$ 9,145         |
| Money market and mutual funds | 52,733            | 316              | (53)              | 52,996           |
| Corporate bonds               | 6,411             | 7                | (79)              | 6,339            |
| Government securities - U.S.  | 12,714            | 66               | (79)              | 12,701           |
| Other fixed-income securities | 9,400             | 22               | (13)              | 9,409            |
| Total                         | <u>\$ 91,359</u>  | <u>\$ 411</u>    | <u>\$ (1,180)</u> | <u>\$ 90,590</u> |

We determine realized gains or losses on the sale of marketable securities on a specific identification method. We reflect these gains and losses as a component of investment and other income in the accompanying unaudited condensed consolidated statements of loss.

We recognized gross realized gains of \$71 and \$143 for the three months ended September 30, 2019, and 2018, respectively. These realized gains were offset by realized losses of \$64 and \$22 for the three months ended September 30, 2019, and 2018, respectively.

We recognized gross realized gains of \$339 and \$378 for the nine months ended September 30, 2019, and 2018, respectively. These realized gains were offset by realized losses of \$211 and \$350 for the nine months ended September 30, 2019 and 2018, respectively. We reflect these gains and losses as a component of investment and other income in the accompanying condensed consolidated statements of income (loss).



The following table summarizes the estimated fair value of our investments in marketable debt securities, accounted for as available-for-sale debt securities and classified by the contractual maturity date of the securities as of September 30, 2019:

| Marketable Debt Securities:   | Maturities       |           |            |                       | Total     |
|-------------------------------|------------------|-----------|------------|-----------------------|-----------|
|                               | Less than 1 Year | 1-5 Years | 5-10 Years | Greater than 10 Years |           |
| Corporate bonds               | \$ 556           | \$ 3,360  | \$ 342     | \$ —                  | \$ 4,258  |
| Government securities - U.S.  | —                | 4,600     | —          | 744                   | 5,344     |
| Other fixed-income securities | 49               | 1,669     | —          | —                     | 1,718     |
| Total                         | \$ 605           | \$ 9,629  | \$ 342     | \$ 744                | \$ 11,320 |

The Company has classified our investment in available-for-sale marketable debt securities as current assets in the unaudited condensed consolidated balance sheets as the securities need to be available for use, if required, to fund current operations. There are no restrictions on the sale of any securities in our investment portfolio.

#### NOTE 7: Inventories

The principal categories of inventories, net reserves of \$1,212 and \$4,757 at September 30, 2019 and December 31, 2018, respectively, are comprised of the following:

| Inventory:     | September 30, 2019 | December 31, 2018 |
|----------------|--------------------|-------------------|
| Finished goods | \$ 1,883           | \$ 4,270          |
| Raw materials  | 377                | 500               |
| Total          | \$ 2,260           | \$ 4,770          |

Total net reserves decreased by \$3,545 during the nine months ended September 30, 2019 largely driven by the deconsolidation of Specialty Pharma.

#### NOTE 8: Goodwill and Intangible Assets

The Company's amortizable and unamortizable intangible assets at September 30, 2019 and December 31, 2018 are as follows:

| Goodwill and Intangible Assets:          | September 30, 2019 |                          |                     | December 31, 2018 |                          |             |                     |
|--|--------------------|--------------------------|---------------------|-------------------|--------------------------|-------------|---------------------|
|  | Gross Value        | Accumulated Amortization | Net Carrying Amount | Gross Value       | Accumulated Amortization | Impairment  | Net Carrying Amount |
| Amortizable intangible assets:           |                    |                          |                     |                   |                          |             |                     |
| Acquired developed technology - Noctiva  | \$ —               | \$ —                     | \$ —                | \$ 73,111         | \$ (7,024)               | \$ (66,087) | \$ —                |
| Acquired developed technology - Vazculep | 12,061             | (11,042)                 | 1,019               | 12,061            | (10,432)                 | —           | 1,629               |
| Total amortizable intangible assets      | \$ 12,061          | \$ (11,042)              | \$ 1,019            | \$ 85,172         | \$ (17,456)              | \$ (66,087) | \$ 1,629            |
| Unamortizable intangible assets:         |                    |                          |                     |                   |                          |             |                     |
| Goodwill                                 | \$ 18,491          | \$ —                     | \$ 18,491           | \$ 18,491         | \$ —                     | \$ —        | \$ 18,491           |
| Total unamortizable intangible assets    | \$ 18,491          | \$ —                     | \$ 18,491           | \$ 18,491         | \$ —                     | \$ —        | \$ 18,491           |

The Company recorded amortization expense related to amortizable intangible assets of \$205 and \$1,620 for the three months ended September 30, 2019 and 2018, respectively and \$610 and \$4,996 for the nine months ended September 30, 2019 and 2018, respectively.

During the fourth quarter 2018, certain conditions came to light, largely the lack of a meaningful increase in Noctiva prescriptions despite the substantial investment of resources, which indicated that the carrying value of the asset, may not be fully recoverable. As such, the Company performed an impairment test based on a comparison of the pretax discounted cash flows expected to be generated by the asset, which is a Level 3 fair value estimate, to the recorded value of the asset and concluded that the associated cash flows did not support any of the carrying value of the intangible asset and the Company recorded a full impairment charge of \$66,087 at December 31, 2018 related to the acquired developed technology associated with Noctiva. The February 6, 2019 Chapter 11 bankruptcy filing of Specialty Pharma, the subsidiary which markets, sells and distributes Noctiva, confirmed management's conclusion on the impairment.

Amortizable intangible assets are amortized over their estimated useful lives, which generally range from three to fifteen years. Estimated amortization of intangible assets for the next five years is as follows:

| <b>Estimated Annual Amortization Expense:</b> | <b>Amount</b> |
|---|---------------|
| 2019  | \$ 815        |
| 2020  | 814           |
| 2021  | —             |
| 2022  | —             |
| 2023  | —             |

#### **NOTE 9: Leases**

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. On January 1, 2019, the Company adopted the ASU using the modified retrospective transition approach and elected the transition option to recognize the adjustment in the period of adoption rather than in the earliest period presented. As of January 1, 2019, adoption of the new guidance resulted in the initial recognition of operating lease right-of-use assets of \$5,046 and operating lease liabilities of \$5,131. At September 30, 2019, the balances of the operating lease right-of-use asset and total operating lease liability were \$4,385 and \$4,462, respectively, of which \$1,596 of the operating lease liability is current.

The Company leases certain facilities for office and manufacturing purposes, comprising approximately 99% of the total lease population. All leased facilities are classified as operating leases with remaining lease terms between one and seven years. The Company determines if a contract is a lease at the inception of the arrangement. The Company reviews all options to extend, terminate, or purchase its right-of-use assets at the inception of the lease and will include these options in the lease term when they are reasonably certain of being exercised. For all of the Company's leases, lease and non-lease components are accounted for as a single lease component, as all non-lease components are immaterial to break out separately.

The components of lease costs, which are included in selling, general and administrative expenses in the unaudited condensed consolidated statements of loss for the three and nine months ended September 30 were as follows:

| <b>Lease cost:</b>                   | <b>Three months ended<br/>September 30, 2019</b> | <b>Nine months ended<br/>September 30, 2019</b> |
|--------------------------------------|--|---|
| Operating lease costs <sup>(1)</sup> | \$ 411   | \$ 1,150  |
| Sublease income <sup>(2)</sup>       | 82   | 187   |
| <b>Total lease cost</b>              | <b>\$ 329</b>                                    | <b>\$ 963</b>                                   |

<sup>(1)</sup> Variable lease costs were immaterial for the three and nine months ended September 30, 2019.

<sup>(2)</sup> Represents sublease income received for the vacated office facility in Charlotte, North Carolina, which was acquired with the FSC acquisition in February 2016. The lease and sublease agreements terminate in December 2020. The Company also vacated portions of its office facility in St. Louis, Missouri during May 2019 and August 2019 and started receiving sublease income starting in May 2019 and August 2019 from two different tenants. The lease agreement ends in April 2025 and the sublease agreement that started in May 2019 ends in May 2020, with a one year renewal and the sublease agreement that started in August 2019 ends in July 2020, and can continue thereafter on a month-to-month basis.

During the three and nine months ended September 30, 2019, the Company reduced its operating lease liabilities by \$411 and \$1,115 for cash paid. In addition, during the nine months ended September 30, 2019, new operating leases commenced resulting

in the recognition of operating lease right-of-use assets and liabilities of \$1,000 and \$0, respectively, as the entire lease payment was paid on March 31, 2019. There were no new leases during the three months ended September 30, 2019. As of September 30, 2019, the Company is aware of one additional embedded lease that has not yet commenced and will not commence until the time of FDA approval of the product (if approved). Once FDA approval is given and the start date is determined, annual production suite fees of approximately \$3,000 to \$4,000 would commence and at that time an operating lease right-of-use asset and corresponding operating lease liability will be recorded.

In connection with the 2019 French Restructuring plan discussed in *Note 15: Restructuring Costs*, during the three months ended September 30, 2019, the Company came to an agreement with the landlord of the leased office space in France, to exit the lease by December 31, 2019 with an early termination payment of approximately \$820. The Company accounted for this change in the lease term as a modification of the original lease. As a result of this modification, the right-of-use asset and liability related to the French office lease that was remeasured, and the asset was subsequently tested for impairment as the fair value was less than the book value. Since the fair value was determined to be less than the book value, the Company recorded an impairment to the right of use asset of \$826, which was recorded as a restructuring cost in the unaudited condensed consolidated statements of loss.

As of September 30, 2019, our operating leases have a weighted-average remaining lease term of 4.3 years and a weighted-average discount rate of 5.3%. Nearly all of Avadel's lease contracts do not provide a readily determinable implicit rate. For these contracts, Avadel's estimated incremental borrowing rate is based on information available at the inception of the lease.

Maturities of the Company's operating lease liabilities were as follows:

| <b>Maturities:</b>                 | <b>Operating Leases</b> |
|------------------------------------|-------------------------|
| Remaining three months of 2019     | \$ 1,117                |
| 2020                               | 879                     |
| 2021                               | 670                     |
| 2022                               | 678                     |
| 2023                               | 690                     |
| Thereafter                         | 941                     |
| Total lease payments               | 4,975                   |
| Less: interest                     | 513                     |
| Present value of lease liabilities | <u>\$ 4,462</u>         |

Under the prior lease guidance, minimum rental commitments for non-cancelable leases as of December 31, 2018 were:

| <b>Lease Commitment:</b>     | <b>Operating Leases</b> |
|------------------------------|-------------------------|
| 2019                         | \$ 1,191                |
| 2020                         | 1,208                   |
| 2021                         | 1,008                   |
| 2022                         | 767                     |
| 2023                         | 695                     |
| Thereafter                   | 967                     |
| Total minimum lease payments | <u>\$ 5,836</u>         |

**NOTE 10: Long-Term Related Party Payable**

Long-term related party payable and related activity are reported at fair value and consist of the following at September 30, 2019 and December 31, 2018:

| Long-Term Related Party Payable:              | Balance,<br>December 31,<br>2018 | Activity during the Nine Months Ended<br>September 30, 2019 |   |                  | Balance,<br>September 30,<br>2019 |
|---|----------------------------------|---|---|------------------|-----------------------------------|
|   |                                  | Payments to<br>Related Parties                              | Changes in Fair Value of Related<br>Party Payable |                  |                                   |
|   |                                  |   | Operating<br>Expense                              | Other<br>Expense |                                   |
| Acquisition-related contingent consideration: |                                  |   |   |                  |                                   |
| Earn-out payments - Éclat Pharmaceuticals (a) | \$ 25,615                        | \$ (8,640)  | \$ 2,384  | \$ —             | \$ 19,359                         |
| Financing-related:                            |                                  |   |   |                  |                                   |
| Royalty agreement - Deerfield (b)             | 2,184                            | (930)   | —   | 330              | 1,584                             |
| Royalty agreement - Broadfin (c)              | 1,041                            | (444)   | —   | 166              | 763                               |
| Total related party payable                   | 28,840                           | \$ (10,014)   | \$ 2,384  | \$ 496           | 21,706                            |
| Less: current portion                         | (9,439)                          |   |   |                  | (7,588)                           |
| Total long-term related party payable         | \$ 19,401                        |   |   |                  | \$ 14,118                         |

