**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: March 31, 2020

———————

**AVADEL PHARMACEUTICALS PLC**

(Exact name of registrant as specified in its charter)

———————

|  |  |  |
| --- | --- | --- |
|  | | |
|  |  |  |
| **Ireland** | **000-28508** | **98-1341933** |
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |

**10 Earlsfort Terrace**

**Dublin 2, Ireland**

**D02 T380**

(Address of Principal Executive Office and Zip Code)

**+011-1-485-1200**

(Registrant’s telephone number, including area code)

**N/A**

(Former name, former address and former fiscal year, if changed since last report)

———————

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

|  |  |  |
| --- | --- | --- |
|  | | |
|  |  |  |
| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
| American Depositary Shares\*  Ordinary Shares, nominal value $0.01 per share\*\* | AVDL  N/A | The Nasdaq Global Market |

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

\*\* Not for trading, but only in connection with the listing of American Depositary Shares on The Nasdaq Global Market.

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 þ 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 þ 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 | ¨ | Accelerated filer | þ |
| Non-accelerated | ¨ | Smaller reporting company | ¨ |
|  |  | Emerging growth company | ¨ |

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

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

At May 7, 2020, 58,129,037 ordinary shares, nominal value $0.01 each, of the Company were outstanding.

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We own various trademark registrations and applications, and unregistered trademarks, include Avadel, MicroPump, Bloxiverz, Vazculep, Akovaz and Nouress.  All other trade names, trademarks and service marks of other companies appearing in this Quarterly Report are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Quarterly Report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

From time to time, we may use our website or our Twitter account (@AvadelPharma) to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at **www.avadelpharmaceuticals.com**. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website or our Twitter posts are not incorporated into, and does not form a part of, this Quarterly Report.

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**Cautionary Disclosure 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, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as “may,” “will,” “could,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “potential,” “continue,” and similar expressions, or the negative of these terms, or similar expressions. Accordingly, these statements involve estimates, assumptions, risks and uncertainties which could cause actual results to differ materially from those expressed in them.

This quarterly report on Form 10-Q contains forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. These statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

|  |  |
| --- | --- |
|  |  |
| • | Our reliance on a single product candidate, FT218, and our ability to obtain regulatory approval of and successfully commercialize FT218, including any delays in submission or approval related to COVID-19; |

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|  |  |
| • | Our plans and expectations regarding the effectiveness of our restructuring plan announced in February 2019, including our ability to achieve the desired cost savings; |

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| • | Any further restructuring actions that may be required and our ability to obtain any required consents (including any consents required pursuant to the Indenture governing our exchange notes due 2023, or the 2023 Notes); |

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| • | Our reliance on a small number of products to generate all or substantially all of our revenue and the competitive pressures that these products face; |

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| --- | --- |
|  |  |
| • | The lack of patent protection for three of our approved products, Bloxiverz, Vazculep and Akovaz; |

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|  |  |
| • | Our ability to successfully launch Nouress in the United States; |

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| --- | --- |
|  |  |
| • | Our consideration of strategic alternatives for our Unapproved Marketed Drugs (“UMD”) Program; |

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| --- | --- |
|  |  |
| • | Our ability to develop and obtain U.S. Food and Drug Administration (“FDA”) approval for any future potential UMD product candidates; |

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|  |  |
| • | Our ability to continue to service the 2023 Notes, including making the ongoing interest payments on the 2023 Notes, settling exchanges of the 2023 Notes in cash or completing any required repurchases of the 2023 Notes; |

|  |  |
| --- | --- |
|  |  |
| • | The ability of our product candidates and products to gain market acceptance; |

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| --- | --- |
|  |  |
| • | Our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our products and product candidates; |

|  |  |
| --- | --- |
|  |  |
| • | Our dependence on a limited number of suppliers for the manufacturing of our products and certain raw materials in our products and any failure of such suppliers to deliver sufficient quantities of these raw materials, which could have a material adverse effect on our business; |

|  |  |
| --- | --- |
|  |  |
| • | Our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships; |

|  |  |
| --- | --- |
|  |  |
| • | Our expectations about the potential market sizes and market participation potential for our approved or proposed products; |

|  |  |
| --- | --- |
|  |  |
| • | The potential impact of COVID-19 on our business and future operating results; |

|  |  |
| --- | --- |
|  |  |
| • | Our ability to retain members of our management team and our employees; and |

|  |  |
| --- | --- |
|  |  |
| • | Competition existing today or that will likely arise in the future. |

These forward-looking statements are neither promises nor guarantees of future performance due to a variety of risks and uncertainties and other factors more fully discussed in the “Risk Factors” section in Part I, Item 1A of the Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (“SEC”) on March 16, 2020 and the risk factors and cautionary statements described in other documents that we file from time to time with the SEC. Given these uncertainties, readers should not place undue reliance on our forward-looking statements. These forward-looking statements speak only as of the date on which the statements were made and are not guarantees of future performance. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to revise any forward-looking statements to reflect events or developments occurring after the date of this quarterly report, even if new information becomes available in the future.

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**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 March 31,** | | | | | | |
|  |  | **2020** | | |  | **2019** | | |
|  |  |  | | |  |  | | |
| Product sales |  | $ | 12,243 |  |  | $ | 16,437 |  |
| Operating expenses: |  |  | |  |  |  | |  |
| Cost of products |  | 2,457 | |  |  | 3,266 | |  |
| Research and development expenses |  | 5,530 | |  |  | 7,329 | |  |
| Selling, general and administrative expenses |  | 7,913 | |  |  | 10,446 | |  |
| Intangible asset amortization |  | 203 | |  |  | 201 | |  |
| Changes in fair value of contingent consideration |  | 2,478 | |  |  | 2,134 | |  |
| Restructuring costs |  | 159 | |  |  | 1,228 | |  |
| Total operating expenses |  | 18,740 | |  |  | 24,604 | |  |
| Operating loss |  | (6,497 | | ) |  | (8,167 | | ) |
| Investment and other income, net |  | (378 | | ) |  | 817 | |  |
| Interest expense |  | (3,190 | | ) |  | (3,062 | | ) |
| Loss on deconsolidation of subsidiary |  | — | |  |  | (2,673 | | ) |
| Other expense - changes in fair value of contingent consideration payable |  | (310 | | ) |  | (307 | | ) |
| Loss before income taxes |  | (10,375 | | ) |  | (13,392 | | ) |
| Income tax benefit |  | (9,510 | | ) |  | (374 | | ) |
| Net loss |  | $ | (865 | ) |  | $ | (13,018 | ) |
|  |  |  | | |  |  | | |
| Net loss per share - basic |  | $ | (0.02 | ) |  | $ | (0.35 | ) |
| Net loss per share - diluted |  | (0.02 | | ) |  | (0.35 | | ) |
|  |  |  | | |  |  | | |
| Weighted average number of shares outstanding - basic |  | 41,057 | |  |  | 37,354 | |  |
| Weighted average number of shares outstanding - diluted |  | 41,057 | |  |  | 37,354 | |  |

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

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**AVADEL PHARMACEUTICALS PLC**

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

*(In thousands)*

*(Unaudited)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  | **Three Months Ended March 31,** | | | | | | |
|  |  | **2020** | | |  | **2019** | | |
|  |  |  | | |  |  | | |
| Net loss |  | $ | (865 | ) |  | $ | (13,018 | ) |
| Other comprehensive (loss) income, net of tax: |  |  | |  |  |  | |  |
| Foreign currency translation loss |  | (177 | | ) |  | (161 | | ) |
| Net other comprehensive (loss) income, net of ($49) and ($18) tax, respectively |  | (644 | | ) |  | 374 | |  |
| Total other comprehensive (loss) income, net of tax |  | (821 | | ) |  | 213 | |  |
| Total comprehensive loss |  | $ | (1,686 | ) |  | $ | (12,805 | ) |

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

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**AVADEL PHARMACEUTICALS PLC**

**UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS**

*(In thousands, except per share data)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  | **March 31, 2020** | | |  | **December 31, 2019** | | |
|  |  | *(unaudited)* | | |  |  | | |
| **ASSETS** |  |  | |  |  |  | |  |
| Current assets: |  |  | |  |  |  | |  |
| Cash and cash equivalents |  | $ | 73,506 |  |  | $ | 9,774 |  |
| Marketable securities |  | 39,977 | |  |  | 54,384 | |  |
| Accounts receivable |  | 8,797 | |  |  | 8,281 | |  |
| Inventories |  | 3,523 | |  |  | 3,570 | |  |
| Research and development tax credit receivable |  | 1,835 | |  |  | 2,107 | |  |
| Prepaid expenses and other current assets |  | 3,337 | |  |  | 4,264 | |  |
| Total current assets |  | 130,975 | |  |  | 82,380 | |  |
| Property and equipment, net |  | 472 | |  |  | 544 | |  |
| Operating lease right-of-use assets |  | 3,365 | |  |  | 3,612 | |  |
| Goodwill |  | 18,491 | |  |  | 18,491 | |  |
| Intangible assets, net |  | 610 | |  |  | 813 | |  |
| Research and development tax credit receivable |  | 6,288 | |  |  | 6,322 | |  |
| Other non-current assets |  | 47,524 | |  |  | 39,274 | |  |
| Total assets |  | $ | 207,725 |  |  | $ | 151,436 |  |
|  |  |  | | |  |  | | |
| **LIABILITIES AND SHAREHOLDERS’ EQUITY (DEFICIT)** |  |  | |  |  |  | |  |
| Current liabilities: |  |  | |  |  |  | |  |
| Current portion of long-term contingent consideration payable |  | $ | 5,855 |  |  | $ | 5,554 |  |
| Current portion of operating lease liability |  | 604 | |  |  | 645 | |  |
| Accounts payable |  | 6,790 | |  |  | 6,100 | |  |
| Accrued expenses |  | 14,858 | |  |  | 19,810 | |  |
| Income taxes |  | 2,297 | |  |  | 43 | |  |
| Other current liabilities |  | 1,932 | |  |  | 3,832 | |  |
| Total current liabilities |  | 32,336 | |  |  | 35,984 | |  |
| Long-term debt |  | 123,258 | |  |  | 121,686 | |  |
| Long-term contingent consideration payable, less current portion |  | 12,195 | |  |  | 11,773 | |  |
| Long-term operating lease liability |  | 2,205 | |  |  | 2,319 | |  |
| Other non-current liabilities |  | 5,664 | |  |  | 8,873 | |  |
| Total liabilities |  | 175,658 | |  |  | 180,635 | |  |
|  |  |  | | |  |  | | |
| Shareholders’ equity (deficit): |  |  | |  |  |  | |  |
| Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at March 31, 2020 and none issued and outstanding at December 31, 2019, respectively |  | 5 | |  |  | — | |  |
| Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 51,812 issued and 46,404 outstanding at March 31, 2020 and 42,927 issued and 37,520 outstanding at December 31, 2019 |  | 518 | |  |  | 429 | |  |
| Treasury shares, at cost, 5,407 shares held at March 31, 2020 and December 31, 2019, respectively |  | (49,998 | | ) |  | (49,998 | | ) |
| Additional paid-in capital |  | 497,249 | |  |  | 434,391 | |  |
| Accumulated deficit |  | (392,080 | | ) |  | (391,215 | | ) |
| Accumulated other comprehensive loss |  | (23,627 | | ) |  | (22,806 | | ) |
| Total shareholders’ equity (deficit) |  | 32,067 | |  |  | (29,199 | | ) |
| Total liabilities and shareholders’ equity (deficit) |  | $ | 207,725 |  |  | $ | 151,436 |  |