Long-term related party payable and related activity are reported at fair value and consist of the following at September 30, 2019 and June 30, 2019:

| Long-Term Related Party Payable:              | Balance,<br>June 30, 2019 | Activity during the Three Months Ended<br>September 30, 2019 |   |                  | Balance,<br>September 30,<br>2019 |
|---|---------------------------|--|---|------------------|-----------------------------------|
|   |                           | Payments to<br>Related Parties                               | Changes in Fair Value of Related<br>Party Payable |                  |                                   |
|   |                           |  | Operating<br>Expense                              | Other<br>Expense |                                   |
| Acquisition-related contingent consideration: |                           |  |   |                  |                                   |
| Earn-out payments - Éclat Pharmaceuticals (a) | \$ 21,582                 | \$ (2,850)   | \$ 627  | \$ —             | \$ 19,359                         |
| Financing-related:                            |                           |  |   |                  |                                   |
| Royalty agreement - Deerfield (b)             | 1,799                     | (309)  | —   | 94               | 1,584                             |
| Royalty agreement - Broadfin (c)              | 866                       | (148)  | —   | 45               | 763                               |
| Total related party payable                   | 24,247                    | \$ (3,307)   | \$ 627  | \$ 139           | 21,706                            |
| Less: current portion                         | (8,264)                   |  |   |                  | (7,588)                           |
| Total long-term related party payable         | \$ 15,983                 |  |   |                  | \$ 14,118                         |

- (a) In March 2012, the Company acquired all of the membership interests of Éclat from Breaking Stick Holdings, L.L.C. (“Breaking Stick”, formerly Éclat Holdings), an affiliate of Deerfield. Breaking Stick is majority owned by Deerfield, with a minority interest owned by the Company’s former CEO, and certain other current and former employees. As part of the consideration, the Company committed to provide quarterly earn-out payments equal to 20% of any gross profit generated by certain Éclat products. These payments will continue in perpetuity, to the extent gross profit of the related products also continue in perpetuity.
- (b) As part of a February 2013 debt financing transaction conducted with Deerfield, the Company received cash of \$2,600 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 1.75% royalty on the net sales of certain Éclat products until December 31, 2024. In connection with such debt financing transaction, the Company granted Deerfield a security interest in the product registration rights of the Eclat products.
- (c) As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund, a related party and current shareholder, the Company received cash of \$2,200 in exchange for entering into a royalty agreement whereby the Company shall pay quarterly a 0.834% royalty on the net sales of certain Éclat products until December 31, 2024.

At September 30, 2019, the fair value of each related party payable listed in (a), (b) and (c) above was estimated using a discounted cash flow model based on estimated and projected annual net revenues or gross profit, as appropriate, of each of the specified Éclat products using an appropriate risk-adjusted discount rate of 15%. These fair value measurements are based on significant inputs not observable in the market and thus represent a level 3 measurement as defined in ASC 820. Subsequent changes in the fair value of the acquisition-related related party payables, resulting primarily from management’s revision of key assumptions, will be recorded in the unaudited condensed consolidated statements of loss in the line items entitled “Changes in fair value of related party contingent consideration” for items noted in (b) above and in “Other expense - changes in fair value of related party payable” for items (b) and (c) above. See *Note 1: Summary of Significant Accounting Policies* under the caption Acquisition-related Contingent Consideration and Financing-related Royalty Agreements in Part II, Item 8 of the Company’s 2018 Annual Report on Form 10-K for more information on key assumptions used to determine the fair value of these liabilities.

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

The following table summarizes changes to the related party payables, a recurring Level 3 measurement, for the nine-month periods ended September 30, 2019 and 2018, respectively:

| <b>Related Party Payable Rollforward:</b> | <b>Balance</b> |          |
|---|----------------|----------|
| Balance, December 31, 2017                | \$             | 98,925   |
| Payments of related party payable         |                | (19,261) |
| Fair value adjustments <sup>(1)</sup>     |                | (18,468) |
| Expiration of warrants                    |                | (2,167)  |
| Disposition of the pediatric assets       |                | (20,337) |
| Balance, September 30, 2018               | \$             | 38,692   |
| Balance, December 31, 2018                | \$             | 28,840   |
| Payments of related party payable         |                | (10,014) |
| Fair value adjustments <sup>(1)</sup>     |                | 2,880    |
| Balance, September 30, 2019               | \$             | 21,706   |

<sup>(1)</sup> Fair value adjustments are reported as changes in fair value of related party contingent consideration and other expense - changes in fair value of related party payable in the unaudited condensed consolidated statements of loss.

#### **NOTE 11: Long-Term Debt**

Long-term debt is summarized as follows:

|   | September 30, 2019 |          | December 31, 2018 |          |
|---|--------------------|----------|-------------------|----------|
| Principal amount of 4.50% exchangeable senior notes due 2023  | \$                 | 143,750  | \$                | 143,750  |
| Less: debt discount and issuance costs, net                   |                    | (23,618) |                   | (28,059) |
| Net carrying amount of liability component                    |                    | 120,132  |                   | 115,691  |
| Other debt  |                    | 35       |                   | 149      |
| Subtotal  |                    | 120,167  |                   | 115,840  |
| Less: current maturities                                      |                    | (35)     |                   | (106)    |
| Long-term debt  | \$                 | 120,132  | \$                | 115,734  |
| Equity component:   |                    |          |                   |          |
| Equity component of exchangeable notes, net of issuance costs | \$                 | (26,699) | \$                | (26,699) |

**NOTE 12: Income Taxes**

The components of loss before income taxes are as follows:

| <b>Loss Before Income Taxes:</b> | <b>Three Months Ended September 30,</b> |                    | <b>Nine Months Ended September 30,</b> |                    |
|----------------------------------|---|--------------------|--|--------------------|
|                                  | <b>2019</b>                             | <b>2018</b>        | <b>2019</b>                            | <b>2018</b>        |
| Ireland                          | \$ (14,302)                             | \$ (18,314)        | \$ (36,625)                            | \$ (34,203)        |
| United States                    | 5,952                                   | 1,773              | 12,309                                 | (1,043)            |
| France                           | 1,720                                   | 79                 | (2,530)                                | 441                |
| Total loss before income taxes   | <u>\$ (6,630)</u>                       | <u>\$ (16,462)</u> | <u>\$ (26,846)</u>                     | <u>\$ (34,805)</u> |

The items accounting for the difference between the income tax provision computed at the statutory rate and the Company's effective tax rate are as follows:

| <b>Income Tax Rate Reconciliation:</b>                         | <b>Three Months Ended September 30,</b> |                 | <b>Nine Months Ended September 30,</b> |                   |
|--|---|-----------------|--|-------------------|
|  | <b>2019</b>                             | <b>2018</b>     | <b>2019</b>                            | <b>2018</b>       |
| Statutory tax rate   | 12.5 %                                  | 12.5 %          | 12.5 %                                 | 12.5 %            |
| International tax rates differential                           | (4.3)%                                  | 7.0 %           | 4.1 %                                  | 6.9 %             |
| Change in valuation allowance                                  | (31.1)%                                 | (18.3)%         | (27.0)%                                | (14.9)%           |
| Change in fair value of nondeductible contingent consideration | 4.1 %                                   | 8.7 %           | (0.1)%                                 | 9.9 %             |
| Nondeductible stock-based compensation                         | — %                                     | (3.5)%          | (0.2)%                                 | (2.6)%            |
| Unrecognized tax benefits                                      | (8.8)%                                  | (3.5)%          | (3.3)%                                 | (3.1)%            |
| State and local income taxes, net of federal                   | (0.2)%                                  | 0.1 %           | (0.2)%                                 | 0.2 %             |
| Nondeductible interest expense                                 | (4.5)%                                  | — %             | (2.6)%                                 | — %               |
| Other  | (1.3)%                                  | 1.2 %           | 3.1 %                                  | 0.8 %             |
| Effective income tax rate                                      | <u>(33.6)%</u>                          | <u>4.2 %</u>    | <u>(13.7)%</u>                         | <u>9.7 %</u>      |
| Income tax benefit - at statutory tax rate                     | \$ (829)                                | \$ (2,058)      | \$ (3,355)                             | \$ (4,351)        |
| International tax rates differential                           | 283                                     | (1,153)         | (1,108)                                | (2,394)           |
| Change in valuation allowance                                  | 2,059                                   | 3,007           | 7,242                                  | 5,188             |
| Change in fair value of nondeductible contingent consideration | (270)                                   | (1,431)         | 33                                     | (3,436)           |
| Nondeductible stock-based compensation                         | 1                                       | 578             | 50                                     | 914               |
| Unrecognized tax benefits                                      | 581                                     | 578             | 873                                    | 1,086             |
| State and local income taxes, net of federal                   | 14                                      | (13)            | 41                                     | (70)              |
| Nondeductible interest expense                                 | 299                                     | —               | 709                                    | —                 |
| Other  | 96                                      | (199)           | (844)                                  | (297)             |
| Income tax provision (benefit) - at effective income tax rate  | <u>\$ 2,234</u>                         | <u>\$ (691)</u> | <u>\$ 3,641</u>                        | <u>\$ (3,360)</u> |

The income tax provision was \$2,234 for the three months ended September 30, 2019 and a benefit of \$691 for the three months ended September 30, 2018. The increase in the income tax provision for the three months ended September 30, 2019 is primarily the result of a decrease in the amount of nontaxable gain from the revaluation of contingent consideration and an increase in the amount of valuation allowances recorded on foreign income tax losses.

The income tax provision was \$3,641 for the nine months ended September 30, 2019 and a benefit of \$3,360 for the nine months ended September 30, 2018. The increase in the income tax provision for the nine months ended September 30, 2019 is primarily the result of a decrease the amount of nontaxable gain from the revaluation of contingent consideration and an increase in the amount of valuation allowances recorded on foreign income tax losses.

The IRS commenced an examination of the Company's U.S. income tax returns for 2016 and 2017 during the second quarter 2019.

**NOTE 13: Other Assets and Liabilities**

Various other assets and liabilities are summarized as follows:

| <b>Prepaid Expenses and Other Current Assets:</b> | <b>September 30, 2019</b> | <b>December 31, 2018</b> |
|---|---------------------------|--------------------------|
| Valued-added tax recoverable                      | \$ 807                    | \$ 1,378                 |
| Prepaid and other expenses                        | 2,757                     | 2,145                    |
| Guarantee from Armistice (see Note 14)            | 560                       | 534                      |
| Income tax receivable                             | 594                       | 921                      |
| Research and development tax credit receivable    | 270                       | 283                      |
| Short-term deposit                                | —                         | 3,350                    |
| Other   | 175                       | 225                      |
| <b>Total</b>                                      | <b>\$ 5,163</b>           | <b>\$ 8,836</b>          |

| <b>Other Non-Current Assets:</b>                            | <b>September 30, 2019</b> | <b>December 31, 2018</b> |
|---|---------------------------|--------------------------|
| Deferred tax assets, net                                    | \$ 21,636                 | \$ 23,029                |
| Long-term deposits  | 1,477                     | 1,477                    |
| Guarantee from Armistice (see Note 14)                      | 5,271                     | 5,697                    |
| Right of use assets at contract manufacturing organizations | 6,494                     | 5,894                    |
| Other   | 49                        | 49                       |
| <b>Total</b>  | <b>\$ 34,927</b>          | <b>\$ 36,146</b>         |

| <b>Accrued Expenses</b>                                 | <b>September 30, 2019</b> | <b>December 31, 2018</b> |
|---|---------------------------|--------------------------|
| Accrued compensation                                    | \$ 2,322                  | \$ 3,971                 |
| Accrued social charges                                  | 482                       | 1,009                    |
| Accrued restructuring (see Note 15)                     | 1,737                     | 879                      |
| Customer allowances                                     | 6,244                     | 6,541                    |
| Accrued contract research organization charges          | 3,389                     | 1,000                    |
| Accrued contract manufacturing organization costs       | 1,284                     | 2,028                    |
| Accrued contract sales organization and marketing costs | —                         | 3,469                    |
| Other   | 1,559                     | 2,798                    |
| <b>Total</b>  | <b>\$ 17,017</b>          | <b>\$ 21,695</b>         |

| <b>Other Non-Current Liabilities:</b> | <b>September 30, 2019</b> | <b>December 31, 2018</b> |
|---------------------------------------|---------------------------|--------------------------|
| Provision for retirement indemnity    | \$ —                      | \$ 1,024                 |
| Customer allowances                   | 923                       | 1,352                    |
| Unrecognized tax benefits             | 7,717                     | 5,315                    |
| Guarantee to Deerfield (see Note 14)  | 5,289                     | 5,717                    |
| Other                                 | 43                        | 594                      |
| <b>Total</b>                          | <b>\$ 13,972</b>          | <b>\$ 14,002</b>         |

**14: Divestiture of the Pediatric Assets**

On February 12, 2018, the Company, together with its subsidiaries Avadel Pharmaceuticals (USA), Inc., Avadel Pediatrics, Inc., FSC Therapeutics, LLC (“FSC Therapeutics”), and Avadel US Holdings, Inc. (“Holdings”), as the “Sellers,” entered into an asset purchase agreement (the “Purchase Agreement”) with Cerecor, Inc. (“Cerecor”). The transaction closed on February 16, 2018 wherein Cerecor purchased from the Sellers four pediatric commercial stage assets – Karbinal™ ER, Cefaclor, Flexichamber™ and AcipHex® Sprinkle™, together with certain associated business assets – which were held by FSC. The Company acquired FSC in February 2016 from Deerfield and certain of its affiliates. Pursuant to the Purchase Agreement, Cerecor assumed the Company’s remaining payment obligations to Deerfield under the Membership Interest Purchase Agreement, dated as of February

5, 2016, between Holdings, Flamel Technologies SA (the predecessor of the Company) and Deerfield and certain of its affiliates, which payment obligations consist of the following (collectively, the “Assumed Obligations”): (i) a quarterly payment of \$263 beginning in July 2018 and ending in October 2020, amounting to an aggregate payment obligation of \$2,625; (ii) a payment in January 2021 of \$15,263; and (iii) a quarterly royalty payment of 15% on net sales of the FSC products through February 5, 2026 (“FSC Product Royalties”), in an aggregate amount of up to approximately \$10,300. Cerecor also assumed certain contracts and other obligations related to the acquired assets, and in that connection Holdings agreed to pay Cerecor certain make-whole payments associated with obligations Cerecor is assuming related to a certain supply contract related to Karbinal™ ER.