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

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**AVADEL PHARMACEUTICALS PLC**

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS’ EQUITY (DEFICIT)**

*(In thousands)*

*(Unaudited)*

**Three Months Ended March 31, 2020**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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|  |  | **Ordinary shares** | | | | | |  | **Preferred shares** | | | | | |  | **Additional** | | |  | **Accumulated** | | |  | **Accumulated**  **other**  **comprehensive** | | |  | **Treasury shares** | | | | | |  | **Total**  **shareholders’** | | |
|  |  | **Shares** | |  | **Amount** | | |  | **Shares** | |  | **Amount** | | |  | **paid-in capital** | | |  | **deficit** | | |  | **loss** | | |  | **Shares** | |  | **Amount** | | |  | **equity (deficit)** | | |
| **Balance, December 31, 2019** |  | 42,927 |  |  | $ | 429 |  |  | — |  |  | $ | — |  |  | $ | 434,391 |  |  | $ | (391,215 | ) |  | $ | (22,806 | ) |  | 5,407 |  |  | $ | (49,998 | ) |  | $ | (29,199 | ) |
| Net loss |  | — |  |  | — | |  |  | — |  |  | — | |  |  | — | |  |  | (865 | | ) |  | — | |  |  | — |  |  | — | |  |  | (865 | | ) |
| Other comprehensive loss |  | — |  |  | — | |  |  | — |  |  | — | |  |  | — | |  |  | — | |  |  | (821 | | ) |  | — |  |  | — | |  |  | (821 | | ) |
| Exercise of stock options |  | 146 |  |  | 2 | |  |  | — |  |  | — | |  |  | 1,387 | |  |  | — | |  |  | — | |  |  | — |  |  | — | |  |  | 1,389 | |  |
| February 2020 private placement |  | 8,680 |  |  | 87 | |  |  | 488 |  |  | 5 | |  |  | 60,641 | |  |  | — | |  |  | — | |  |  | — |  |  | — | |  |  | 60,733 | |  |
| Vesting of restricted shares |  | 19 |  |  | — | |  |  | — |  |  | — | |  |  | — | |  |  | — | |  |  | — | |  |  | — |  |  | — | |  |  | — | |  |
| Employee share purchase plan share issuance |  | 40 |  |  | — | |  |  | — |  |  | — | |  |  | 88 | |  |  | — | |  |  | — | |  |  | — |  |  | — | |  |  | 88 | |  |
| Stock-based compensation expense |  | — |  |  | — | |  |  | — |  |  | — | |  |  | 742 | |  |  | — | |  |  | — | |  |  | — |  |  | — | |  |  | 742 | |  |
| **Balance, March 31, 2020** |  | 51,812 |  |  | $ | 518 |  |  | 488 |  |  | $ | 5 |  |  | $ | 497,249 |  |  | $ | (392,080 | ) |  | $ | (23,627 | ) |  | 5,407 |  |  | $ | (49,998 | ) |  | $ | 32,067 |  |

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**AVADEL PHARMACEUTICALS PLC**

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS’ EQUITY (DEFICIT)**

*(In thousands)*

*(Unaudited)*

**Three Months Ended March 31, 2019**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
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|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | **Ordinary shares** | | | | | |  | **Additional** | | |  | **Accumulated** | | |  | **Accumulated**  **other**  **comprehensive** | | |  | **Treasury shares** | | | | | |  | **Total**  **shareholders’** | | |
|  |  | **Shares** | |  | **Amount** | | |  | **paid-in capital** | | |  | **deficit** | | |  | **(loss) income** | | |  | **Shares** | |  | **Amount** | | |  | **equity (deficit)** | | |
| **Balance, December 31, 2018** |  | 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 share issuance |  | 42 |  |  | — | |  |  | 92 | |  |  | — | |  |  | — | |  |  | — |  |  | — | |  |  | 92 | |  |
| Stock-based compensation expense |  | — |  |  | — | |  |  | 351 | |  |  | — | |  |  | — | |  |  | — |  |  | — | |  |  | 351 | |  |
| **Balance, March 31, 2019** |  | 42,763 |  |  | $ | 427 |  |  | $ | 434,199 |  |  | $ | (371,007 | ) |  | $ | (23,203 | ) |  | 5,407 |  |  | $ | (49,998 | ) |  | $ | (9,582 | ) |

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**AVADEL PHARMACEUTICALS PLC**

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

*(In thousands)*

*(Unaudited)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  | **Three Months Ended March 31,** | | | | | | |
|  |  | **2020** | | |  | **2019** | | |
|  |  |  | | |  |  | | |
| **Cash flows from operating activities:** |  |  | |  |  |  | |  |
| Net loss |  | $ | (865 | ) |  | $ | (13,018 | ) |
| Adjustments to reconcile net loss to net cash provided by operating activities: |  |  | |  |  |  | |  |
| Depreciation and amortization |  | 456 | |  |  | 369 | |  |
| Remeasurement of acquisition-related contingent consideration |  | 2,478 | |  |  | 2,134 | |  |
| Remeasurement of financing-related contingent consideration |  | 310 | |  |  | 307 | |  |
| Amortization of debt discount and debt issuance costs |  | 1,573 | |  |  | 1,445 | |  |
| Change in deferred tax and income tax deferred charge |  | (8,440 | | ) |  | (222 | | ) |
| Stock-based compensation expense |  | 742 | |  |  | 351 | |  |
| Loss on deconsolidation of subsidiary |  | — | |  |  | 1,750 | |  |
| Other adjustments |  | 573 | |  |  | (541 | | ) |
| Net changes in assets and liabilities |  |  | |  |  |  | |  |
| Accounts receivable |  | (517 | | ) |  | (1,021 | | ) |
| Inventories |  | 47 | |  |  | 467 | |  |
| Prepaid expenses and other current assets |  | 899 | |  |  | (3,228 | | ) |
| Research and development tax credit receivable |  | 160 | |  |  | (449 | | ) |
| Accounts payable & other current liabilities |  | (1,187 | | ) |  | 752 | |  |
| Accrued expenses |  | (4,905 | | ) |  | (4,750 | | ) |
| Accrued income taxes |  | 2,253 | |  |  | (46 | | ) |
| Earn-out payments for contingent consideration in excess of acquisition-date fair value |  | (1,774 | | ) |  | (3,181 | | ) |
| Royalty payments for contingent consideration payable in excess of original fair value |  | (291 | | ) |  | (507 | | ) |
| Other assets and liabilities |  | (3,148 | | ) |  | (1,818 | | ) |
| Net cash used in operating activities |  | (11,636 | | ) |  | (21,206 | | ) |
|  |  |  | | |  |  | | |
| **Cash flows from investing activities:** |  |  | |  |  |  | |  |
| Purchases of property and equipment |  | — | |  |  | (30 | | ) |
| Proceeds from sales of marketable securities |  | 14,788 | |  |  | 34,864 | |  |
| Purchases of marketable securities |  | (1,562 | | ) |  | (13,444 | | ) |
| Net cash provided by investing activities |  | 13,226 | |  |  | 21,390 | |  |
|  |  |  | | |  |  | | |
| **Cash flows from financing activities:** |  |  | |  |  |  | |  |
| Proceeds from the February 2020 private placement |  | 60,733 | |  |  | — | |  |
| Proceeds from stock option exercises and ESPP |  | 1,477 | |  |  | 92 | |  |
| Net cash provided by financing activities |  | 62,210 | |  |  | 92 | |  |
|  |  |  | | |  |  | | |
| Effect of foreign currency exchange rate changes on cash and cash equivalents |  | (68 | | ) |  | 29 | |  |
|  |  |  | | |  |  | | |
| Net change in cash and cash equivalents |  | 63,732 | |  |  | 305 | |  |
| Cash and cash equivalents at January 1, |  | 9,774 | |  |  | 9,325 | |  |
| Cash and cash equivalents at March 31, |  | $ | 73,506 |  |  | $ | 9,630 |  |
|  |  |  | | |  |  | | |
| Supplemental disclosures of cash flow information: |  |  | | |  |  | | |
| Interest paid |  | $ | 3,234 |  |  | $ | 3,234 |  |
| Income taxes paid |  | $ | — |  |  | $ | 72 |  |

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

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**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 an emerging biopharmaceutical company. Our lead product candidate, FT218, is an investigational once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness (“EDS”) and cataplexy in narcolepsy patients. FT218 uses our Micropump drug-delivery technology. In addition, we have three approved commercial products developed under our unapproved marketed drug (“UMD”) program, Akovaz, Bloxiverz and Vazculep, and a fourth approved product, Nouress, which are sterile injectable drugs used in the hospital setting.

We are primarily focused on the development and potential United States (“U.S.”) Food and Drug Administration (“FDA”) approval of FT218. In addition, we continue to market and distribute our current approved hospital products portfolio and, pending resolution of the existing patent infringement claim (as described below), we plan to commercialize Nouress. Outside of our product candidate and our existing commercial products, we continue to evaluate opportunities to expand our product portfolio.

***FT218 (Micropump sodium oxybate)***

FT218 is a once-nightly formulation of sodium oxybate that uses our *Micropump* controlled release drug- delivery technology for the treatment of EDS and cataplexy in patients suffering from narcolepsy. Sodium oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid. 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 December 2019, we completed patient enrollment of our Phase 3 REST-ON clinical trial of FT218 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 and on April 27, 2020, we announced topline results from our Phase 3 REST-ON clinical trial of FT218.

*Existing Commercial Products*

To date, we have received FDA approvals for three previously unapproved prescription drugs:

|  |  |
| --- | --- |
|  |  |
| *•* | **Bloxiverz (neostigmine methylsulfate injection)** - Bloxiverz was approved by the FDA in May 2013 and was launched in July 2013. Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery. Bloxiverz was the first FDA-approved version of neostigmine methylsulfate. Today, neostigmine is one of the two most frequently used products for the reversal of the effects of other agents used for neuromuscular blocks. |

|  |  |
| --- | --- |
|  |  |
| • | **Vazculep (phenylephrine hydrochloride injection)** - Vazculep was approved by the FDA in June 2014 and was launched in October 2014. Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. |

|  |  |
| --- | --- |
|  |  |
| • | **Akovaz (ephedrine sulfate injection)** - Akovaz, was approved by the FDA in April 2016 and was launched in August 2016. Akovaz was the first FDA approved formulation of ephedrine sulfate, an alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. |

*Nouress*

In December 2019, we received FDA approval for Nouress (cysteine hydrochloride injection), a sterile injectable product for use in the hospital setting, and currently have two patents covering that product. Several additional patent applications for Nouress are pending with the U.S. Patent and Trademark Office (“USPTO”). In light of the recently filed patent suit by Exela Pharma Sciences, LLC, we are currently evaluating the timing and process for a commercial launch of Nouress in the U.S.  See *Note 18: Commitments and Contingencies*.