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

#### *License and Development Agreement*

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

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

Effective October 25, 2019, Cerecor and Avadel Ireland agreed to terminate the License and Development Agreement.

#### *Deerfield Guarantee*

In connection with the closing under the Purchase Agreement, the Company and Holdings provided their guarantee (the “Deerfield Guarantee”) in favor of Deerfield. Under the Deerfield Guarantee, the Company and Holdings guaranteed to Deerfield the payment by Cerecor of the Assumed Obligations under the Membership Interest Purchase Agreement between the Company and Deerfield dated February 5, 2016. The Assumed Obligations include (i) a quarterly payment of \$263 beginning in July 2018 and ending in October 2020, amounting to an aggregate payment obligation of \$2,625; (ii) a payment in January 2021 of \$15,263; and (iii) a quarterly royalty payment of 15% on net sales of the FSC products through February 6, 2026 (“FSC Product Royalties”), in an aggregate amount of up to approximately \$10,300. In addition, under the Deerfield Guarantee, the Company and Holdings guaranteed that Deerfield would receive certain minimum annual FSC Product Royalties through February 6, 2026 (the “Minimum Royalties”). Given the Company’s explicit guarantee to Deerfield, the Company recorded the guarantee in accordance with ASC 460. A valuation was performed, which was based largely on an analysis of the potential timing of each possible cash outflow described above and the likelihood of Cerecor’s default on such payments assuming an S&P credit rating of CCC+. The result of this valuation identified a guarantee liability of \$6,643. This liability is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield. At September 30, 2019, the carrying value of this liability was \$5,851.

#### *Armistice Guarantee*

In connection with the closing under the Purchase Agreement, Armistice Capital Master Fund, Ltd., the then majority shareholder of Cerecor, guaranteed to Holdings the payment by Cerecor of the Assumed Obligations, including the Minimum Royalties. A valuation of the guarantee asset was performed in accordance with ASC 460 and a guarantee asset of \$6,620 was recorded. This asset is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield noted above. At September 30, 2019, the carrying value of this asset was \$5,831.

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



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

#### *Recent Updates to Guarantees*

On October 10, 2019 Cerecor entered into a purchase and sale agreement with a Aytu BioScience, Inc (“Buyer”) pursuant to which the Buyer will purchase certain assets from Cerecor and assume certain of Cerecor’s liabilities, including all of Cerecor’s liabilities assumed as part of the Purchase Agreement noted above. As part of this transaction, on November 1, 2019, Armistice has agreed to deposit \$15,000 in an escrow account governed by an escrow agreement between Armistice and Deerfield having the purpose of securing the \$15,000 balloon payment due January 2021 as part of the Membership Interest Purchase Agreement. As part of the Cerecor transaction with the buyer, Deerfield contractually acknowledges and agrees that they will seek payment from the escrow funds before requesting payment from the Company pursuant to the Deerfield Guarantee discussed above. As a result, the Company is in process of assessing the impact this escrow deposit has on the fair values of the guarantees and will adjust such carrying values in the quarter ending December 31, 2019.

The net impact of this transaction was not material to the unaudited condensed consolidated statements of loss.

#### **NOTE 15: Restructuring Costs**

##### *2019 French Restructuring*

During the second quarter of 2019, the Company initiated a plan to substantially reduce all of its workforce at its Vénissieux, France site (“2019 French Restructuring”). This reduction is an effort to align the Group’s cost structure with our ongoing and future planned projects. The reduction in workforce is projected to be substantially complete by the end of calendar year 2019, and to result in employee severance, benefits and other costs of up to approximately \$3,500, which are likely to be recognized through December 31, 2019. Restructuring charges associated with this plan of \$1,259 and \$3,198 were recognized during the three and nine months ended September 30, 2019. Included in the 2019 French Restructuring charges of \$3,198 were charges for employee severance, benefits and other costs of \$2,774, a charge of \$598 related to fixed asset impairment, a charge of \$826 related to the early termination penalty related to the office lease termination (see *Note 9: Leases*) as well as a benefit of \$1,000 related to the reversal of the French retirement indemnity obligation.

The following table sets forth activities for the Company’s cost reduction plan obligations for the three and nine months ended September 30, 2019:

| <b>2019 French Restructuring Obligation:</b>             | <b>2019</b>   |
|--|---------------|
| Balance of restructuring accrual at January 1,           | \$ —          |
| Charges for employee severance, benefits and other costs | 2,774         |
| Payments   | (1,837)       |
| Foreign currency impact                                  | (42)          |
| Balance of restructuring accrual at September 30,        | <u>\$ 895</u> |

The 2019 French Restructuring liabilities of \$884 and \$11 are included in the unaudited condensed consolidated balance sheet in accrued expenses and accounts payable at September 30, 2019, respectively.

##### *2019 Corporate Restructuring*

During the first quarter of 2019, the Company announced a plan to reduce its Corporate workforce by more than 50% (“2019 Corporate Restructuring”). The reduction in workforce is primarily a result of the exit of Noctiva during the first quarter of 2019 (see *Note 3: Subsidiary Bankruptcy and Deconsolidation*), as well as an effort to better align the Company’s remaining cost structure at our U.S. and Ireland locations with our ongoing and future planned projects. The reduction in workforce is projected to be substantially complete by the end of calendar year 2019, and to result in employee severance, benefits and other costs of up to approximately \$3,000, which are likely to be recognized through December 31, 2019. The restructuring charges associated with this plan of \$607 and \$1,570 were recognized during the three and nine months ended September 30, 2019, respectively. Included in the 2019 Corporate Restructuring expense of \$607 for the three months ended September 30, 2019 were charges for employee severance, benefit and other costs. Included in the 2019 Corporate Restructuring charges of \$1,570 for the nine months

ended September 30, 2019, were charges for employee severance, benefit and other costs of \$2,966, as well as a benefit of \$1,396 related to share based compensation forfeitures related to the employees affected by the global reduction in workforce.

The following table sets forth activities for the Company's cost reduction plan obligations for the nine months ended September 30, 2019:

| <b>2019 Corporate Restructuring Obligation:</b>          | <b>2019</b> |         |
|--|-------------|---------|
| Balance of restructuring accrual at January 1,           | \$          | —       |
| Charges for employee severance, benefits and other costs |             | 2,966   |
| Payments   |             | (2,113) |
| Balance of restructuring accrual at September 30,        | \$          | 853     |

2019 Corporate Restructuring liabilities of \$853 are included in the unaudited condensed consolidated balance sheet in accrued expenses at September 30, 2019.

#### *2017 French Restructuring*

During the first quarter of 2017, the Company announced a plan to reduce its workforce at the Venissieux, France site by approximately 50% ("2017 French Restructuring"). This reduction was an effort to align the Company's cost structure with our ongoing and future planned projects. In July 2017, the Company completed negotiations with the works council for our French operations and received approval from the French Labor Commission (DIRECCTE) to implement the plan. The reduction was substantially complete at September 30, 2019. The 2017 French restructuring costs for the three months ended September 30, 2019 and 2018 were immaterial. The 2017 French Restructuring income of \$168 and restructuring charges of \$268 were recognized during the nine months ended September 30, 2019 and 2018, respectively. The following table sets forth activities for the Company's cost reduction plan obligations for the nine months ended September 30, 2019 and 2018:

| <b>2017 French Restructuring Obligation:</b>       | <b>2019</b> |       | <b>2018</b> |       |
|--|-------------|-------|-------------|-------|
| Balance of restructuring accrual at January 1,     | \$          | 879   | \$          | 1,000 |
| Charges for employee severance, benefits and other |             | (168) |             | 268   |
| Payments   |             | (663) |             | (668) |
| Foreign currency impact                            |             | (10)  |             | (19)  |
| Balance of restructuring accrual at September 30,  | \$          | 38    | \$          | 581   |

The 2017 French Restructuring accrual is included in the unaudited condensed consolidated balance sheet in other non-current liabilities at September 30, 2019 and 2018.

#### **NOTE 16: Net Loss Per Share**

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding during each period. Diluted net (loss) income per share is calculated by dividing net (loss) income by the diluted number of shares outstanding during each period. Except where the result would be anti-dilutive to net loss, diluted net loss per share would be calculated assuming the impact of the conversion of the 2023 Notes, the exercise of outstanding equity compensation awards, ordinary shares expected to be issued under our employee stock purchase plan ("ESPP") and the exercise of contingent consideration warrants, all which have been exercised or have expired during the first quarter of 2018.

We have a choice to settle the conversion obligation under the 2023 Notes in cash, shares or any combination of the two. We utilize the if-converted method to reflect the impact of the conversion of the 2023 Notes, unless the result is anti-dilutive. This method assumes the conversion of the 2023 Notes into shares of our ordinary shares and reflects the elimination of the interest expense related to the 2023 Notes.

The dilutive effect of the warrants, stock options, RSU's and ordinary shares expected to be issued under or ESPP has been calculated using the treasury stock method.

A reconciliation of basic and diluted net loss per share, together with the related shares outstanding in thousands is as follows:

| Net Loss Per Share:  | Three Months Ended September 30, |             | Nine Months Ended September 30, |             |
|--|----------------------------------|-------------|---------------------------------|-------------|
|  | 2019                             | 2018        | 2019                            | 2018        |
| Net loss   | \$ (8,864)                       | \$ (15,771) | \$ (30,487)                     | \$ (31,445) |
| Weighted average shares:   |                                  |             |                                 |             |
| Basic shares   | 37,436                           | 36,904      | 37,382                          | 37,410      |
| Effect of dilutive securities—employee and director equity awards outstanding and 2023 Notes | —                                | —           | —                               | —           |
| Diluted shares   | 37,436                           | 36,904      | 37,382                          | 37,410      |
| Net loss per share - basic   | \$ (0.24)                        | \$ (0.43)   | \$ (0.82)                       | \$ (0.84)   |
| Net loss per share - diluted   | \$ (0.24)                        | \$ (0.43)   | \$ (0.82)                       | \$ (0.84)   |

Potential common shares of 19,544 and 18,742 were excluded from the calculation of weighted average shares for the three months ended September 30, 2019 and 2018, respectively, because their effect was considered to be anti-dilutive. Potential common shares of 20,512 and 16,647 were excluded from the calculation of weighted average shares for the nine months ended September 30, 2019 and 2018, respectively. For the three and nine months ended September 30, 2019 and 2018, the effects of dilutive securities were entirely excluded from the calculation of net loss per share as a net loss was reported in this period.

#### NOTE 17: Comprehensive Loss

The following table shows the components of accumulated other comprehensive loss for the three and nine months ended September 30, 2019 and 2018, respectively, net of tax effects:

| Accumulated Other Comprehensive Loss:  | Three Months Ended September 30, |             | Nine Months Ended September 30, |             |
|--|----------------------------------|-------------|---------------------------------|-------------|
|  | 2019                             | 2018        | 2019                            | 2018        |
| Foreign currency translation adjustment:   |                                  |             |                                 |             |
| Beginning balance  | \$ (23,720)                      | \$ (23,435) | \$ (23,621)                     | \$ (23,202) |
| Net other comprehensive loss   | (210)                            | (60)        | (309)                           | (293)       |
| Balance at September 30,   | \$ (23,930)                      | \$ (23,495) | \$ (23,930)                     | \$ (23,495) |
| Unrealized gain (loss) on marketable debt securities, net  |                                  |             |                                 |             |
| Beginning balance  | \$ 872                           | \$ (224)    | \$ 205                          | \$ (64)     |
| Net other comprehensive income (loss), net of (\$5), (\$18), (\$46) and (\$88) tax, respectively | 86                               | 68          | 753                             | (92)        |
| Balance at September 30,   | \$ 958                           | \$ (156)    | \$ 958                          | \$ (156)    |
| Accumulated other comprehensive loss at September 30,  | \$ (22,972)                      | \$ (23,651) | \$ (22,972)                     | \$ (23,651) |

The effect on the Company's unaudited condensed consolidated financial statements of amounts reclassified out of accumulated other comprehensive loss was immaterial for all periods presented.

#### NOTE 18: Revenue by Product

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

The following table presents a summary of total revenues by these products:

| Revenues by Product: | Three Months Ended September 30, |           | Nine Months Ended September 30, |           |
|----------------------|----------------------------------|-----------|---------------------------------|-----------|
|                      | 2019                             | 2018      | 2019                            | 2018      |
| Bloxiverz            | \$ 1,466                         | \$ 3,656  | \$ 6,392                        | \$ 16,691 |
| Vazculep             | 8,786                            | 8,759     | 27,669                          | 33,097    |
| Akovaz               | 4,208                            | 5,991     | 13,946                          | 28,083    |
| Other                | (231)                            | 1,420     | 213                             | 4,232     |
| Total product sales  | 14,229                           | 19,826    | 48,220                          | 82,103    |
| License revenue      | —                                | —         | —                               | 246       |
| Total revenues       | \$ 14,229                        | \$ 19,826 | \$ 48,220                       | \$ 82,349 |

**NOTE 19: Commitments and Contingencies**

**Litigation**

The Company is subject to potential liabilities generally incidental to our business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At September 30, 2019 and December 31, 2018, there were no contingent liabilities with respect to any litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Company's unaudited condensed consolidated financial position, results of operations, cash flows or liquidity.

Litigation Related to Noctiva

*Note 3: Subsidiary Bankruptcy and Deconsolidation* briefly describes the Chapter 11 bankruptcy case which our subsidiary Specialty Pharma commenced on February 6, 2019, and which on April 26, 2019 resulted in the bankruptcy court-approved sale of all of Specialty Pharma's intangible assets and inventory to an unaffiliated third party. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business. During the pendency of the bankruptcy case, all pending litigation against Specialty Pharma is automatically stayed and any new litigation against Specialty Pharma is precluded unless the bankruptcy court orders otherwise. Below are descriptions of a litigation to which Specialty Pharma is a party and a contract dispute involving Specialty Pharma, both of which matters are subject to the automatic stay during the bankruptcy case.

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

*Contract Dispute.* On January 21, 2019, Serenity gave notice to Specialty Pharma of an alleged breach of the parties' Noctiva license agreement. Serenity alleges that Specialty Pharma breached its contractual obligation to devote commercially reasonable efforts to the commercialization of Noctiva and seeks unspecified damages. On January 27, 2019, Specialty Pharma notified Serenity of a claim for \$1.7 million in damages as a result of Serenity's breach of its contractual obligation to pay the costs of the Ferring Litigation. Serenity's notice to Specialty Pharma invoked the dispute resolution provisions of the Noctiva license agreement, which culminate in arbitration, but neither party has yet initiated an arbitration proceeding or filed suit.

### **Material Commitments**

Due to the Chapter 11 bankruptcy case of Specialty Pharma, the Company's various commitments to purchase finished product from suppliers has changed from what was included in Part II, Item 8 of the Company's 2018 Annual Report on Form 10-K. As of September 30, 2019, commitments for these arrangements, at maximum quantities and at contractual prices over the remaining life of the contract, and excluding any waived commitments, are as follows for the years ended December 31:

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

Other than commitments disclosed in *Note 15: Contingent Liabilities and Commitments* to the Company's audited consolidated financial statements included in Part II, Item 8 of the Company's 2018 Annual Report on Form 10-K, 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 obligations which are disclosed in *Note 10: Long-Term Debt*, respectively, to the Company's consolidated financial statements included in Part II, Item 8 of the Company's 2018 Annual Report on Form 10-K and long-term contingent consideration payable as disclosed in *Note 10: Long-Term Related Party Payable*, to the Company's unaudited condensed consolidated financial statements included in Part I, Item 1 of this report.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Management's Discussion and Analysis

(In thousands, except per share data)

(Unaudited)

*You should read the discussion and analysis of our financial condition and results of operations set forth in this Item 2 together with our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this quarterly report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties, and reference is made to the "Cautionary Note Regarding Forward-Looking Statements" set forth immediately following the Table of Contents of this Quarterly Report on Form 10-Q for further information on the forward looking statements herein. In addition, you should read the "Risk Factors" section in Part I, Item 1A of our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 15, 2019 and Part II, Item 1A in this quarterly report on Form 10-Q for a discussion of additional important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this quarterly report.*

#### Overview

##### **General Overview**

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

Avadel is developing FT218, an investigational once-nightly formulation of sodium oxybate based on its propriety Micropump® drug delivery technology, for the treatment of EDS and cataplexy in patients suffering from narcolepsy. FT218 is currently being evaluated in a Phase 3 clinical trial called REST-ON. In addition, the Company submitted a new drug application ("NDA") in March 2019 on a fourth sterile injectable drug which we refer to as AV001, for use in the hospital setting. AV001, if approved, could contribute revenues to Avadel starting in 2020. In May 2019, the FDA accepted the NDA for AV001, with a Prescription Drug User Fee Act (PDUFA) target action date of December 15, 2019.

Our current marketed products include:

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

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

##### **Business Strategies**

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

**FT218 (Micropump® sodium oxybate):** FT218 (Micropump® sodium oxybate): Avadel is developing a product that uses our Micropump® drug-delivery technology for the treatment of EDS and cataplexy in patients suffering from narcolepsy. Avadel

currently refers to this product as FT218. FT218 is a Micropump®-based formulation of sodium oxybate. Sodium oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid. Sodium oxybate has been described as a therapeutic agent with high medical value. Sodium oxybate is approved in Europe and the United States as a twice nightly formulation indicated for the treatment of EDS and cataplexy in patients with narcolepsy.

In preparation for a clinical trial of FT218, Avadel reached an agreement with the FDA for the design and planned analysis of our pivotal Phase 3 study, Rest-On through a Special Protocol Assessment (“SPA”). A SPA is an acknowledgment by the FDA that the design and planned analysis of a pivotal clinical trial adequately addresses the objectives necessary to support a regulatory submission. Pursuant to the SPA, in December 2016, Avadel initiated patient enrollment and dosing for the Rest-On clinical trial to assess the safety and efficacy of a once-nightly formulation of FT218 for the treatment of EDS and cataplexy in patients suffering from narcolepsy. The study is a randomized, double-blind, placebo-controlled study of 264 patients being conducted in 45 to 55 clinical sites in the U.S., Canada, Western Europe and Australia. Avadel believes that, if successful, this study could demonstrate improved efficacy, safety and patient satisfaction over the current primary product serving this market, which is a twice nightly sodium oxybate formulation, for which the marketer has forecasted revenues of approximately \$1.6 billion for the year ended December 31, 2019.

In September 2019, the Company announced that the FDA agreed to the Company’s proposed amendments to the statistical analysis plan and protocol under its SPA for FT218, resulting in a lower sample size needed to demonstrate significance for both excessive daytime sleepiness and cataplexy in narcolepsy patients. No modifications were made to the fundamental design of the study, including the primary or secondary endpoints, dosing scheme or duration of the study, and the SPA remains intact. The study will now target enrolling 205 patients. Based on this updated target size and current enrollment, the Company expects to complete enrollment by the end of 2019 and have topline data in the second quarter of 2020.

In January 2018, the FDA granted FT218 Orphan Drug Designation, which makes the drug eligible for certain development and commercial incentives, including a potential U.S. market exclusivity for up to seven years as the only once-nightly formulation. However, please see the information set forth under the caption “- Risks Related to Regulatory and Legal Matters - If FT218 is approved by the FDA, we may not obtain orphan drug marketing exclusivity” in the “Risk Factors” included in Part I, Item 1A of the Company’s Annual Report on Form 10-K filed with the SEC on March 15, 2019.

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

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

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

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

To date, Avadel has received FDA approvals for three UMD products which we currently market under the brand names *Bloxiverz*® (neostigmine methylsulfate injection), *Vazculep*® (phenylephrine hydrochloride injection) and *Akovaz*® (ephedrine sulfate injection).

*Additional UMD Products.* Avadel is developing and intends to seek FDA approval of an NDA for AV001, a sterile injectable product for use in the hospital setting. If the NDA is approved, AV001 could contribute revenues to Avadel starting in 2020. The Company submitted the NDA in March 2019, and it was originally granted Priority Review status by the FDA resulting in a six-month review period with an initial assigned PDUFA target date of September 15, 2019. However, on July 31, 2019, the Company received notification that the FDA extended the PDUFA date to December 15, 2019. This extension relates to recent submissions the Company made in response to FDA requests for additional analytical information. The FDA determined that these submissions constitute a major amendment and will require additional time to review. The Company believes that this three-month extension

should not impact the launch timeline, which is still anticipated for early 2020. In addition, Avadel continues to monitor and evaluate other UMDs with large existing markets and limited competition for feasibility of possible future NDAs. Avadel believes its strategy to create opportunities to commercialize UMD products in markets with a limited number of competitors may have a limited number of opportunities given the lack of patent protection from competition. Avadel believes this shorter-term strategy may provide us with near term revenue growth and provide cash flows that can be used to fund R&D and inorganic initiatives for the development of FT218 and, perhaps, other products.

### **Corporate Information**

The Company was incorporated on December 1, 2015 as an Irish private limited company, and re-registered as an Irish public limited company, or plc, on November 21, 2016. Our principal place of business is located at Block 10-1, Blanchardstown Corporate Park, Ballycoolin, Dublin 15, Ireland. Avadel's phone number is 011-353-1-485-1200. Our website is [www.avadel.com](http://www.avadel.com), where we make available free of charge our reports (and any amendments thereto) on Forms 10-K, 10-Q and 8-K as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission ("SEC"). These filings are also available to the public at [www.sec.gov](http://www.sec.gov).

The Company is the successor to Flamel Technologies S.A., a French *société anonyme* ("Flamel"), as the result of the France-to-Ireland redomestication merger of Flamel with and into the Company completed on December 31, 2016 (the "Merger"). In the Merger, we changed our company name to Avadel Pharmaceuticals plc and our jurisdiction of organization to Ireland; we assumed all the assets and liabilities of Flamel; and we issued one Avadel ordinary share (either directly or in the form of an American Depositary Share (ADS)) in exchange for each formerly outstanding share of Flamel, all of which were canceled. Thus, an Avadel ordinary share held (either directly or represented by an ADS) immediately after the Merger continued to represent the same proportional interest in our equity owned by the holder of a share of Flamel immediately prior to the Merger. References in this Annual Report on Form 10-K to "Avadel," the "Company," "we," "our," "us," and similar terms shall be deemed to be references to Flamel prior to the completion of the Merger, unless the context otherwise requires. Additional details about the Merger are set forth in Item 1 under the caption "The Reincorporation Merger" of the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2019.

The Company currently has five direct wholly-owned subsidiaries: (a) Avadel US Holdings, Inc., (b) Flamel Ireland Limited, which conducts business under the name Avadel Ireland, (c) Avadel Investment Company Limited, (d) Avadel Finance Ireland Designated Activity Company and (e) Avadel France Holding SAS. Avadel US Holdings, Inc., a Delaware corporation, is the holding entity of (i) Avadel Specialty Pharmaceuticals, LLC (currently the subject of a voluntary Chapter 11 bankruptcy proceeding as noted in *Note 3: Subsidiary Bankruptcy and Deconsolidation*), (ii) Avadel Legacy Pharmaceuticals, LLC, (iii) Avadel Management Corporation, (iv) FSC Holding Company and (v) Avadel Operations Company, Inc. Avadel Finance Ireland Designated Activity Company is the holding entity of Avadel Finance Cayman Limited. Flamel Ireland Limited (operating under the trade name Avadel Ireland) is an Irish corporation which, since December 16, 2014, has been the owner of substantially all of Avadel's intellectual property. Avadel France Holding SAS, a French *société par actions simplifiée*, is the holding entity of Avadel Research SAS through which Avadel conducts substantially all of its R&D activities.