We were incorporated in Ireland on December 1, 2015 as a private limited company, and re-registered as an Irish public limited company on November 21, 2016. Our headquarters are in Dublin, Ireland and we have operations in St. Louis, Missouri, U.S.

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***Basis of Presentation.*** The unaudited condensed consolidated balance sheet as of March 31, 2020, which is derived from the prior year 2019 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 2019 Annual Report on Form 10-K filed with the SEC on March 16, 2020.

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 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, our 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.

***Revenue.*** Revenue includes sales of pharmaceutical products.

*Product Sales*

We sell products primarily through wholesalers and considers these wholesalers to be our customers. Revenue from product sales is recognized when the customer obtains control of our product and our performance obligations are met, which occurs typically upon receipt of delivery to the customer. As is customary in the pharmaceutical industry, our 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.

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

***Accounts Receivable.*** Accounts receivable are stated at amounts invoiced and certain other gross to net variable consideration deductions. An allowance for credit losses is established based on expected losses. Expected losses are estimated by reviewing individual accounts, considering aging, financial condition of the debtor, payment history, current and forecast economic conditions and other relevant factors. A majority of our accounts receivable are due from four significant customers.

**NOTE 2: Newly Issued Accounting Standards**

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

In December 2019, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. The FASB’s amendments primarily impact *ASC 740, Income Taxes*, and may impact both interim and annual reporting periods. ASU 2019-12 will be effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years and early adoption is permitted. We are currently evaluating the impact of adopting ASU 2019-12.

***Recently Adopted Accounting Guidance***

In August 2018, 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

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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. We adopted ASU 2018-13 in the first quarter of 2020.

In June 2016, the FASB issued ASU No. 2016-13, *“Financial Instruments - Credit Losses (Topic326): 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. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. The standard limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. ASU 2016-13 is 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 adopted the provisions of ASU 2016-13 in the first quarter of 2020. Adoption of the new standard did not have any impact on our unaudited 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 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 $2,673 for the three months ended March 31, 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 disagreed with the merits of the amended IRS claim, and Specialty Pharma entered into negotiations regarding the treatment of the claim in the bankruptcy case.  On November 19, 2019, Specialty Pharma and the IRS resolved their dispute, subject to Bankruptcy Court approval in Specialty Pharma's Chapter 11 plan, and without prejudice to the claims, rights and defenses of the IRS and other Avadel entities outside of the bankruptcy case.  The resolution provided for allowance of the IRS claim as a priority claim but for the IRS to receive a distribution of not less than $125 from Specialty Pharma following confirmation of its chapter 11 plan, leaving a substantial amount of the bankruptcy estate for general unsecured creditors.

*Debtor in Possession (“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 March 31, 2020, 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 and the $407 has been recorded as part of the loss on deconsolidation of subsidiary within the unaudited condensed consolidated statements of loss for the three months ended March 31, 2019.

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**NOTE 4: Revenue Recognition**

The Company generates revenue primarily from the sale of pharmaceutical products to customers.

*Product Sales*

We sell products primarily through wholesalers and considers these wholesalers to be our customers. Revenue from product sales is recognized when the customer obtains control of our product and our performance obligations are met, which occurs typically upon receipt of delivery to the customer. As is customary in the pharmaceutical industry, our 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.

***Disaggregation of revenue***

The Company’s 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 17: Revenue by Product*.

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***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 March 31, 2020.

***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 the first quarter of 2020 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. |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | **As of March 31, 2020** | | | | | | | | | | |  | **As of December 31, 2019** | | | | | | | | | | |
| **Fair Value Measurements:** |  | **Level 1** | | |  | **Level 2** | | |  | **Level 3** | | |  | **Level 1** | | |  | **Level 2** | | |  | **Level 3** | | |
|  |  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |
| Marketable securities (see *Note 6*) |  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |
| Equity securities |  | $ | — |  |  | $ | — |  |  | $ | — |  |  | $ | 4,404 |  |  | $ | — |  |  | $ | — |  |
| Money market and mutual funds |  | 28,472 | |  |  | — | |  |  | — | |  |  | 38,799 | |  |  | — | |  |  | — | |  |
| Corporate bonds |  | — | |  |  | 4,013 | |  |  | — | |  |  | — | |  |  | 4,098 | |  |  | — | |  |
| Government securities - U.S. |  | — | |  |  | 6,085 | |  |  | — | |  |  | — | |  |  | 5,446 | |  |  | — | |  |
| Other fixed-income securities |  | — | |  |  | 1,407 | |  |  | — | |  |  | — | |  |  | 1,637 | |  |  | — | |  |
| Total assets |  | $ | 28,472 |  |  | $ | 11,505 |  |  | $ | — |  |  | $ | 43,203 |  |  | $ | 11,181 |  |  | $ | — |  |
|  |  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |
| Contingent consideration payable (see *Note 9*) |  | $ | — |  |  | $ | — |  |  | $ | 18,050 |  |  | $ | — |  |  | $ | — |  |  | $ | 17,327 |  |
| Total liabilities |  | $ | — |  |  | $ | — |  |  | $ | 18,050 |  |  | $ | — |  |  | $ | — |  |  | $ | 17,327 |  |

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 March 31, 2020 and December 31, 2019, respectively, there were no transfers in and out of Level 1, 2, or 3. During the three month periods ended March 31, 2020 and 2019, 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 March 31, 2020 of $123,258, which is the same as book value.

See *Note 10: 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 loss in shareholders’ equity (deficit), net of income tax effects. As of March 31, 2020, we considered any decreases in fair value on our marketable securities to be driven by factors other than credit risk, including market risk.

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 March 31, 2020 and December 31, 2019, respectively:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | **March 31, 2020** | | | | | | | | | | | | | | |
| **Marketable Securities:** |  | **Adjusted Cost** | | |  | **Unrealized Gains** | | |  | **Unrealized Losses** | | |  | **Fair Value** | | |
|  |  |  | | |  |  | | |  |  | | |  |  | | |
| Money market and mutual funds |  | $ | 28,370 |  |  | $ | 410 |  |  | $ | (308 | ) |  | $ | 28,472 |  |
| Corporate bonds |  | 4,074 | |  |  | 33 | |  |  | (94 | | ) |  | 4,013 | |  |
| Government securities - U.S. |  | 5,777 | |  |  | 308 | |  |  | — | |  |  | 6,085 | |  |
| Other fixed-income securities |  | 1,418 | |  |  | 7 | |  |  | (18 | | ) |  | 1,407 | |  |
| Total |  | $ | 39,639 |  |  | $ | 758 |  |  | $ | (420 | ) |  | $ | 39,977 |  |

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|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | **December 31, 2019** | | | | | | | | | | | | | | |
| **Marketable Securities:** |  | **Adjusted Cost** | | |  | **Unrealized Gains** | | |  | **Unrealized Losses** | | |  | **Fair Value** | | |
|  |  |  | | |  |  | | |  |  | | |  |  | | |
| Equity securities |  | $ | 4,234 |  |  | $ | 170 |  |  | $ | — |  |  | $ | 4,404 |  |
| Money market and mutual funds |  | 38,028 | |  |  | 771 | |  |  | — | |  |  | 38,799 | |  |
| Corporate bonds |  | 4,021 | |  |  | 77 | |  |  | — | |  |  | 4,098 | |  |
| Government securities - U.S. |  | 5,341 | |  |  | 110 | |  |  | (5 | | ) |  | 5,446 | |  |
| Other fixed-income securities |  | 1,614 | |  |  | 23 | |  |  | — | |  |  | 1,637 | |  |
| Total |  | $ | 53,238 |  |  | $ | 1,151 |  |  | $ | (5 | ) |  | $ | 54,384 |  |

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 $276 and $94 for the three months ended March 31, 2020, and 2019, respectively. These realized gains were offset by realized losses of $872 and $147 for the three months ended March 31, 2020, and 2019, respectively.

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 March 31, 2020:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | **Maturities** | | | | | | | | | | | | | | | | | | |
| **Marketable Debt Securities:** |  | **Less than 1 Year** | | |  | **1-5 Years** | | |  | **5-10 Years** | | |  | **Greater than 10 Years** | | |  | **Total** | | |
|  |  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |
| Corporate bonds |  | $ | 592 |  |  | $ | 3,030 |  |  | $ | 391 |  |  | $ | — |  |  | $ | 4,013 |  |
| Government securities - U.S. |  | — | |  |  | 5,269 | |  |  | 329 | |  |  | 487 | |  |  | 6,085 | |  |
| Other fixed-income securities |  | 50 | |  |  | 1,357 | |  |  | — | |  |  | — | |  |  | 1,407 | |  |
| Total |  | $ | 642 |  |  | $ | 9,656 |  |  | $ | 720 |  |  | $ | 487 |  |  | $ | 11,505 |  |

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.

The following table shows the gross unrealized losses and fair value of our available-for-sale debt securities at March 31, 2020. The unrealized losses in the table below are driven by factors other than credit risk and have been in a unrealized loss position for less than one year. We do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost bases.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
| **Marketable Debt Securities:** |  | **Fair Value** | | |  | **Unrealized Losses** | | |
|  |  |  | | |  |  | | |
| Corporate bonds |  | $ | 2,442 |  |  | $ | 94 |  |
| Other fixed-income securities |  | 694 | |  |  | 18 | |  |
| Total |  | $ | 3,136 |  |  | $ | 112 |  |

**NOTE 7:** **Inventories**

The principal categories of inventories, net reserves of $348 and $914 at March 31, 2020 and December 31, 2019, respectively, are comprised of the following:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
| **Inventory:** |  | **March 31, 2020** | | |  | **December 31, 2019** | | |
|  |  |  | | |  |  | | |
| Finished goods |  | $ | 2,845 |  |  | $ | 3,020 |  |
| Raw materials |  | 678 | |  |  | 550 | |  |
| Total |  | $ | 3,523 |  |  | $ | 3,570 |  |

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**NOTE 8:** **Goodwill and Intangible Assets**

The Company’s amortizable and unamortizable intangible assets at March 31, 2020 and December 31, 2019 are as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | **March 31, 2020** | | | | | | | | | | |  | **December 31, 2019** | | | | | | | | | | |
| **Goodwill and Intangible Assets:** |  | **Gross**  **Value** | | |  | **Accumulated**  **Amortization** | | |  | **Net Carrying**  **Amount** | | |  | **Gross**  **Value** | | |  | **Accumulated**  **Amortization** | | |  | **Net Carrying**  **Amount** | | |
|  |  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |
| Amortizable intangible assets - Acquired developed technology - Vazculep |  | $ | 12,061 |  |  | $ | (11,451 | ) |  | $ | 610 |  |  | $ | 12,061 |  |  | $ | (11,248 | ) |  | $ | 813 |  |
|  |  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |
| Unamortizable intangible assets - Goodwill |  | $ | 18,491 |  |  | $ | — |  |  | $ | 18,491 |  |  | $ | 18,491 |  |  | $ | — |  |  | $ | 18,491 |  |

The Company recorded amortization expense related to amortizable intangible assets of $203 and $201 for the three months ended March 31, 2020 and 2019, respectively.