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

### **Key Business Trends and Highlights**

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

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



- **Competition and Technological Change:** Competition in the pharmaceutical and biotechnology industry continues to be intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing niche branded or generic specialty pharmaceutical products or drug delivery platforms. Furthermore, major technological changes can happen quickly in the pharmaceutical and biotechnology industries. Such rapid technological change, or the development by our competitors of technologically improved or differentiated products, could render our drug delivery platforms obsolete or noncompetitive.
- **Pricing Environment for Pharmaceuticals:** The pricing environment continues to be in the political spotlight in the U.S. As a result, the need to obtain and maintain appropriate pricing for our products may become more challenging due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide.
- **Generics Playing a Larger Role in Healthcare:** Generic pharmaceutical products will continue to play a large role in the U.S. healthcare system. Specifically, we have seen, or likely will see, additional generic competition to our current and future products and we continue to expect generic competition in the future.
- **Access to and Cost of Capital:** The process of raising capital and associated cost of such capital for a company of our financial profile can be difficult and potentially expensive. If the need were to arise to raise additional capital, access to that capital may be difficult and/or expensive and, as a result, could create liquidity challenges for the Company.
- **Net Loss from Operations in 2019:** In part because we expect sales of our hospital products to significantly decline from 2018's levels and we will incur substantial expenses to further the clinical development of FT218, we likely will incur a net loss in 2019 the amount of which is not known to us at this time.

### **Financial Highlights**

Highlights of our consolidated results for the three and nine months ended September 30, 2019 are as follows:

- Revenue was \$14,229 and \$48,220 for the three and nine months ended September 30, 2019, respectively, compared to \$19,826 and \$82,349 in the same periods last year, respectively. This year over year decrease was primarily the result of increased competition driving lower prices as noted above in our discussion of *Key Business Trends and Highlights*. We experienced price and unit volume declines across all our hospital products due to additional competition.
- Operating loss was \$4,147 and \$16,765 for the three and nine months ended September 30, 2019, respectively, compared to operating loss of \$14,095 and \$29,505 and for the same periods last year, respectively. The decrease in operating loss for the three months ended September 30, 2019 was largely driven by lower selling, general and administrative (SG&A) expenses of \$19,513 driven by the exit of Noctiva, partially offset by higher expense related to the changes in fair value of related party contingent consideration of \$7,742 and lower gross margin of \$5,300. The primary reasons for the decrease in operating loss for the nine months ended September 30, 2019 were (i) a \$54,639 decline in SG&A expense and (ii) a \$8,083 decline in research and development expense, partially offset by (iii) a \$30,616 decline in gross margin (*i.e.*, total revenues minus cost of products) and (iv) a \$19,420 increase in expense related to the changes in fair value of related party contingent consideration.
- Net loss was \$8,864 and \$30,487 for the three and nine months ended September 30, 2019, respectively, compared to net loss of \$15,771 and \$31,445 in the same periods last year, respectively. Included in the net loss during the nine months ended September 30, 2019 was a loss on the deconsolidation of Avadel Specialty Pharmaceuticals, LLC ("Specialty Pharma") of \$2,840. As a result of Avadel Specialty Pharmaceuticals, LLC bankruptcy filing on February 6, 2019, the Company concluded that it no longer controls the operations of this subsidiary and accordingly deconsolidated this subsidiary.
- Diluted net loss per share was \$0.24 and \$0.82 for the three and nine months ended September 30, 2019, respectively, compared to diluted net loss per share of \$0.43 and \$0.84 in the same period last year, respectively.
- Cash and marketable securities decreased \$27,461 to \$72,454 at September 30, 2019, from \$99,915 at December 31, 2018. This decrease was largely driven from \$30,072 use of cash in operations.

## Critical Accounting Estimates

The Company's unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. To prepare these financial statements, management makes estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, as well as the disclosures of contingent assets and liabilities. Actual results could be significantly different from these estimates.

Our significant accounting policies are described in Note 1 of the audited consolidated financial statements included in our Annual Report Form 10-K for the year ended December 31, 2018 (the "2018 Form 10-K"). The SEC suggests companies provide additional disclosure on those accounting policies considered most critical. The SEC considers an accounting policy to be critical if it is important to our financial condition and results of operations and requires significant judgments and estimates on the part of management in its application. Our estimates are often based on complex judgments, probabilities and assumptions that management believes to be reasonable, but that are inherently uncertain and unpredictable. It is also possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range of alternative estimated amounts. For a complete discussion of our critical accounting policies, see the "Critical Accounting Policies" section of the MD&A in our 2018 Form 10-K. Effective January 1, 2019, the Company implemented ASC 842, *Leases*. The impact of adopting this new accounting standard required the Company to recognize \$5,046 and \$5,131 of assets and liabilities, respectively, related to the Company's operating leases. See *Note 9: Leases* in the notes to the unaudited condensed consolidated financial statements for further information.

## Results of Operations

The following is a summary of our financial results (in thousands, except per share amounts) for the three months ended September 30, 2019 and 2018, respectively:

| Comparative Statements of Loss  | Three Months Ended September 30, |             | Three Months Ended<br>Increase / (Decrease)<br>2019 vs. 2018 |           |
|---|----------------------------------|-------------|--|-----------|
|   | 2019                             | 2018        | \$   | %         |
|   |                                  |             |  |           |
| Product sales   | \$ 14,229                        | \$ 19,826   | \$ (5,597)   | (28.2)%   |
| Total revenues  | 14,229                           | 19,826      | (5,597)  | (28.2)%   |
| Operating expenses:   |                                  |             |  |           |
| Cost of products  | 2,823                            | 3,120       | (297)  | (9.5)%    |
| Research and development expenses                                       | 7,539                            | 11,402      | (3,863)  | (33.9)%   |
| Selling, general and administrative expenses                            | 5,316                            | 24,829      | (19,513)   | (78.6)%   |
| Intangible asset amortization   | 205                              | 1,620       | (1,415)  | (87.3)%   |
| Changes in fair value of related party contingent consideration         | 627                              | (7,115)     | 7,742  | 108.8 %   |
| Restructuring costs   | 1,866                            | 65          | 1,801  | 2,770.8 % |
| Total operating expenses  | 18,376                           | 33,921      | (15,545)   | (45.8)%   |
| Operating loss  | (4,147)                          | (14,095)    | 9,948  | 70.6 %    |
| Investment and other income, net  | 781                              | 208         | 573  | 275.5 %   |
| Interest expense  | (3,125)                          | (3,000)     | (125)  | (4.2)%    |
| Other (expense) income - changes in fair value of related party payable | (139)                            | 425         | (564)  | (132.7)%  |
| Loss before income taxes  | (6,630)                          | (16,462)    | 9,832  | 59.7 %    |
| Income tax provision (benefit)  | 2,234                            | (691)       | 2,925  | 423.3 %   |
| Net loss  | \$ (8,864)                       | \$ (15,771) | \$ 6,907   | 43.8 %    |
| Net loss per share - diluted  | \$ (0.24)                        | \$ (0.43)   | \$ 0.19  | 44.2 %    |

The following is a summary of our financial results (in thousands, except per share amounts) for the nine months ended September 30, 2019 and 2018, respectively:

| Comparative Statements of Loss  | Nine Months Ended September 30, |             | Six Months Ended<br>Increase / (Decrease) |           |
|---|---------------------------------|-------------|---|-----------|
|   | 2019                            | 2018        | 2019 vs. 2018                             |           |
|   |                                 |             | \$  | %         |
| Product sales   | \$ 48,220                       | \$ 82,103   | \$ (33,883)                               | (41.3)%   |
| License revenue   | —                               | 246         | (246)                                     | (100.0)%  |
| Total revenues  | 48,220                          | 82,349      | (34,129)                                  | (41.4)%   |
| Operating expenses:   |                                 |             |   |           |
| Cost of products  | 9,711                           | 13,224      | (3,513)                                   | (26.6)%   |
| Research and development expenses                                       | 25,160                          | 33,243      | (8,083)                                   | (24.3)%   |
| Selling, general and administrative expenses                            | 22,520                          | 77,159      | (54,639)                                  | (70.8)%   |
| Intangible asset amortization   | 610                             | 4,996       | (4,386)                                   | (87.8)%   |
| Changes in fair value of related party contingent consideration         | 2,384                           | (17,036)    | 19,420                                    | 114.0 %   |
| Restructuring costs   | 4,600                           | 268         | 4,332                                     | 1,616.4 % |
| Total operating expenses  | 64,985                          | 111,854     | (46,869)                                  | (41.9)%   |
| Operating loss  | (16,765)                        | (29,505)    | 12,740                                    | 43.2 %    |
| Investment and other income, net  | 2,548                           | 845         | 1,703                                     | 201.5 %   |
| Interest expense  | (9,293)                         | (7,577)     | (1,716)                                   | (22.6)%   |
| Loss on deconsolidation of subsidiary                                   | (2,840)                         | —           | (2,840)                                   | n/a       |
| Other (expense) income - changes in fair value of related party payable | (496)                           | 1,432       | (1,928)                                   | (134.6)%  |
| Loss before income taxes  | (26,846)                        | (34,805)    | 7,959                                     | 22.9 %    |
| Income tax provision (benefit)  | 3,641                           | (3,360)     | 7,001                                     | 208.4 %   |
| Net loss  | \$ (30,487)                     | \$ (31,445) | \$ 958                                    | 3.0 %     |
| Net loss per share - diluted  | \$ (0.82)                       | \$ (0.84)   | \$ 0.02                                   | 2.4 %     |

The revenues for each of the Company's significant products for the three months ended September 30, 2019 and 2018 were as follows:

| Revenues:       | Three Months Ended September 30, |           | Three Months Ended<br>Increase / (Decrease) |          |
|-----------------|----------------------------------|-----------|---|----------|
|                 | 2019                             | 2018      | 2019 vs. 2018                               |          |
|                 |                                  |           | \$  | %        |
| Bloxiverz       | \$ 1,466                         | \$ 3,656  | \$ (2,190)                                  | (59.9)%  |
| Vazculep        | 8,786                            | 8,759     | 27  | 0.3 %    |
| Akovaz          | 4,208                            | 5,991     | (1,783)                                     | (29.8)%  |
| Other           | (231)                            | 1,420     | (1,651)                                     | (116.3)% |
| Product sales   | 14,229                           | 19,826    | (5,597)                                     | (28.2)%  |
| License revenue | —                                | —         | —   | n/a      |
| Total revenues  | \$ 14,229                        | \$ 19,826 | \$ (5,597)                                  | (28.2)%  |

Total revenues were \$14,229 for the three months ended September 30, 2019, compared to \$19,826 for the same prior year period. Bloxiverz's revenue declined \$2,190 in the current quarter when compared to the same prior year period primarily due to lower net selling price and lower unit volumes sold driven largely by new competition which entered the market driving price and unit volumes lower. Vazculep's revenue remained flat during the quarter when compared to the prior year period due primarily to slightly higher pricing, offset by lower volumes. Akovaz's revenue declined \$1,783 driven largely by lower net selling price due to new competition which entered the market driving lower prices. The decrease of other revenue is driven by lower net product sales related to Noctiva, as it was deconsolidated in February 2019.