Our amortizable intangible asset is amortized over its estimated useful life, which is seven years, using the straight-line method. At March 31, 2020, total amortization of intangible assets for the year ended December 31, 2020 will be $813. There is no estimated amortization during the years ended December 31, 2021-2024 as the acquired developed technology, Vazculep, will be fully amortized at December 31, 2020.

**NOTE 9:** **Contingent Consideration Payable**

Contingent consideration payable and related activity are reported at fair value and consist of the following at March 31, 2020 and December 31, 2019:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | | |  | **Activity during the three months ended**  **March 31, 2020** | | | | | | | | | | |  |  | | |
|  |  | | |  |  | | |  | **Changes in Fair Value of Contingent Consideration Payable** | | | | | | |  |  | | |
| **Contingent Consideration Payable:** | **Balance,**  **December 31, 2019** | | |  | **Payments** | | |  | **Operating Expense** | | |  | **Other**  **Expense** | | |  | **Balance, March 31, 2020** | | |
|  |  | | |  |  | | |  |  | | |  |  | | |  |  | | |
| Acquisition-related contingent consideration: |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |
| Earn-out payments - Éclat Pharmaceuticals (a) (d) | $ | 15,472 |  |  | $ | (1,774 | ) |  | $ | 2,478 |  |  | $ | — |  |  | $ | 16,176 |  |
| Financing-related: |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | | |
| Royalty agreement - Deerfield (b) (d) | 1,251 | |  |  | (197 | | ) |  | — | |  |  | 188 | |  |  | 1,242 | |  |
| Royalty agreement - Broadfin (c) (d) | 604 | |  |  | (94 | | ) |  | — | |  |  | 122 | |  |  | 632 | |  |
| Total contingent consideration payable | 17,327 | |  |  | $ | (2,065 | ) |  | $ | 2,478 |  |  | $ | 310 |  |  | 18,050 | |  |
| Less: current portion | (5,554 | | ) |  |  | |  |  |  | |  |  |  | |  |  | (5,855 | | ) |
| Long-term contingent consideration payable | $ | 11,773 |  |  |  | |  |  |  | |  |  |  | |  |  | $ | 12,195 |  |

(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 is obligated to pay quarterly a 1.75% royalty on the |

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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 Éclat products.

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

|  |  |
| --- | --- |
|  |  |
| (d) | Deerfield and Broadfin Healthcare Master Trust disposed of their 2023 Notes and ordinary shares in the Company during the three months ended March 31, 2020 and are no longer considered related parties. |

At March 31, 2020, the fair value of each contingent consideration 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 14%. 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 contingent consideration 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 contingent consideration” for items noted in (b) above and in “Other expense - changes in fair value of contingent consideration 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 2019 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 contingent consideration payable” on the unaudited condensed consolidated statements of loss.

The following table summarizes changes to the contingent consideration payables, a recurring Level 3 measurement, for the three-month periods ended March 31, 2020 and 2019, respectively:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | | |
|  |  |  |  |  |
| **Contingent Consideration Payable Rollforward:** |  | **Balance** | | |
|  |  |  | | |
| Balance, December 31, 2018 |  | $ | 28,840 |  |
| Payments of contingent consideration |  | (3,688 | | ) |
| Fair value adjustments (1) |  | 2,441 | |  |
| Balance, March 31, 2019 |  | $ | 27,593 |  |
|  |  |  | | |
| Balance, December 31, 2019 |  | $ | 17,327 |  |
| Payments of contingent consideration |  | (2,065 | | ) |
| Fair value adjustments (1) |  | 2,788 | |  |
| Balance, March 31, 2020 |  | $ | 18,050 |  |

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

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**NOTE 10: Long-Term Debt**

Long-term debt is summarized as follows:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  | March 31, 2020 | | |  | December 31, 2019 | | |
| Principal amount of 4.50% exchangeable senior notes due 2023 |  | $ | 143,750 |  |  | $ | 143,750 |  |
| Less: debt discount and issuance costs, net |  | (20,492 | | ) |  | (22,064 | | ) |
| Net carrying amount of liability component |  | 123,258 | |  |  | 121,686 | |  |
| Other debt |  | — | |  |  | — | |  |
| Subtotal |  | 123,258 | |  |  | 121,686 | |  |
| Less: current maturities |  | — | |  |  | — | |  |
| Long-term debt |  | $ | 123,258 |  |  | $ | 121,686 |  |
|  |  |  | | |  |  | | |
| Equity component: |  |  | | |  |  | | |
| Equity component of exchangeable notes, net of issuance costs |  | $ | (26,699 | ) |  | $ | (26,699 | ) |

**NOTE 11:** **Income Taxe**s

The Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”), enacted on March 27, 2020, includes significant business tax provisions. In particular, the CARES Act modified the rules associated with net operating losses (“NOLs”). Under the temporary provisions of CARES Act, NOL carryforwards and carrybacks may offset 100% of taxable income for taxable years beginning before 2021. In addition, NOLs arising in 2018, 2019 and 2020 taxable years may be carried back to each of the preceding five years to generate a refund. During the three months ended March 31, 2020, the income tax benefit includes a discrete tax benefit of $9,124 as a result of our ability under the CARES Act to carry back NOLs incurred to periods when the statutory U.S. Federal tax rate was 35% versus our current U.S. Federal tax rate of 21%.

The income tax benefit was $9,510 for the three months ended March 31, 2020 resulting in an effective tax rate of 91.7%. The income tax benefit was $374 for the three months ended March 31, 2019 resulting in an effective tax rate of 2.7%. The net increase in the effective income tax rate for the three months ended March 31, 2020, as compared to the same period in 2019, is primarily due to the discrete tax benefits recognized under the CARES Act as described above, favorable income tax benefits from the U.S. Orphan Drug and Research & Development Tax Credit and agreement with the IRS in the first quarter of 2020 on audit adjustments resulting from the U.S. Federal Income Tax audit of the tax years 2015, 2016 and 2017, all of which was recorded during the three months ended March 31, 2020.

During the three months ended March 31, 2020, the Company substantially completed the 2015 through 2017 U.S. Federal Tax Audit. Completion of the audit resulted in an assessment of $1,937 for the 2015 through 2017 U.S. Federal Tax Returns compared to the IRS Claims of $50,695 made on July 2, 2019 and the updated IRS Claims of $9,302 on October 2, 2019 made as part of the Specialty Pharma bankruptcy proceedings, which at this time does not include interest and penalties. The Company expects interest and penalties to be approximately $300. While there are still additional approval and administrative procedures to complete, the Company expects the completion of the 2015 through 2017 U.S. Federal Tax Audit to be completed by the quarter ended September 30, 2020. The audit of the 2017 French tax return was also completed during the three months ended March 31, 2020 with no material changes.

**NOTE 12:** **Other Assets and Liabilities**

Various other assets and liabilities are summarized as follows:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
| **Prepaid Expenses and Other Current Assets:** |  | **March 31, 2020** | | |  | **December 31, 2019** | | |
|  |  |  | | |  |  | | |
| Valued-added tax recoverable |  | $ | 257 |  |  | $ | 1,051 |  |
| Prepaid and other expenses |  | 1,933 | |  |  | 2,116 | |  |
| Guarantee from Armistice |  | 456 | |  |  | 454 | |  |
| Income tax receivable |  | 536 | |  |  | 536 | |  |
| Other |  | 155 | |  |  | 107 | |  |
| Total |  | $ | 3,337 |  |  | $ | 4,264 |  |

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|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
| **Other Non-Current Assets:** |  | **March 31, 2020** | | |  | **December 31, 2019** | | |
|  |  |  | | |  |  | | |
| Deferred tax assets, net |  | $ | 37,860 |  |  | $ | 29,427 |  |
| Long-term deposits |  | 1,477 | |  |  | 1,477 | |  |
| Guarantee from Armistice |  | 1,252 | |  |  | 1,367 | |  |
| Right of use assets at contract manufacturing organizations |  | 6,362 | |  |  | 6,428 | |  |
| Other |  | 573 | |  |  | 575 | |  |
| Total |  | $ | 47,524 |  |  | $ | 39,274 |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
| **Accrued Expenses** |  | **March 31, 2020** | | |  | **December 31, 2019** | | |
|  |  |  | | |  |  | | |
| Accrued compensation |  | $ | 1,724 |  |  | $ | 3,944 |  |
| Accrued social charges |  | 192 | |  |  | 592 | |  |
| Accrued restructuring (see *Note 14*) |  | 1,705 | |  |  | 2,949 | |  |
| Customer allowances |  | 6,200 | |  |  | 6,470 | |  |
| Accrued contract research organization charges |  | 1,802 | |  |  | 2,098 | |  |
| Accrued contract manufacturing organization costs |  | 426 | |  |  | 735 | |  |
| Other |  | 2,809 | |  |  | 3,022 | |  |
| Total |  | $ | 14,858 |  |  | $ | 19,810 |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
| **Other Non-Current Liabilities:** |  | **March 31, 2020** | | |  | **December 31, 2019** | | |
|  |  |  | | |  |  | | |
| Customer allowances |  | $ | 1,210 |  |  | $ | 981 |  |
| Unrecognized tax benefits |  | 3,143 | |  |  | 6,465 | |  |
| Guarantee to Deerfield |  | 1,256 | |  |  | 1,372 | |  |
| Other |  | 55 | |  |  | 55 | |  |
| Total |  | $ | 5,664 |  |  | $ | 8,873 |  |

**NOTE 13: Equity Transactions**

*Shelf Registration Statement on Form S-3*

In February 2020, we filed with the SEC a new shelf registration statement on Form S-3 (the 2020 Shelf Registration Statement) (File No. 333-236258) that allows issuance and sale by us, from time to time, of:

|  |  |
| --- | --- |
|  |  |
| (a) | up to $250,000 in aggregate of ordinary shares, nominal value US$0.01 per share (the “Ordinary Shares”), each of which may be represented by American Depositary Shares (“ADSs”), preferred shares, nominal value US$0.01 per share (the “Preferred Shares”), debt securities (the “Debt Securities”), warrants to purchase Ordinary Shares, ADSs, Preferred Shares and/or Debt Securities (the “Warrants”), and/or units consisting of Ordinary Shares, ADSs, Preferred Shares, one or more Debt Securities or Warrants in one or more series, in any combination, pursuant to the terms of the 2020 Shelf Registration Statement, the base prospectus contained in the 2020 Shelf Registration Statement (the “Base Prospectus”), and any amendments or supplements thereto (together, the “Securities”); including |

|  |  |
| --- | --- |
|  |  |
| (b) | up to $50,000 of ADSs that may be issued and sold from time to time pursuant to the terms of an Open Market Sale AgreementSM (“the Sales Agreement”), entered into with Jefferies LLC on February 4, 2020 (the “Sales Agreement”), the 2020 Shelf Registration Statement, the Base Prospectus and the terms of the sales agreement prospectus contained in the 2020 Shelf Registration Statement. |

The transactions costs associated with the 2020 Shelf Registration Statement of approximately $340 were capitalized as a prepaid asset.

*February 2020 Private Placement*

On February 21, 2020, we announced that we entered into a definitive agreement for the sale of our ADSs and Series A Non-Voting Convertible Preferred Shares (“Series A Preferred”) in a private placement to a group of institutional accredited investors.

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The private placement resulted in gross proceeds of approximately $65,000 before deducting placement agent and other offering expenses, which resulted in net proceeds of $60,733.

Pursuant to the terms of the private placement, we issued 8,680 ADSs and 488 shares of Series A Preferred at a price of $7.09 per share, priced at-the-market under Nasdaq rules. Each share of non-voting Series A Preferred is convertible into one ADS, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.99% of the total number of Avadel ADSs outstanding. The closing of the private placement occurred on February 25, 2020.

Issuance costs of $4,267 were recorded as a reduction of additional paid-in capital.

*May 2020 Public Offering*

In connection with the shelf registration statement described above, on April 28, 2020 we announced the pricing of an underwritten public offering of 11,630 ordinary shares, in the form of American Depositary Shares (“ADSs”) at a price to the public of $10.75 per ADS. Each ADS represents the right to receive one Ordinary Share. All of the ADSs are being offered by Avadel. The gross proceeds to us from the offering were approximately $125,000, before deducting underwriting discounts and commissions and estimated offering expenses.

In connection with the public offering, we granted the underwriters a 30-day option to purchase up to an additional 1,745 ADSs at the public offering price less the underwriting discounts and commissions. The offering closed on May 1, 2020. See *Note 19: Subsequent Events*.

**NOTE 14: 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 was part of an effort to align the Company’s cost structure with our ongoing and future planned projects. The reduction in workforce has been substantially completed as of March 31, 2020. Restructuring charges associated with this plan recognized during the three months ended March 31, 2020 were immaterial.

The following table sets forth activities for the Company’s cost reduction plan obligations for the three months ended March 31, 2020:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | | |
|  |  |  |  |  |
| **2019 French Restructuring Obligation:** |  | **2020** | | |
|  |  |  | | |
| Balance of restructuring accrual at January 1, |  | $ | 1,922 |  |
| Charges for employee severance, benefits and other costs |  | 171 | |  |
| Payments |  | (1,294 | | ) |
| Foreign currency impact |  | (34 | | ) |
| Balance of restructuring accrual at March 31, |  | $ | 765 |  |

The 2019 French Restructuring liabilities of $765 are included in the unaudited condensed consolidated balance sheet in accrued expenses at March 31, 2020, 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 was substantially complete at the end of March 31, 2020, and has resulted in employee severance, benefits and other costs of up to approximately $3,000, which are likely to be recognized through May 31, 2020. The restructuring charges associated with this plan recognized during the three months ended March 31, 2020 were immaterial, compared to $1,398 of restructuring charges recognized during the three months ended March 31, 2019.

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The following table sets forth activities for the Company’s cost reduction plan obligations for the three months ended March 31, 2020 and 2019:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
| **2019 Corporate Restructuring Obligation:** |  | **2020** | | |  | **2019** | | |
|  |  |  | | |  |  | | |
| Balance of restructuring accrual at January 1, |  | $ | 1,080 |  |  | $ | — |  |
| Charges for employee severance, benefits and other costs |  | 62 | |  |  | 1,398 | |  |
| Payments |  | (202 | | ) |  | (754 | | ) |
| Balance of restructuring accrual at March 31, |  | $ | 940 |  |  | $ | 644 |  |

The 2019 Corporate Restructuring liabilities of $940 are included in the unaudited condensed consolidated balance sheet in accrued expenses at March 31, 2020.

**NOTE 15:** **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 conversion of our preferred shares, the exercise of outstanding equity compensation awards, and ordinary shares expected to be issued under our employee stock purchase plan (“ESPP”).

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, restricted stock units, preferred shares 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:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  | **Three Months Ended March 31,** | | | | | | |
| **Net Loss Per Share:** |  | **2020** | | |  | **2019** | | |
|  |  |  | | |  |  | | |
| Net loss |  | $ | (865 | ) |  | $ | (13,018 | ) |
|  |  |  | | |  |  | | |
| Weighted average shares: |  |  | | |  |  | | |
| Basic shares |  | 41,057 | |  |  | 37,354 | |  |
| Effect of dilutive securities—employee and director equity awards outstanding, preferred shares and 2023 Notes |  | — | |  |  | — | |  |
| Diluted shares |  | 41,057 | |  |  | 37,354 | |  |
|  |  |  | | |  |  | | |
| Net loss per share - basic |  | $ | (0.02 | ) |  | $ | (0.35 | ) |
| Net loss per share - diluted |  | $ | (0.02 | ) |  | $ | (0.35 | ) |

Potential common shares of 15,858 and 19,762 were excluded from the calculation of weighted average shares for the three months ended March 31, 2020 and 2019, respectively, because their effect was considered to be anti-dilutive. For the three months ended March 31, 2020 and 2019, 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.

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**NOTE 16:** **Comprehensive Loss**

The following table shows the components of accumulated other comprehensive loss for the three months ended March 31, 2020 and 2019, respectively, net of tax effects:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  | **Three Months Ended March 31,** | | | | | | |
| **Accumulated Other Comprehensive Loss:** |  | **2020** | | |  | **2019** | | |
|  |  |  | | |  |  | | |
| Foreign currency translation adjustment: |  |  | | |  |  | | |
| Beginning balance |  | $ | (23,738 | ) |  | $ | (23,621 | ) |
| Net other comprehensive loss |  | (177 | | ) |  | (161 | | ) |
| Balance at March 31, |  | $ | (23,915 | ) |  | $ | (23,782 | ) |
|  |  |  | | |  |  | | |
| Unrealized gain (loss) on marketable debt securities, net |  |  | | |  |  | | |
| Beginning balance |  | $ | 932 |  |  | $ | 205 |  |
| Net other comprehensive (loss) income, net of ($49) and ($18) tax, respectively |  | (644 | | ) |  | 374 | |  |
| Balance at March 31, |  | $ | 288 |  |  | $ | 579 |  |
| Accumulated other comprehensive loss at March 31, |  | $ | (23,627 | ) |  | $ | (23,203 | ) |

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 17:** **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:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
|  |  | **Three Months Ended March 31,** | | | | | | |
| **Revenues by Product:** |  | **2020** | | |  | **2019** | | |
|  |  |  | | |  |  | | |
| Bloxiverz |  | $ | 1,401 |  |  | $ | 2,568 |  |
| Vazculep |  | 5,514 | |  |  | 9,473 | |  |
| Akovaz |  | 5,349 | |  |  | 3,792 | |  |
| Other |  | (21 | | ) |  | 604 | |  |
| Total product sales |  | $ | 12,243 |  |  | $ | 16,437 |  |

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**NOTE 18:** **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 March 31, 2020 and December 31, 2019, 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, Ferring B.V. and Ferring International Center S.A., 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.  Ferring initiated this litigation initially against Serenity Pharmaceuticals, LLC (“Serenity”) (the licensor of the Noctiva Patents) and Reprise Biopharmaceutics, LLC (“Reprise”) on April 28, 2017.  Avadel subsequently joined the litigation on June 28, 2018, shortly after Ferring received FDA approval for Nocdurna.  In this litigation, filed in the United States District Court for the Southern District of New York, 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, Serenity, and Reprise 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 a pending settlement of the litigation with respect to just Ferring and Specialty Pharma. On February 25, 2020, Ferring and Specialty Pharma jointly moved for bankruptcy court approval of a settlement agreement with respect to the claims alleged in the litigation.  In accordance with the terms of the settlement agreement, promptly following bankruptcy court approval of the settlement agreement, the parties would dismiss with prejudice their respective claims against each other in the litigation.  On March 13, 2020, the Bankruptcy Court entered an order approving the settlement with Ferring.  Pursuant to the terms of the settlement, the parties are to dismiss their respective claims against each other in the District Court litigation in the Southern District of New York, with such dismissals to be effective concurrently.  The joint dismissal has not yet been filed with District Court for the Southern District of New York.

*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.

*Exela Litigation*.  On January 7, 2020, Exela filed a complaint against us and our subsidiary, Avadel Legacy, in the United States District for the District of Delaware. The complaint alleges infringement of a certain Exela patent related to its cysteine hydrochloride product. Exela is most notably seeking i) a declaratory judgment that the Nouress product infringes its patent, ii) an injunction (both preliminary and permanent) precluding the launch of Nouress, and iii) monetary damages (including enhanced damages, prejudgment interest and attorneys’ fees) in the event Nouress is commercially launched and found to infringe Exela’s patent.  The current deadline for Avadel to respond to Exela’s complaint is May 29, 2020.

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***Material Commitments***

Other than commitments disclosed in *Note 16: Contingent Liabilities and Commitments* to the Company’s audited consolidated financial statements included in Part II, Item 8 of the Company’s 2019 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* and long-term contingent consideration payable as disclosed in *Note 9: Contingent Consideration Payable,* to the Company’s unaudited condensed consolidated financial statements included in Part I, Item 1 of this report.

***Guarantees***

*Deerfield Guarantee*

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

In connection with our February 2018 divestiture of our pediatric assets, we have guaranteed to Deerfield the 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. Given our explicit guarantee to Deerfield, the Company recorded the guarantee in accordance with ASC 460. The balance of this guarantee liability was $1,713 at March 31, 2020. This liability is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

*Armistice Guarantee*

In connection with our February 2018 divestiture of the pediatric assets, Armistice Capital Master Fund, Ltd., the majority shareholder of Cerecor, guaranteed to us the FSC Product Royalties. The Company recorded the guarantee in accordance with ASC 460. The balance of this guarantee asset was $1,708 at March 31, 2020. This liability is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

***Off-Balance Sheet Arrangements***

As of March 31, 2020, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

**NOTE 19: Subsequent Events**

*May 2020 Public Offering*

On April 28, 2020, we announced the pricing of an underwritten public offering of 11,630 ordinary shares, in the form of ADSs at a price to the public of $10.75 per ADS. Each ADS represents the right to receive one ordinary share. The gross proceeds to us from the offering were approximately $125,000, before deducting underwriting discounts and commissions and estimated offering expenses.

In connection with the public offering, we granted the underwriters a 30-day option to purchase up to an additional 1,745 ADSs at the public offering price less the underwriting discounts and commissions. The offering closed on May 1, 2020.