The revenues for each of the Company's significant products for the nine months ended September 30, 2019 and 2018 were as follows:

| Revenues:       | Nine Months Ended September 30, |           | Six Months Ended<br>Increase / (Decrease) |          |
|-----------------|---------------------------------|-----------|---|----------|
|                 |                                 |           | 2019 vs. 2018                             |          |
|                 | 2019                            | 2018      | \$  | %        |
| Bloxiverz       | \$ 6,392                        | \$ 16,691 | \$ (10,299)                               | (61.7)%  |
| Vazculep        | 27,669                          | 33,097    | (5,428)                                   | (16.4)%  |
| Akovaz          | 13,946                          | 28,083    | (14,137)                                  | (50.3)%  |
| Other           | 213                             | 4,232     | (4,019)                                   | (95.0)%  |
| Product sales   | 48,220                          | 82,103    | (33,883)                                  | (41.3)%  |
| License revenue | —                               | 246       | (246)                                     | (100.0)% |
| Total revenues  | \$ 48,220                       | \$ 82,349 | \$ (34,129)                               | (41.4)%  |

Total revenues were \$48,220 for the nine months ended September 30, 2019, compared to \$82,349 for the same prior year period. Bloxiverz's revenue declined \$10,299 when compared to the same period last year, primarily due to lower unit volumes and net selling prices driven largely by new competitors that entered the market. Vazculep's revenue declined \$5,428 compared to the same period last year, due primarily to lower unit volumes and net selling prices driven largely by new competitors that entered the market. Akovaz's revenue declined \$14,137 driven by lower unit volumes and net selling prices driven largely by new competitors that entered the market. The decrease in other revenues during the nine months ended September 30, 2019 is driven by the deconsolidation of Specialty Pharma on February 6, 2019 as well as a reduction in revenue related to the February 2018 divestiture of the pediatric products.

| Cost of Products:            | Three Months Ended September 30, |          | Three Months Ended<br>Increase / (Decrease) |        |
|------------------------------|----------------------------------|----------|---|--------|
|                              |                                  |          | 2019 vs. 2018                               |        |
|                              | 2019                             | 2018     | \$  | %      |
| Cost of products             | \$ 2,823                         | \$ 3,120 | \$ (297)                                    | (9.5)% |
| Percentage of total revenues | 19.8%                            | 15.7%    |   |        |

Cost of products decreased \$297 or 9.5% during the three months ended September 30, 2019 compared to the same prior year period. As a percentage of total revenue, cost of products sold was higher than the prior year period due to lower net selling prices of the Company's hospital products.

| Cost of Products:            | Nine Months Ended September 30, |           | Six Months Ended<br>Increase / (Decrease) |         |
|------------------------------|---------------------------------|-----------|---|---------|
|                              |                                 |           | 2019 vs. 2018                             |         |
|                              | 2019                            | 2018      | \$  | %       |
| Cost of products             | \$ 9,711                        | \$ 13,224 | \$ (3,513)                                | (26.6)% |
| Percentage of total revenues | 20.1%                           | 16.1%     |   |         |

Cost of products decreased \$3,513 or 26.6% during the nine months ended September 30, 2019 compared to the same prior year period driven by lower sold units. As a percentage of total revenue, cost of products sold was higher than the prior year period primarily due to lower net selling prices of the Company's hospital products.

| Research and Development Expenses: | Three Months Ended September 30, |           | Three Months Ended<br>Increase / (Decrease) |         |
|------------------------------------|----------------------------------|-----------|---|---------|
|                                    | 2019                             | 2018      | 2019 vs. 2018                               |         |
|                                    |                                  |           | \$  | %       |
| Research and development expenses  | \$ 7,539                         | \$ 11,402 | \$ (3,863)                                  | (33.9)% |
| Percentage of total revenues       | 53.0%                            | 57.5%     |   |         |

Research and development expenses decreased \$3,863 or 33.9% during the three months ended September 30, 2019 as compared to the same period in 2018. This decline was a result of \$600 of lower spending associated with the exit of Noctiva, lower payroll, benefits and share-based compensation of \$1,100 due to the 2019 Corporate and French restructuring plans and \$2,200 of cost reductions at the Company's Lyon, France R&D center. The Company continues to invest a substantial portion of R&D in its FT218 development program.

| Research and Development Expenses: | Nine Months Ended September 30, |           | Six Months Ended<br>Increase / (Decrease) |         |
|------------------------------------|---------------------------------|-----------|---|---------|
|                                    | 2019                            | 2018      | 2019 vs. 2018                             |         |
|                                    |                                 |           | \$  | %       |
| Research and development expenses  | \$ 25,160                       | \$ 33,243 | \$ (8,083)                                | (24.3)% |
| Percentage of total revenues       | 52.2%                           | 40.4%     |   |         |

Research and development expenses decreased \$8,083 or 24.3% during the nine months ended September 30, 2019 as compared to the same period in 2018. This decline was a result of \$2,600 of lower spending associated with the exit of Noctiva, lower payroll, benefits and share-based compensation of \$2,000 related to the 2019 Corporate and French restructuring plans and \$3,400 of cost reductions at the Company's Lyon, France R&D center. The Company continues to invest a substantial portion of R&D in its FT218 development program.

| Selling, General and Administrative Expenses: | Three Months Ended September 30, |           | Three Months Ended<br>Increase / (Decrease) |         |
|---|----------------------------------|-----------|---|---------|
|   | 2019                             | 2018      | 2019 vs. 2018                               |         |
|   |                                  |           | \$  | %       |
| Selling, general and administrative expenses  | \$ 5,316                         | \$ 24,829 | \$ (19,513)                                 | (78.6)% |
| Percentage of total revenues                  | 37.4%                            | 125.2%    |   |         |

Selling, general and administrative expenses decreased \$19,513 or 78.6% during the three months ended September 30, 2019 as compared to the same prior year period. This decrease was primarily due to a decrease of \$16,000 of sales and marketing costs related to the exit of Noctiva that was incurred during the three months ended September 30, 2018. Also contributing to the decrease is lower other payroll and share-based compensation of \$2,700 due to reduced headcount as a result of the 2019 Corporate and French restructuring plans.

| Selling, General and Administrative Expenses: | Nine Months Ended September 30, |           | Six Months Ended<br>Increase / (Decrease) |         |
|---|---------------------------------|-----------|---|---------|
|   | 2019                            | 2018      | 2019 vs. 2018                             |         |
|   |                                 |           | \$  | %       |
| Selling, general and administrative expenses  | \$ 22,520                       | \$ 77,159 | \$ (54,639)                               | (70.8)% |
| Percentage of total revenues                  | 46.7%                           | 93.7%     |   |         |

Selling, general and administrative expenses decreased \$54,639 or 70.8% during the nine months ended September 30, 2019 as compared to the same prior year period. This decrease was primarily due to a decrease of \$44,200 of sales and marketing costs related to the exit of Noctiva during the first quarter 2019 as well as \$2,700 of decreased costs due to the 2018 divestiture of the pediatric products. Also contributing to the decrease is lower other payroll and share-based compensation of \$7,700 due to reduced headcount as a result of the 2019 Corporate and French restructuring plans.

| Intangibles Asset Amortization: | Three Months Ended September 30, |          | Three Months Ended<br>Increase / (Decrease) |         |
|---------------------------------|----------------------------------|----------|---|---------|
|                                 |                                  |          | 2019 vs. 2018                               |         |
|                                 | 2019                             | 2018     | \$  | %       |
| Intangible asset amortization   | \$ 205                           | \$ 1,620 | \$ (1,415)                                  | (87.3)% |
| Percentage of total revenues    | 1.4%                             | 8.2%     |   |         |

Intangible asset amortization expense decreased \$1,415 or 87.3% during the three months ended September 30, 2019 driven by the impairment of the intangible asset related to Noctiva at December 31, 2018.

| Intangibles Asset Amortization: | Nine Months Ended September 30, |          | Six Months Ended<br>Increase / (Decrease) |         |
|---------------------------------|---------------------------------|----------|---|---------|
|                                 |                                 |          | 2019 vs. 2018                             |         |
|                                 | 2019                            | 2018     | \$  | %       |
| Intangible asset amortization   | \$ 610                          | \$ 4,996 | \$ (4,386)                                | (87.8)% |
| Percentage of total revenues    | 1.3%                            | 6.1%     |   |         |

Intangible asset amortization expense decreased \$4,386 or 87.8% during the nine months ended September 30, 2019 driven by the impairment of the intangible asset related to Noctiva at December 31, 2018.

| Changes in Fair Value of Related Party Contingent Consideration: | Three Months Ended September 30, |            | Three Months Ended<br>Increase / (Decrease) |        |
|--|----------------------------------|------------|---|--------|
|  |                                  |            | 2019 vs. 2018                               |        |
|  | 2019                             | 2018       | \$  | %      |
| Changes in fair value of related party contingent consideration  | \$ 627                           | \$ (7,115) | \$ 7,742                                    | 108.8% |
| Percentage of total revenues                                     | 4.4%                             | (35.9)%    |   |        |

We compute the fair value of the related party contingent consideration using several significant assumptions and when these assumptions change, due to underlying market conditions, the fair value of these liabilities change as well. 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 unaudited condensed consolidated statements of loss and balance sheet.

As a result of changes in the underlying assumptions used to determine the estimated fair values of our acquisition-related contingent consideration earn-out payments - Éclat, we recorded a gain of \$627 and expense of \$7,115 and increased/lowered the fair value of the acquisition-related contingent consideration earn-out payments - Éclat for the three months ended September 30, 2019 and 2018, respectively. As noted in our critical accounting estimates included in the 2018 Form 10-K, there are numerous assumptions and estimates we use when determining the fair value of the acquisition-related earn-out payments - Éclat. These assumptions include estimates of pricing, market size, the market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows.

For the three months ended September 30, 2019, as a result of changes to these estimates when compared to the same estimates at June 30, 2019, we recorded an increase in the fair value of our contingent consideration liabilities due to changes in certain underlying market conditions of the acquisition-related contingent consideration earn-out payments - Éclat.

For the three months ended September 30, 2018, as a result of changes to these estimates when compared to the same estimates at June 30, 2018, we recorded a decrease in the fair value of our contingent consideration liabilities, largely due to changes in certain underlying market conditions of the acquisition-related contingent consideration earn-out payments - Éclat.

| Changes in Fair Value of Related Party Contingent Consideration: | Nine Months Ended September 30, |             | Six Months Ended      |        |
|--|---------------------------------|-------------|-----------------------|--------|
|  |                                 |             | Increase / (Decrease) |        |
|  | 2019                            | 2018        | 2019 vs. 2018         |        |
|  |                                 |             | \$                    | %      |
| Changes in fair value of related party contingent consideration  | \$ 2,384                        | \$ (17,036) | \$ 19,420             | 114.0% |
| Percentage of total revenues                                     | 4.9%                            | (20.7)%     |                       |        |

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

As a result of changes in the underlying assumptions used to determine the estimated fair values of our acquisition-related contingent consideration earn-out payments - Éclat, we recorded an expense of \$2,384 and a gain of \$17,036 and increased/lowered the fair value of the acquisition-related contingent consideration earn-out payments - Éclat for the nine months ended September 30, 2019 and 2018, respectively. As noted in our critical accounting estimates included in the 2018 Form 10-K, there are numerous assumptions and estimates we use when determining the fair value of the acquisition-related earn-out payments - Éclat. These assumptions include estimates of pricing, market size, the market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows.

For the nine months ended September 30, 2019, as a result of changes to these estimates when compared to the same estimates at December 31, 2018, we recorded an increase in the fair value of our contingent consideration liabilities due to changes in certain underlying market conditions of the acquisition-related contingent consideration earn-out payments - Éclat.