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**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 16, 2020 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 an emerging biopharmaceutical company. Our lead product candidate, FT218, is an investigational once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness (“EDS”) and cataplexy in narcolepsy patients. FT218 uses our Micropump drug-delivery technology. In addition, we have three approved commercial products developed under our unapproved marketed drug (“UMD”) program, Akovaz, Bloxiverz and Vazculep, and a fourth approved product, Nouress, which are sterile injectable drugs used in the hospital setting.

We are primarily focused on the development and potential United States (“U.S.”) Food and Drug Administration (“FDA”) approval of FT218. In addition, we continue to market and distribute our current approved hospital products portfolio and, pending resolution of the existing patent infringement claim (as described below), we plan to commercialize Nouress. Outside of our product candidate and our existing commercial products, we continue to evaluate opportunities to expand our product portfolio.

***FT218 (Micropump sodium oxybate)***

FT218 is a once-nightly formulation of sodium oxybate that uses our Micropump controlled release drug-delivery technology for the treatment of EDS and cataplexy in patients suffering from narcolepsy. Sodium oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid. Sodium oxybate is approved in Europe and the United States (“U.S.”) as a twice-nightly formulation indicated for the treatment of EDS and cataplexy in patients with narcolepsy.

The REST-ON trial is a randomized, double-blind, placebo-controlled study that enrolled 212 patients and was being conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient, last visit was completed at the end of the first quarter of 2020 and positive top line data from the REST-ON trial was announced on April 27, 2020. Patients who received 9g of once-nightly FT218 demonstrated a statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test, or MWT, clinical global impression-improvement, or CGI-I, and mean weekly cataplexy attacks. We observed the 9g dose of once-nightly FT218 to be generally well tolerated. Adverse reactions commonly associated with sodium oxybate were observed in a small number of patients (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3%, enuresis 9%) and 3.9% of the patients who received 9g of FT218 discontinued the trial due to adverse reactions. We also assessed the three co-primary endpoints in patients who received 7.5g and 6g of once-nightly FT218. Patients who received either 7.5g or 6g of once-nightly FT218 also demonstrated statistically significant, clinically meaningful improvements compared to placebo for each of the three co-primary endpoints.

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. Additionally, in April 2019, our first FT218 patent was issued, providing intellectual property protection into 2037. There are additional patent applications currently in development and/or pending at the USPTO, as well as foreign patent offices.

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We believe FT218 has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standard of care for EDS and cataplexy in patients with narcolepsy, which is a twice-nightly sodium oxybate formulation. If approved, we believe FT218 has the potential to take a significant share of the sodium oxybate market. The current market size for the twice-nightly administration of sodium oxybate is estimated at an annualized revenue run rate of $1.7 billion.

***Micropump Drug-Delivery Technology***

Our Micropump drug-delivery technology allows for the delayed delivery of small molecule drugs taken orally, which has the potential to improve dosing compliance, reduce toxicity and improve patient compliance. Beyond FT218, we believe there could be other product development opportunities for our Micropump drug delivery technology, 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.

***Unapproved Marketed Drugs Program***

The FDA allows certain unapproved prescription drugs to be marketed if (i) they are relied on by health care professionals to treat serious medical conditions, and (ii) there is no FDA-approved drug to treat such condition or insufficient supply of FDA-approved drugs. In most cases, these prescription drugs pre-date the establishment of the FDA. In most cases, these prescription drugs pre-date the establishment of the FDA. Although these products are typically not protected by patents or similar intellectual property, FDA guidance states that, if it approves an NDA for any such products, the FDA is more likely to seek enforcement action, such as seizure or injunction, against remaining unapproved drugs of the same type, potentially after a grace period provided by the FDA. Given the topline data from our Phase 3 trial, we are currently considering strategic alternatives for our UMD program.

*Existing Commercial Products*

To date, we have received FDA approvals for three previously unapproved prescription drugs:

|  |  |
| --- | --- |
|  |  |
| *•* | **Bloxiverz (neostigmine methylsulfate injection)** - Bloxiverz was approved by the FDA in May 2013 and was launched in July 2013. Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery. Bloxiverz was the first FDA-approved version of neostigmine methylsulfate. Today, neostigmine is one of the two most frequently used products for the reversal of the effects of other agents used for neuromuscular blocks. There are approximately 2,500 vials of neostigmine sold annually in the U.S. |

|  |  |
| --- | --- |
|  |  |
| *•* | **Vazculep (phenylephrine hydrochloride injection)** - Vazculep was approved by the FDA in June 2014 and was launched in October 2014. Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. There are approximately 7,400 vials of *Vazculep* sold annually in the U.S. |

|  |  |
| --- | --- |
|  |  |
| *•* | **Akovaz (ephedrine sulfate injection)** - Akovaz, was approved by the FDA in April 2016 and was launched in August 2016. Akovaz was the first FDA approved formulation of ephedrine sulfate, an alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. There are approximately 6,800 vials of *Akovaz* sold annually in the U.S. |

*Nouress*

In December 2019, we received FDA approval for Nouress (cysteine hydrochloride injection), a sterile injectable product for use in the hospital setting, and currently have two patents covering that product. Several additional patent applications for Nouress are pending with the USPTO. In light of the recently filed patent suit by Exela Pharma Sciences, LLC, we are currently evaluating the timing and process for a commercial launch of Nouress in the U.S.  See *Note 18: Commitments and Contingencies*.

We use the revenue from our UMD products to fund the research and development of FT218. In addition, we believe evaluating opportunities to commercialize other unapproved drugs in markets with a limited number of competitors may provide us with near-term revenue growth and potentially provide cash flows that can also be used to fund research and development initiatives for the development of FT218 and other potential product candidates.

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***Corporate Information***

We were incorporated on December 1, 2015 as an Irish private limited company, and re-registered as an Irish public limited company (“plc”), on November 21, 2016. Our registered address is at 10 Earlsfort Terrace, Dublin 2, Ireland and our phone number is +353-1-920-1000. We file annual, quarterly and current reports, proxy statements and other documents with the U.S. Securities and Exchange Commission (“SEC”) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Our website is 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 SEC. These filings are also available to the public at www.sec.gov.

We currently have 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), (ii) Avadel Legacy Pharmaceuticals, LLC, (iii) Avadel Management Corporation, (iv) FSC Holding Company, (v) Avadel Operations Company, Inc. and (vi) Avadel CNS Pharmaceuticals LLC. 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. 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. A complete list of our subsidiaries can be found in Exhibit 21.1 of our Annual Report on Form 10-K filed with the SEC on March 16, 2020.

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 2020:** Since we expect sales of our hospital products to decline in 2020 as compared to 2019 and we will incur substantial expenses to further the clinical development of FT218, we expect to incur a net loss in 2020, which we are unable to estimate at this time. |

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***Impact of COVID-19***

Over the past few months, we have seen the profound impact that the novel coronavirus (COVID-19) is having on human health, the global economy and society at large. We have been actively monitoring the COVID-19 situation and have taken measures to mitigate the potential impacts to our employees and business, such as implementing a work from home policy. We believe the impact of COVID-19 and measures to prevent its spread could impact our business in a number of ways, including weakened customer demand, disruptions to our supply chain and third parties that we use and requiring that our employees work from home for an extended period of time.

***Financial Highlights***

Highlights of our consolidated results for the three months ended March 31, 2020 are as follows:

|  |  |
| --- | --- |
|  |  |
| • | Revenue was $12,243 for the three months ended March 31, 2020, compared to $16,437 in the same period last year. 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****.*** Our Bloxiverz and Vazculep products experienced price and unit volume declines due to additional competition. |

|  |  |
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| • | Operating loss was $6,497 for the three months ended March 31, 2020, compared to an operating loss of $8,167 and for the same period last year. The decrease in operating loss for the three months ended March 31, 2020 was largely driven by lower selling, general and administrative (SG&A) expenses of $2,533, a $1,799 decline in research and development (“R&D”) expense and a decrease in restructuring costs of $1,069, partially offset by a $3,385 decline in gross margin (*i.e.*, total revenues minus cost of products). |

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| • | Net loss was $865 for the three months ended March 31, 2020, respectively, compared to net loss of $13,018 in the same period last year, respectively. Included in the net loss during the three months ended March 31, 2019 was a loss on the deconsolidation of Avadel Specialty Pharmaceuticals, LLC (“Specialty Pharma”) of $2,673. |

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| • | Diluted net loss per share was $0.02 for the three months ended March 31, 2020, compared to diluted net loss per share of $0.35 in the same period last year, respectively. |

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| • | Cash and marketable securities increased $49,325 to $113,483 at March 31, 2020, from $64,158 at December 31, 2019. This increase was driven by the February private placement which resulted in proceeds, net of placement fees of approximately $61,000, partially offset by $11,636 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, 2019 (the “2019 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 2019 Form 10-K.

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**Results of Operations**

The following is a summary of our financial results (in thousands, except per share amounts) for the three months ended March 31, 2020 and 2019, respectively:

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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Comparative Statements of Loss** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Product sales |  | $ | 12,243 |  |  | $ | 16,437 |  |  | $ | (4,194 | ) |  | (25.5 | )% |
| Operating expenses: |  |  | |  |  |  | |  |  |  | | |  |  | |
| Cost of products |  | 2,457 | |  |  | 3,266 | |  |  | (809 | | ) |  | (24.8 | )% |
| Research and development expenses |  | 5,530 | |  |  | 7,329 | |  |  | (1,799 | | ) |  | (24.5 | )% |
| Selling, general and administrative expenses |  | 7,913 | |  |  | 10,446 | |  |  | (2,533 | | ) |  | (24.2 | )% |
| Intangible asset amortization |  | 203 | |  |  | 201 | |  |  | 2 | |  |  | 1.0 | % |
| Changes in fair value of contingent consideration |  | 2,478 | |  |  | 2,134 | |  |  | 344 | |  |  | 16.1 | % |
| Restructuring costs |  | 159 | |  |  | 1,228 | |  |  | (1,069 | | ) |  | (87.1 | )% |
| Total operating expenses |  | 18,740 | |  |  | 24,604 | |  |  | (5,864 | | ) |  | (23.8 | )% |
| Operating loss |  | (6,497 | | ) |  | (8,167 | | ) |  | 1,670 | |  |  | 20.4 | % |
| Investment and other income, net |  | (378 | | ) |  | 817 | |  |  | (1,195 | | ) |  | (146.3 | )% |
| Interest expense |  | (3,190 | | ) |  | (3,062 | | ) |  | (128 | | ) |  | (4.2 | )% |
| Loss on deconsolidation of subsidiary |  | — | |  |  | (2,673 | | ) |  | 2,673 | |  |  | 100.0 | % |
| Other expense - changes in fair value of contingent consideration payable |  | (310 | | ) |  | (307 | | ) |  | (3 | | ) |  | (1.0 | )% |
| Loss before income taxes |  | (10,375 | | ) |  | (13,392 | | ) |  | 3,017 | |  |  | 22.5 | % |
| Income tax benefit |  | (9,510 | | ) |  | (374 | | ) |  | (9,136 | | ) |  | (2,442.8 | )% |
| Net loss |  | $ | (865 | ) |  | $ | (13,018 | ) |  | $ | 12,153 |  |  | 93.4 | % |
| Net loss per share - diluted |  | $ | (0.02 | ) |  | $ | (0.35 | ) |  | $ | 0.33 |  |  | 94.3 | % |

The revenues for each of the Company’s significant products for the three months ended March 31, 2020 and 2019 were as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Product sales:** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Bloxiverz |  | $ | 1,401 |  |  | $ | 2,568 |  |  | $ | (1,167 | ) |  | (45.4 | )% |
| Vazculep |  | 5,514 | |  |  | 9,473 | |  |  | (3,959 | | ) |  | (41.8 | )% |
| Akovaz |  | 5,349 | |  |  | 3,792 | |  |  | 1,557 | |  |  | 41.1 | % |
| Other |  | (21 | | ) |  | 604 | |  |  | (625 | | ) |  | (103.5 | )% |
| Product sales |  | $ | 12,243 |  |  | $ | 16,437 |  |  | $ | (4,194 | ) |  | (25.5 | )% |

Product sales were $12,243 for the three months ended March 31, 2020, compared to $16,437 for the same prior year period. Bloxiverz’s revenue declined $1,167 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 $3,959 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 increased $1,557 driven by higher unit volumes driven largely by increased sales to compounders during the current period when compared to the prior period. The decrease in other revenue during the three months ended March 31, 2020 is driven by the deconsolidation of Specialty Pharma on February 6, 2019 as well as lower revenue on our Dextro product as we stopped selling this during the fourth quarter of 2019.

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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Cost of Products:** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Cost of products |  | $ | 2,457 |  |  | $ | 3,266 |  |  | $ | (809 | ) |  | (24.8 | )% |
| Percentage of total revenues |  | 20.1 | | % |  | 19.9 | | % |  |  | |  |  |  |  |

Cost of products decreased $809 or 24.8% during the three months ended March 31, 2020 compared to the same prior year period driven by lower sold units. As a percentage of total revenue, cost of products sold was comparable to the prior year.

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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Research and Development Expenses:** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Research and development expenses |  | $ | 5,530 |  |  | $ | 7,329 |  |  | $ | (1,799 | ) |  | (24.5 | )% |
| Percentage of total revenues |  | 45.2 | | % |  | 44.6 | | % |  |  | |  |  |  |  |

Research and development (“R&D”) expenses decreased $1,799 or 24.5% during the three months ended March 31, 2020 as compared to the same period in 2019. This decline was driven by lower payroll, benefits and share-based compensation of $1,400 related to the 2019 Corporate and French restructuring plans and $400 of other 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.

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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Selling, General and Administrative Expenses:** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Selling, general and administrative expenses |  | $ | 7,913 |  |  | $ | 10,446 |  |  | $ | (2,533 | ) |  | (24.2 | )% |
| Percentage of total revenues |  | 64.6 | | % |  | 63.6 | | % |  |  | |  |  |  |  |

Selling, general and administrative expenses decreased $2,533 or 24.2% during the three months ended March 31, 2020 as compared to the same prior year period. This decrease was primarily due to a decrease of $2,200 of sales and marketing costs related to the exit of Noctiva during the first quarter 2019.

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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Intangibles Asset Amortization:** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Intangible asset amortization |  | $ | 203 |  |  | $ | 201 |  |  | $ | 2 |  |  | 1.0 | % |
| Percentage of total revenues |  | 1.7 | | % |  | 1.2 | | % |  |  | |  |  |  |  |

Intangible asset amortization expense for the three months ended March 31, 2020 and 2019 relates to the amortization of our Acquired developed technology - Vazculep.

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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Changes in Fair Value of Contingent Consideration:** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Changes in fair value of contingent consideration |  | $ | 2,478 |  |  | $ | 2,134 |  |  | $ | 344 |  |  | 16.1 | % |
| Percentage of total revenues |  | 20.2 | | % |  | 13.0 | | % |  |  | |  |  |  |  |

We compute the fair value of the 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 $2,478 and $2,134 and increased the fair value of the acquisition-related contingent consideration earn-out payments - Éclat for the three months ended March 31, 2020 and 2019, respectively. As noted in our critical accounting estimates included in the 2019 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 March 31, 2020, as a result of changes to these estimates when compared to the same estimates at December 31, 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 March 31, 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, largely due to changes in certain underlying market conditions of the acquisition-related contingent consideration earn-out payments - Éclat.

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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Restructuring Costs** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Restructuring costs |  | $ | 159 |  |  | $ | 1,228 |  |  | $ | (1,069 | ) |  | (87.1 | )% |
| Percentage of total revenues |  | 1.3 | | % |  | 7.5 | | % |  |  | |  |  |  |  |

Restructuring charges of $159 and $1,228 were recognized during the three months ended March 31, 2020 and 2019. These charges were primarily related to the 2019 French and Corporate restructuring actions and mainly included severance and legal costs, see *Note 14: Restructuring Costs* for further details.

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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Investment and Other Income, net** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Investment and other income, net |  | $ | (378 | ) |  | $ | 817 |  |  | $ | (1,195 | ) |  | (146.3 | )% |
| Percentage of total revenues |  | (3.1 | | )% |  | 5.0 | | % |  |  | |  |  |  |  |

Investment and other income, net decreased for the three months ended March 31, 2020 when compared to the same period in the prior year driven by net unrealized losses on our marketable equity securities during the current period when compared to net unrealized gains on our marketable securities during the prior period.

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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Interest Expense** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Interest expense |  | $ | 3,190 |  |  | $ | 3,062 |  |  | $ | 128 |  |  | 4.2 | % |
| Percentage of total revenues |  | 26.1 | | % |  | 18.6 | | % |  |  | |  |  |  |  |

Interest expense of $3,190 and $3,062 for the three months end March 31, 2020 and 2019 is related to interest on the 2023 Notes that issued in February 2018.

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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Loss on Deconsolidation of Subsidiary** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Loss on deconsolidation of subsidiary |  | $ | — |  |  | $ | (2,673 | ) |  | $ | 2,673 |  |  | 100.0 | % |
| Percentage of total revenues |  | — | | % |  | (16.3 | | )% |  |  | |  |  |  |  |

As a result of Specialty Pharma’s 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 during the three months ended March 31, 2019 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.

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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Other Expense - Changes in Fair Value of Contingent Consideration Payable** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Other expense - changes in fair value of contingent consideration payable |  | $ | (310 | ) |  | $ | (307 | ) |  | $ | (3 | ) |  | (1.0 | )% |
| Percentage of total revenues |  | (2.5 | | )% |  | (1.9 | | )% |  |  | |  |  |  |  |

We recorded expense of $310 and $307 to increase the fair value of these liabilities during the three months ended March 31, 2020 and 2019, 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 our Annual Report on Form 10-K, there are a number of assumptions and estimates we use when determining the fair value of the contingent consideration 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.

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The items accounting for the difference between the income tax benefit computed at the statutory rate and the Company’s effective tax rate for the three months ended March 31, 2020 and 2019, are as follows:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Income Tax Benefit:** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Income tax benefit |  | $ | (9,510 | ) |  | $ | (374 | ) |  | $ | (9,136 | ) |  | (2,442.8 | )% |
| Percentage of loss before income taxes |  | 91.7 | | % |  | 2.8 | | % |  |  | |  |  |  |  |

The Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”), enacted on March 27, 2020, includes significant business tax provisions. In particular, the CARES Act modified the rules associated with net operating losses (“NOLs”). Under the temporary provisions of CARES Act, NOL carryforwards and carrybacks may offset 100% of taxable income for taxable years beginning before 2021. In addition, NOLs arising in 2018, 2019 and 2020 taxable years may be carried back to each of the preceding five years to generate a refund. During the three months ended March 31, 2020, the income tax benefit includes a discrete tax benefit of $9,124 as a result of our ability under the CARES Act to carry back NOLs incurred to periods when the statutory U.S. Federal tax rate was 35% versus our current U.S. Federal tax rate of 21%.

The income tax benefit was $9,510 for the three months ended March 31, 2020 resulting in an effective tax rate of 91.7%. The income tax benefit was $374 for the three months ended March 31, 2019 resulting in an effective tax rate of 2.7%. The net increase in the effective income tax rate for the three months ended March 31, 2020, as compared to the same period in 2019, is primarily due to the discrete tax benefits recognized under the CARES Act as described above, favorable income tax benefits from the U.S. Orphan Drug and Research & Development Tax Credit and agreement with the IRS in the first quarter of 2020 on audit adjustments resulting from the U.S. Federal Income Tax audit of the tax years 2015, 2016 and 2017, all of which was recorded during the three months ended March 31, 2020.

During the three months ended March 31, 2020, the Company substantially completed the 2015 through 2017 U.S. Federal Tax Audit. Completion of the audit resulted in an assessment of $1,937 for the 2015 through 2017 U.S. Federal Tax Returns compared to the IRS Claims of $50,695 made on July 2, 2019 and the updated IRS Claims of $9,302 on October 2, 2019 made as part of the Specialty Pharma bankruptcy proceedings, which at this time does not include interest and penalties. The Company expects interest and penalties to be approximately $300. While there are still additional approval and administrative procedures to complete, the Company expects the completion of the 2015 through 2017 U.S. Federal Tax Audit to be completed by the quarter ended September 30, 2020. The audit of the 2017 French tax return was also completed during the three months ended March 31, 2020 with no material changes.

**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:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
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|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | | |  |  | | |  | **Three Months Ended** | | | | | |
|  |  | **Three Months Ended March 31,** | | | | | | |  | ***Increase / (Decrease)*** | | | | | |
|  |  |  | **2020 vs. 2019** | | | | | |
| **Net cash (used in) provided by:** |  | **2020** | | |  | **2019** | | |  | **$** | | |  | **%** | |
|  |  |  | | |  |  | | |  |  | | |  |  | |
| Operating activities |  | $ | (11,636 | ) |  | $ | (21,206 | ) |  | $ | 9,570 |  |  | 45.1 | % |
| Investing activities |  | 13,226 | |  |  | 21,390 | |  |  | (8,164 | | ) |  | 38.2 | % |
| Financing activities |  | 62,210 | |  |  | 92 | |  |  | 62,118 | |  |  | 67,519.6 | % |

***Operating Activities***

Net cash used in operating activities of $11,636 for the three months ended March 31, 2020 decreased $9,570 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 $4,252 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 prepaid expenses and other long-term assets and liabilities of $4,127 and $1,330,

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respectively, when compared to the same period last year, and lower cash payments for contingent consideration of $1,623 during the current period when compared to the prior period.

***Investing Activities***

Cash provided by investing activities was $13,226 and $21,390 for the three months ended March 31, 2020 and 2019, respectively and was related to net cash proceeds received from the excess of sales over purchases of marketable securities in both periods.

***Financing Activities***

Cash provided by financing activities for the three months ended March 31, 2020 was $62,210 and was driven by the February private placement that resulted in net proceeds of $60,733, and stock option exercises of $1,389.