For the nine months ended September 30, 2018, as a result of changes to these estimates when compared to the same estimates at December 31, 2017, we recorded a decrease in the fair value of our contingent consideration liabilities, largely due to changes in certain underlying market conditions of the acquisition-related contingent consideration earn-out payments - Éclat.

| Restructuring Costs          | Three Months Ended September 30, |       | Three Months Ended    |          |
|------------------------------|----------------------------------|-------|-----------------------|----------|
|                              |                                  |       | Increase / (Decrease) |          |
|                              | 2019                             | 2018  | 2019 vs. 2018         |          |
|                              |                                  |       | \$                    | %        |
| Restructuring costs          | \$ 1,866                         | \$ 65 | \$ 1,801              | 2,770.8% |
| Percentage of total revenues | 13.1%                            | 0.3%  |                       |          |

During the first quarter of 2019, the Company announced a plan to reduce its Corporate workforce at our U.S. and Ireland sites by more than 50%. This reduction is an effort to align the Company's cost structure with its ongoing and future planned projects and revenue stream. Additionally, during the second quarter of 2019, the Company announced a plan to reduce its French workforce. This reduction is an effort to align the Company's cost structure with our ongoing and future planned projects. See *Note 15: Restructuring Costs* for further details. As a result of these actions, the Company recorded restructuring charges of \$1,866 that are primarily related to the 2019 French and Corporate restructuring plans. These charges included severance costs and the termination payment for vacating the French office leases by the end of the year.

|                              | Nine Months Ended September 30, |        | Six Months Ended      |          |
|------------------------------|---------------------------------|--------|-----------------------|----------|
|                              |                                 |        | Increase / (Decrease) |          |
|                              | 2019                            | 2018   | 2019 vs. 2018         |          |
| Restructuring Costs          |                                 |        | \$                    | %        |
| Restructuring costs          | \$ 4,600                        | \$ 268 | \$ 4,332              | 1,616.4% |
| Percentage of total revenues | 9.5%                            | 0.3%   |                       |          |

Restructuring charges of \$4,600 were recognized during the nine months ended September 30, 2019. These charges were primarily related to the 2019 French and Corporate restructuring actions and included severance and legal costs, impairment of certain assets, the reversal of certain retirement indemnity obligations, share-based compensation and the termination payment for vacating the French office leases by the end of the year. See *Note 15: Restructuring Costs* for further details.

|                                  | Three Months Ended September 30, |        | Three Months Ended    |        |
|----------------------------------|----------------------------------|--------|-----------------------|--------|
|                                  |                                  |        | Increase / (Decrease) |        |
|                                  | 2019                             | 2018   | 2019 vs. 2018         |        |
| Investment and Other Income, net |                                  |        | \$                    | %      |
| Investment and other income, net | \$ 781                           | \$ 208 | \$ 573                | 275.5% |
| Percentage of total revenues     | 5.5%                             | 1.0%   |                       |        |

Investment and other income, net increased for the three months ended September 30, 2019 when compared to the same period in the prior year driven by the accrual of the 2018 employment tax audit in the prior year, which was paid by the Company in 2019.

|                                  | Nine Months Ended September 30, |        | Six Months Ended      |        |
|----------------------------------|---------------------------------|--------|-----------------------|--------|
|                                  |                                 |        | Increase / (Decrease) |        |
|                                  | 2019                            | 2018   | 2019 vs. 2018         |        |
| Investment and Other Income, net |                                 |        | \$                    | %      |
| Investment and other income, net | \$ 2,548                        | \$ 845 | \$ 1,703              | 201.5% |
| Percentage of total revenues     | 5.3%                            | 1.0%   |                       |        |

Investment and other income, net increased for the nine months ended September 30, 2019 when compared to the same period in the prior year driven by higher unrealized gains on our marketable equity securities during the current period when compared to the prior period.

|                              | Three Months Ended September 30, |          | Three Months Ended    |      |
|------------------------------|----------------------------------|----------|-----------------------|------|
|                              |                                  |          | Increase / (Decrease) |      |
|                              | 2019                             | 2018     | 2019 vs. 2018         |      |
| Interest Expense             |                                  |          | \$                    | %    |
| Interest expense             | \$ 3,125                         | \$ 3,000 | \$ 125                | 4.2% |
| Percentage of total revenues | 22.0%                            | 15.1%    |                       |      |

Interest expense for the three months end September 30, 2019 was largely comparable to the same period in the prior year. Interest expense represents the imputed interest on the 2023 Notes.



| Interest Expense             | Nine Months Ended September 30, |          | Six Months Ended      |       |
|------------------------------|---------------------------------|----------|-----------------------|-------|
|                              |                                 |          | Increase / (Decrease) |       |
|                              | 2019                            | 2018     | 2019 vs. 2018         |       |
|                              |                                 |          | \$                    | %     |
| Interest expense             | \$ 9,293                        | \$ 7,577 | \$ 1,716              | 22.6% |
| Percentage of total revenues | 19.3%                           | 9.2%     |                       |       |

Interest expense increased \$1,716 for the nine months end September 30, 2019 when compared to the same period in the prior year as a result of a nine months of interest recorded in 2019 versus 7.5 months of this amount in 2018 due to the 2023 Notes issued in February 2018.

| Loss on Deconsolidation of Subsidiary | Nine Months Ended September 30, |      | Six Months Ended      |     |
|---------------------------------------|---------------------------------|------|-----------------------|-----|
|                                       |                                 |      | Increase / (Decrease) |     |
|                                       | 2019                            | 2018 | 2019 vs. 2018         |     |
|                                       |                                 |      | \$                    | %   |
| Loss on deconsolidation of subsidiary | \$ (2,840)                      | \$ — | \$ (2,840)            | n/a |
| Percentage of total revenues          | (5.9)%                          | —%   |                       |     |

As a result of Avadel Specialty Pharmaceuticals, LLC bankruptcy filing on February 6, 2019, the Company concluded that it no longer controls its operations and accordingly deconsolidated this subsidiary. The Company recorded a loss on the deconsolidation as a result of removing the net assets and certain liabilities of this subsidiary from our unaudited condensed consolidated financial statements. See *Note 3: Subsidiary Bankruptcy and Deconsolidation* for more discussion.

| Other (Expense) Income - Changes in Fair Value of Related Party Payable | Three Months Ended September 30, |        | Three Months Ended    |          |
|---|----------------------------------|--------|-----------------------|----------|
|   |                                  |        | Increase / (Decrease) |          |
|   | 2019                             | 2018   | 2019 vs. 2018         |          |
|   |                                  |        | \$                    | %        |
| Other (expense) income - changes in fair value of related party payable | \$ (139)                         | \$ 425 | \$ (564)              | (132.7)% |
| Percentage of total revenues  | (1.0)%                           | 2.1%   |                       |          |

We recorded expense of \$139 and income of \$425 to increase and reduce the fair value of these liabilities during the three months ended September 30, 2019 and 2018, respectively, due to the same reasons associated with the Éclat product sales forecasts as described in the section “Changes in Fair Value of Related Party Contingent Consideration” for these periods. As noted in our critical accounting estimates section included in the 2018 Form 10-K, there are a number of assumptions and estimates we use when determining the fair value of the related party payable payments. These estimates include pricing, market size, the market share the related products are forecast to achieve and an appropriate discount rate to use when present valuing the related cash flows. These estimates often do change based on changes in current market conditions, competition and other factors.

| Other (Expense) Income - Changes in Fair Value of Related Party Payable | Nine Months Ended September 30, |          | Six Months Ended      |          |
|---|---------------------------------|----------|-----------------------|----------|
|   |                                 |          | Increase / (Decrease) |          |
|   | 2019                            | 2018     | 2019 vs. 2018         |          |
|   |                                 |          | \$                    | %        |
| Other (expense) income - changes in fair value of related party payable | \$ (496)                        | \$ 1,432 | \$ (1,928)            | (134.6)% |
| Percentage of total revenues  | (1.0)%                          | 1.7%     |                       |          |

We recorded expense of \$496 and income of \$1,432 to increase and reduce the fair value of these liabilities during the nine months ended September 30, 2019 and 2018, respectively, due to the same reasons associated with the Éclat product sales forecasts as described in the section “Changes in Fair Value of Related Party Contingent Consideration” for these periods. As noted in our

critical accounting estimates section included in the 2018 Form 10-K, there are a number of assumptions and estimates we use when determining the fair value of the related party payable payments. These estimates include pricing, market size, the market share the related products are forecast to achieve and an appropriate discount rate to use when present valuing the related cash flows. These estimates often do change based on changes in current market conditions, competition and other factors.

| Income Tax Provision (Benefit):        | Three Months Ended September 30, |          | Three Months Ended<br>Increase / (Decrease) |        |
|--|----------------------------------|----------|---|--------|
|  | 2019                             | 2018     | 2019 vs. 2018                               |        |
|  |                                  |          | \$  | %      |
| Income tax provision (benefit)         | \$ 2,234                         | \$ (691) | \$ 2,925                                    | 423.3% |
| Percentage of loss before income taxes | 33.7%                            | (4.2)%   |   |        |

The items accounting for the difference between the income tax provision (benefit) computed at the statutory rate and the Company's effective tax rate for the three months ended September 30, 2019 and 2018, are as follows:

|  | Three Months Ended September 30, |            |
|--|----------------------------------|------------|
|  | 2019                             | 2018       |
| Statutory tax rate   | 12.5 %                           | 12.5 %     |
| International tax rates differential                           | (4.3)%                           | 7.0 %      |
| Change in valuation allowance                                  | (31.1)%                          | (18.3)%    |
| Change in fair value of nondeductible contingent consideration | 4.1 %                            | 8.7 %      |
| Nondeductible stock-based compensation                         | — %                              | (3.5)%     |
| Unrecognized tax benefits                                      | (8.8)%                           | (3.5)%     |
| State and local income taxes, net of federal                   | (0.2)%                           | 0.1 %      |
| Nondeductible interest expense                                 | (4.5)%                           | — %        |
| Other  | (1.3)%                           | 1.2 %      |
| Effective income tax rate                                      | (33.6)%                          | 4.2 %      |
| Income tax benefit - at statutory tax rate                     | \$ (829)                         | \$ (2,058) |
| International tax rates differential                           | 283                              | (1,153)    |
| Change in valuation allowance                                  | 2,059                            | 3,007      |
| Change in fair value of nondeductible contingent consideration | (270)                            | (1,431)    |
| Nondeductible stock-based compensation                         | 1                                | 578        |
| Unrecognized tax benefits                                      | 581                              | 578        |
| State and local income taxes, net of federal                   | 14                               | (13)       |
| Nondeductible interest expense                                 | 299                              | —          |
| Other  | 96                               | (199)      |
| Income tax provision (benefit) - at effective income tax rate  | \$ 2,234                         | \$ (691)   |

The income tax provision was \$2,234 for the three months ended September 30, 2019 and a benefit of \$691 for the three months ended September 30, 2018. The increase in the income tax provision for the three months ended September 30, 2019 is primarily the result of a decrease in the amount of nontaxable gain from the revaluation of contingent consideration and an increase in the amount of valuation allowances recorded on foreign income tax losses.

| Income Tax Provision (Benefit):        | Nine Months Ended September 30, |            | Six Months Ended<br>Increase / (Decrease) |        |
|--|---------------------------------|------------|---|--------|
|  | 2019                            | 2018       | 2019 vs. 2018                             |        |
|  |                                 |            | \$  | %      |
| Income tax provision (benefit)         | \$ 3,641                        | \$ (3,360) | \$ 7,001                                  | 208.4% |
| Percentage of loss before income taxes | 13.6%                           | (9.7)%     |   |        |

The items accounting for the difference between the income tax provision (benefit) computed at the statutory rate and the Company's effective tax rate for the six months ended September 30, 2019 and 2018, are as follows:

|  | Nine Months Ended September 30, |            |
|--|---------------------------------|------------|
|  | 2019                            | 2018       |
| Statutory tax rate   | 12.5 %                          | 12.5 %     |
| International tax rates differential                           | 4.1 %                           | 6.9 %      |
| Change in valuation allowance                                  | (27.0)%                         | (14.9)%    |
| Change in fair value of nondeductible contingent consideration | (0.1)%                          | 9.9 %      |
| Nondeductible stock-based compensation                         | (0.2)%                          | (2.6)%     |
| Unrecognized tax benefits                                      | (3.3)%                          | (3.1)%     |
| State and local income taxes, net of federal                   | (0.2)%                          | 0.2 %      |
| Nondeductible interest expense                                 | (2.6)%                          | — %        |
| Other  | 3.1 %                           | 0.8 %      |
| Effective income tax rate                                      | (13.7)%                         | 9.7 %      |
| Income tax benefit - at statutory tax rate                     | \$ (3,355)                      | \$ (4,351) |
| International tax rates differential                           | (1,108)                         | (2,394)    |
| Change in valuation allowance                                  | 7,242                           | 5,188      |
| Change in fair value of nondeductible contingent consideration | 33                              | (3,436)    |
| Nondeductible stock-based compensation                         | 50                              | 914        |
| Unrecognized tax benefits                                      | 873                             | 1,086      |
| State and local income taxes, net of federal                   | 41                              | (70)       |
| Nondeductible interest expense                                 | 709                             | —          |
| Other  | (844)                           | (297)      |
| Income tax provision (benefit) - at effective income tax rate  | \$ 3,641                        | \$ (3,360) |

The income tax provision was \$3,641 for the nine months ended September 30, 2019 and a benefit of \$3,360 for the nine months ended September 30, 2018. The increase in the income tax provision for the nine months ended September 30, 2019 is primarily the result of a decrease the amount of nontaxable gain from the revaluation of contingent consideration and an increase in the amount of valuation allowances recorded on foreign income tax losses.

The IRS commenced an examination of the Company's U.S. income tax returns for 2016 and 2017 during the second quarter 2019.

## **Liquidity and Capital Resources**

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

|  | Nine Months Ended September 30, |             | Nine Months Ended<br>Increase / (Decrease)<br>2019 vs. 2018 |          |
|--|---------------------------------|-------------|---|----------|
|  | 2019                            | 2018        | \$  | %        |
| <b>Net cash provided by (used in):</b> |                                 |             |   |          |
| Operating activities                   | \$ (30,072)                     | \$ (58,190) | \$ 28,118   | 48.3 %   |
| Investing activities                   | 33,553                          | (53,188)    | 86,741  | 163.1 %  |
| Financing activities                   | 14                              | 112,735     | (112,721)   | (100.0)% |

### ***Operating Activities***

Net cash used in operating activities of \$30,072 for the nine months ended September 30, 2019 decreased \$28,118 compared to the same prior year period. This decrease in cash used in operating cash flow is due to higher cash earnings (net loss adjusted for non-cash credits and charges) of \$16,943 when compared to the same period last year. The decrease in cash used in operating cash flow was also due to lower cash used for accrued expenses of \$9,281 when compared to the same period last year and lower cash payments for related party contingent consideration of \$8,602 during the current period when compared to the prior period.

### ***Investing Activities***

Cash provided by investing activities was \$33,553 for the nine months ended September 30, 2019, was related to net cash proceeds received from the excess of sales over purchases of marketable securities. Cash used in investing activities of \$53,188 during the same prior year period was related to the use of cash to purchase marketable securities in excess of sales of marketable securities. The Company also made a payment of \$20,000 during the second quarter of 2018 related to the Company's purchase of developed technology as part of the ELAA with Serenity Pharmaceuticals, LLC.

### ***Financing Activities***

Cash provided by financing activities for the nine months ended September 30, 2019 was \$14, which decreased \$112,721 from the same prior year period. During the nine months ended September 30, 2018, \$143,750 of cash was provided by financing activities through the issuance of the 2018 Notes. A portion of the proceeds from the offering of the 2018 Notes was used for share repurchases totaling \$27,637 and to pay direct expenses of \$6,190 associated with the issuance of the 2018 Notes.

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

The adequacy of our cash resources depends on the outcome of certain business conditions including the cost of our FT218 clinical development plan, our cost structure, our hospital products revenue stream and other factors set forth in "Risk Factors" within Part I, Item 1A of the 2018 Form 10-K and within Part II, Item 1A of this quarterly report on Form 10-Q. To complete the FT218 clinical development plan and to ensure an adequate and robust NDA for filing with the FDA 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 concerning the outcome of certain business conditions 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. If available to us raising additional capital may be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders.

### ***Borrowings***

In February 2018, we issued the 2023 Notes. We received net proceeds of approximately \$137,560 from the sale of the 2023 Notes, after deducting fees and expenses of \$6,190.

### ***Share Repurchase Programs***

The Company fully completed its authorized share buyback program during the year ended December 31, 2018.

## **Other Matters**

### ***Litigation***

The Company is subject to potential liabilities generally incidental to our business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At September 30, 2019 and December 31, 2018, there were no contingent liabilities with respect to any litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on the Company's unaudited condensed consolidated financial position, results of operations, cash flows or liquidity.

#### Litigation Related to Noctiva

*Note 3: Subsidiary Bankruptcy and Deconsolidation* briefly describes the Chapter 11 bankruptcy case which our subsidiary Specialty Pharma commenced on February 6, 2019, and which on April 26, 2019 resulted in the bankruptcy court-approved sale of all of Specialty Pharma's intangible assets and inventory to an unaffiliated third party. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business. During the pendency of the bankruptcy case, all pending litigation against Specialty Pharma is automatically stayed and any new litigation against Specialty Pharma is precluded unless the bankruptcy court orders otherwise. Below are descriptions of a litigation to which Specialty Pharma is a party and a contract dispute involving Specialty Pharma, both of which matters are subject to the automatic stay during the bankruptcy case.

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

*Contract Dispute.* On January 21, 2019, Serenity gave notice to Specialty Pharma of an alleged breach of the parties' Noctiva license agreement. Serenity alleges that Specialty Pharma breached its contractual obligation to devote commercially reasonable efforts to the commercialization of Noctiva and seeks unspecified damages. On January 27, 2019, Specialty Pharma notified Serenity of a claim for \$1.7 million in damages as a result of Serenity's breach of its contractual obligation to pay the costs of the Ferring Litigation. Serenity's notice to Specialty Pharma invoked the dispute resolution provisions of the Noctiva license agreement, which culminate in arbitration, but neither party has yet initiated an arbitration proceeding or filed suit.

*Tax Matters.* On July 2, 2019, Specialty Pharma was made aware of a \$50,695 claim made by the Internal Revenue Service (IRS) as part of the bankruptcy claims process against Specialty Pharma. On October 2, 2019 the IRS amended the original claim filed in July, reducing the claim to \$9,302. Specialty Pharma files its U.S. federal tax return as a member of the Company's consolidated U.S. tax group. As such, the IRS claim was filed against Specialty Pharma in the bankruptcy proceedings due to IRS tax law requirements for joint and several liability of all members in a consolidated U.S. tax group. Both Specialty Pharma and the Company disagree with the merits of the amended IRS claim and intend to defend their positions vigorously.

### ***Material Commitments***

Due to the Chapter 11 bankruptcy case of Specialty Pharma, the Company's various commitments to purchase finished product from suppliers has changed from what was included in Part II, Item 8 of the Company's 2018 Annual Report on Form 10-K. As of September 30, 2019, commitments for these arrangements, at maximum quantities and at contractual prices over the remaining life of the contract, and excluding any waived commitments, are as follows for the years ended December 31:

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

Other than commitments disclosed in *Note 15: Contingent Liabilities and Commitments* to the Company's audited consolidated financial statements included in Part II, Item 8 of the Company's 2018 Annual Report on Form 10-K, 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 obligations which are disclosed in *Note 10: Long-Term Debt*, respectively, to the Company's consolidated financial statements included in Part II, Item 8 of the Company's 2018 Annual Report on Form 10-K and long-term contingent consideration payable as disclosed in *Note 10: Long-Term Related Party Payable*, to the Company's unaudited condensed consolidated financial statements included in Part I, Item 1 of this report.

#### ***Contractual Obligations***

Disclosures regarding contractual obligations are included in Part II, Item 7 of the Company's 2018 Annual Report on Form 10-K and updated in *Note 10: Long-Term Related Party Payable* to the Company's unaudited condensed consolidated financial statements included in Part I, Item 1 of this Report.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

#### **Interest Rate Risk**

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

### **ITEM 4. CONTROLS AND PROCEDURES.**

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of September 30, 2019, the end of the period covered by this quarterly report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to provide reasonable assurance that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on their evaluation, as of the end of the period covered by this Form 10-Q, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective as of September 30, 2019.

#### ***Changes in Internal Control over Financial Reporting***

During the nine months ended September 30, 2019, as part of our restructuring initiatives described in this Quarterly Report under Item 1 "Financial Statements - Note 15 (Restructuring Costs)" and Item 2 "Management Discussion and Analysis of Results of Operations and Financial Condition - Results of Operation," we moved all of our Irish and a portion of our French accounting operations to St. Louis, Missouri. Further, as part of these restructuring initiatives, the Company completed the outsourcing of a majority of its Information Technology resources to a third party. These moves were made in order to consolidate our accounting

systems, gain efficiencies of scale, reduce costs and make internal control over financial reporting more consistent across our various entities. These moves were not made in response to any identified deficiency or weakness in the Company's internal control over financial reporting. Other than these changes, there has been no change in our internal control over financial reporting during the quarter ended September 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS.

The information contained in *Note 19: Commitments and Contingencies* to the Company's unaudited condensed consolidated financial statements included in Part I, Item 1 of this Report is incorporated by reference herein.

### ITEM 1A. RISK FACTORS.

Except as set forth below, there have been no material changes in our risk factors from those disclosed in our annual report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 15, 2019.

***The trading price of our American Depositary Shares (ADSs) could fall, causing them to be delisted from trading on Nasdaq, making it more difficult for investors to sell our ADSs.***

The closing price of our American Depositary Shares (ADSs) was between \$1.09 and \$2.05 during the period from February 26, 2019 to June 6, 2019. Under Nasdaq Listing Rules 5550 (a)(2) and 5810(c)(3)(A), if the bid price of our ADSs closes below \$1.00 for 30 consecutive business days, our ADSs could be subject to delisting from Nasdaq, after a grace period of 180 calendar days to regain compliance. To regain compliance, the closing bid price of our ADSs would need to meet or exceed \$1.00 for a minimum of 10 consecutive business days during the grace period. If we do not regain compliance Nasdaq would provide notice that our ADSs will be subject to delisting. While the trading prices of our ADSs are currently above \$3.00, such prices have been and continue to be volatile, and there is no assurance that our ADSs would not trade below \$1.00 for 30 consecutive business days in the future and be subject to Nasdaq delisting. If our ADSs were to be delisted from Nasdaq, and not listed on another national securities exchange, trading of our ADSs could be conducted in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In that event, it may be more difficult to dispose of, or obtain accurate price quotations for, our ADSs, and there would likely also be a reduction in our coverage by security analysts and the news media, which could cause the price of our ADSs to decline further. As a result, the trading market for our ADSs could become limited, possibly impairing your ability to liquidate your investment in our company and causing the value of your investment to decline. Also, it may be difficult for us to raise additional capital if we are not listed on Nasdaq or another major exchange.

***Although we recently announced an accelerated estimated timetable for completing our REST-ON clinical trial for FT218, we could experience unanticipated difficulties with enrolling the final patients or with other aspects of the clinical trial or the full FT218 development program, which could increase the cost of the program and further delay its completion.***

Our FT218 product development program has become substantially more important to our success in the aftermath of the disappointing sales results for Noctiva and the Specialty Pharma bankruptcy filing. In September 2019, we announced FDA approval of amendments to the statistical analysis plan and protocol for our REST-ON phase 3 clinical trial for FT218, resulting in a lower sample size needed to demonstrate statistical significance. As a result of these amendments, we expect to complete enrollment in the REST-ON clinical trial by the end of 2019 and have topline data in the second quarter of 2020, which dates are earlier than we had previously estimated. As of November 12, 2019, we had enrolled 200 new patients in the REST-ON clinical trial, with an additional 5 patients needed to complete the sample size. Notwithstanding the new estimated timetable announced in September 2019, we could experience unanticipated difficulties in enrolling patients or with other aspects of the program, and as a result there is no assurance that we will complete enrollment by the end of 2019 as predicted, or that we will complete the clinical trial and collect all data before the end of the second quarter of 2020. Any such unanticipated difficulties could delay the completion of the REST-ON clinical trial and increase its cost.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

The Company fully completed its authorized share buyback program during the year ended December 31, 2018.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

None.

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

**ITEM 5. OTHER INFORMATION.**

None.

**ITEM 6. EXHIBITS.**

| <b>Exhibit No.</b> | <b>Description</b>  |
|--------------------|---|
| 31.1*              | <a href="#">Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act</a>                         |
| 31.2*              | <a href="#">Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act</a>                         |
| 32.1**             | <a href="#">Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a> |
| 32.2**             | <a href="#">Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a> |
| 101.INS*           | XBRL Instance Document  |
| 101.SCH*           | XBRL Taxonomy Extension Schema Document   |
| 101.CAL*           | XBRL Taxonomy Extension Calculation Linkbase Document   |
| 101.DEF*           | XBRL Taxonomy Extension Definition Linkbase Document  |
| 101.LAB*           | XBRL Taxonomy Extension Label Linkbase Document   |
| 101.PRE*           | XBRL Taxonomy Extension Presentation Linkbase Document  |

\* Filed herewith.

\*\* Furnished herewith.



**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 thereunto duly authorized.

**AVADEL PHARMACEUTICALS PLC**

(Registrant)

Date: November 12, 2019

By: /s/ Michael F. Kanan

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Michael F. Kanan

*Senior Vice President and Chief Financial Officer*

*(Duly Authorized Officer and Principal Financial and Accounting Officer)*

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Gregory J. Divis, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ Gregory J. Divis

Gregory J. Divis

Chief Executive Officer

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael F. Kanan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc:

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ Michael F. Kanan

Michael F. Kanan

Senior Vice President and Chief Financial Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc (the “Company”) for the period ended September 30, 2019 (the “Report”), the undersigned hereby certifies in his capacity as Chief Executive Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2019

/s/ Gregory J. Divis

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Gregory J. Divis

Chief Executive Officer

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc (the “Company”) for the period ended September 30, 2019 (the “Report”), the undersigned hereby certifies in his capacity as Chief Financial Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2019

/s/ Michael F. Kanan

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Michael F. Kanan

Senior Vice President and Chief Financial Officer