***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 2019 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. Additionally, we are unable to estimate the near or long term impact that COVID-19, which may have a material adverse impact on our business.

In February 2020, we announced that we had entered into a definitive agreement for the sale of our ADSs and Series A Non-Voting Convertible Preferred Shares (“Series A Preferred”) in a private placement to a group of institutional accredited investors. The private placement resulted in gross proceeds of approximately $65,000 before deducting placement agent and other offering expenses, which resulted in net proceeds of approximately $60,733.

Also, in February 2020, we filed a shelf registration statement on Form S-3 that allows issuance and sale by us, from time to time, of :

|  |  |
| --- | --- |
|  |  |
| • | up to $250,000 in aggregate of ordinary shares, nominal value US$0.01 per share (the “Ordinary Shares”), each of which may be represented by ADSs, preferred shares, nominal value US$0.01 per share (the “Preferred Shares”), debt securities (the “Debt Securities”), warrants to purchase Ordinary Shares, ADSs, Preferred Shares and/or Debt Securities (the “Warrants”), and/or units consisting of Ordinary Shares, ADSs, Preferred Shares, one or more Debt Securities or Warrants in one or more series, in any combination, pursuant to the terms of the 2020 Shelf Registration Statement, the base prospectus contained in the 2020 Shelf Registration Statement (the “Base Prospectus”), and any amendments or supplements thereto (together, the “Securities”); including |

|  |  |
| --- | --- |
|  |  |
| • | up to $50,000 of ADSs that may be issued and sold from time to time pursuant to the terms of an Open Market Sale AgreementSM (“the Sales Agreement”), entered into with Jefferies LLC on February 4, 2020, the 2020 Shelf Registration Statement, the Base Prospectus and the terms of the sales agreement prospectus contained in the 2020 Shelf Registration Statement. |

On April 28, 2020, we announced the pricing of an underwritten public offering of 11,630 ordinary shares, in the form of American Depositary Shares (“ADSs”) at a price to the public of $10.75 per ADS. Each ADS represents the right to receive one ordinary share. All of the ADSs are being offered by Avadel. The gross proceeds to us from the offering are expected to be approximately $125,000, before deducting underwriting discounts and commissions and estimated offering expenses.

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.

Cash, cash equivalent and marketable security balances as of March 31, 2020, proceeds from the offering completed on May 1, 2020 which described further in *Note 18: Subsequent Events*, unused financing sources are expected to provide the Company with the flexibility to meet its liquidity needs in 2020, including its operating requirements related to the development of FT218.

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**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 March 31, 2020 and December 31, 2019, 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, Ferring B.V. and Ferring International Center S.A., 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.  Ferring initiated this litigation initially against Serenity Pharmaceuticals, LLC (“Serenity”) (the licensor of the Noctiva Patents) and Reprise Biopharmaceutics, LLC (“Reprise”) on April 28, 2017.  Avadel subsequently joined the litigation on June 28, 2018, shortly after Ferring received FDA approval for Nocdurna.  In this litigation, filed in the United States District Court for the Southern District of New York, 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, Serenity, and Reprise 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 a pending settlement of the litigation with respect to just Ferring and Specialty Pharma. On February 25, 2020, Ferring and Specialty Pharma jointly moved for bankruptcy court approval of a settlement agreement with respect to the claims alleged in the litigation.  In accordance with the terms of the settlement agreement, promptly following bankruptcy court approval of the settlement agreement, the parties would dismiss with prejudice their respective claims against each other in the litigation.  On March 13, 2020, the Bankruptcy Court entered an order approving the settlement with Ferring.  Pursuant to the terms of the settlement, the parties are to dismiss their respective claims against each other in the District Court litigation in the Southern District of New York, with such dismissals to be effective concurrently.  The joint dismissal has not yet been filed with District Court for the Southern District of New York.

*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.

*Exela Litigation*.  On January 7, 2020, Exela filed a complaint against us and our subsidiary, Avadel Legacy, in the United States District for the District of Delaware. The complaint alleges infringement of a certain Exela patent related to its cysteine hydrochloride product. Exela is most notably seeking i) a declaratory judgment that the Nouress product infringes its patent, ii) an injunction (both preliminary and permanent) precluding the launch of Nouress, and iii) monetary damages (including enhanced damages, prejudgment interest and attorneys’ fees) in the event Nouress is commercially launched and found to infringe Exela’s patent.  The current deadline for Avadel to respond to Exela’s complaint is May 29, 2020.

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*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 disagreed with the merits of the amended IRS claim, and Specialty Pharma entered into negotiations regarding the treatment of the claim in the bankruptcy case.  On November 19, 2019, Specialty Pharma and the IRS resolved their dispute, subject to Bankruptcy Court approval in Specialty Pharma's Chapter 11 plan, and without prejudice to the claims, rights and defenses of the IRS and other Avadel entities outside of the bankruptcy case.  The resolution provided for allowance of the IRS claim as a priority claim but for the IRS to receive a distribution of not less than $125 from Specialty Pharma following confirmation of its chapter 11 plan, leaving a substantial amount of the bankruptcy estate for general unsecured creditors.

***Material Commitments***

Other than commitments disclosed in *Note 16: Contingent Liabilities and Commitments* to the Company’s audited consolidated financial statements included in Part II, Item 8 of the Company’s 2019 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* and long-term contingent consideration payable as disclosed in *Note 9: Contingent Consideration 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 2019 Annual Report on Form 10-K and updated in *Note 9: Contingent Consideration 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.A hypothetical 50 basis point change in interest rates would not result in a material decrease or increase in the fair value of our securities due to the general short-term nature of our investment portfolio.

**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 March 31, 2020, 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 March 31, 2020.

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

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 or 15d-15 that occurred during the three months ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have implemented a work from home policy due to the COVID-19 pandemic and will continue to monitor the impact on the design and operating effectiveness of our internal controls.

**PART II – OTHER INFORMATION**

|  |  |
| --- | --- |
|  |  |
| **ITEM 1.** | **LEGAL PROCEEDINGS.** |

The information contained in *Note 18: 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, 2019 filed with the SEC on March 16, 2020.

*COVID-19 may materially and adversely affect our business and our financial results.*

The recent COVID-19 pandemic is understood to have originated in Wuhan, China in December 2019 and has since spread globally, including to the United States and European countries. The continued spread of COVID-19 could adversely impact our operations, including our ability to initiate or complete clinical trials, manufacture sufficient supply of our product candidates, file our New Drug Application, or NDA, for FT218 or to manufacture FT218 at sufficient scale for commercialization, if approved. Any delay in submission of our NDA could adversely affect our ability to obtain regulatory approval for and to commercialize FT218, particularly on our current projected timelines, increase our operating expenses and have a material adverse effect on our business and financial results. In addition, many hospitals have recommend canceling or delaying elective procedures, which could weaken demand for our hospital products portfolio and have a negative impact on our financial condition.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely. We have already suspended non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may induce absenteeism, disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in the geographies where we or our third party suppliers and contract manufacturers, including those for our approved hospital products portfolio, or contract research organizations operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, including any impact on our hospital products portfolio related to the cancellation of elective procedures. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial condition.

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

Third parties may claim infringement of their patents and other intellectual property rights by the manufacture, use, import, offer for sale or sale of our drug delivery technologies or our other products. For example, an Orange Book patent exists related to Exela’s currently marketed cysteine hydrochloride injection product. In this regard, Exela filed a complaint against us and our subsidiary, Avadel Legacy Pharmaceuticals, LLC (“Avadel Legacy”), in the United States District for the District of Delaware in January of 2020 alleging infringement of that Orange Book patent by our recently approved Nouress product. As another example, approximately 14 Orange Book patents exist related to Jazz Pharmaceuticals’ currently marketed sodium oxybate product and other Jazz Pharmaceuticals patent applications are pending with claims directed to sodium oxybate formulations, and, in connection with us seeking regulatory approval for FT218, Jazz may allege that FT218 infringes its patents or other intellectual property rights

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and file suit attempting to prevent us from commercializing FT218. In response to any claim of infringement, we may choose or be forced to seek licenses, defend infringement actions or challenge the validity or enforceability of those patent rights in court or administrative proceedings. If we cannot obtain required licenses on commercially reasonably terms, or at all, are found liable for infringement or are not able to have such patent rights declared invalid or unenforceable, our business could be materially harmed. We may be subject to claims (and even held liable) for significant monetary damages (including enhanced damages and/or attorneys’ fees), encounter significant delays in bringing products to market or be precluded from the manufacture, use, import, offer for sale or sale of products or methods of drug delivery covered by the patents of others. Even if a license is available, it may not be available on commercially reasonable terms or may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. We may not have identified, or be able to identify in the future, U.S. or foreign patents that pose a risk of potential infringement claims.

Parties making claims against us may be able to sustain the costs of patent litigation more effectively than we can because they have substantially greater resources. In addition, any claims, with or without merit, that our products or drug delivery technologies infringe proprietary rights of third parties could be time-consuming, result in costly litigation or divert the efforts of our technical and management personnel, any of which could disrupt our relationships with our partners and could significantly harm our financial positions and operating results.

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

*Securities Purchase Agreement*

On February 21, 2020, we announced that we entered into a definitive agreement for the sale of our ADSs and Series A Non-Voting Convertible Preferred Shares (“Series A Preferred”) in a private placement to a group of institutional accredited investors. The private placement resulted in gross proceeds of approximately $65 million before deducting placement agent and other offering expenses which resulted in net proceeds of approximately $61 million.

Pursuant to the terms of the private placement, we issued 8,680,225 ADSs and 487,614 shares of Series A Preferred at a price of $7.09 per share, priced at-the-market under Nasdaq rules. Each share of non-voting Series A Preferred is convertible into one ADS, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.99% of the total number of Avadel ADSs outstanding. The closing of the private placement occurred on February 25, 2020. Proceeds from the private placement will be used to fund continued clinical and program development of FT218, including an open-label extension study for REST-ON, a switch study to evaluate patients switching from twice-nightly sodium oxybate to once-nightly FT218, as well as for general corporate purposes.

The private placement was exempt from registration pursuant to Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering.

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

None.

**ITEM 4.    MINE SAFETY DISCLOSURES.**

Not applicable.

**ITEM 5.    OTHER INFORMATION.**

None.

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**ITEM 6.    EXHIBITS.**

|  |  |  |
| --- | --- | --- |
|  | | |
|  |  |  |
| **Exhibit No.** |  | **Description** |
|  |  |  |
| 10.1 |  | [Securities Purchase Agreement, dated February 20, 2020, by and among Avadel Pharmaceuticals plc and the Investors named therein (incorporated by reference to Exhibit 10.1 to the registrant’s current report on Form 8-K, filed on February 24, 2020)](http://www.sec.gov/Archives/edgar/data/1012477/000110465920024077/tm209736d1_ex10-1.htm) |
| 10.2 |  | [Registration Rights Agreement, dated February 25, 2020, by and among Avadel Pharmaceuticals plc and the Investors named therein (incorporated by reference to Exhibit 10.40 to the registrant’s annual report on Form 10-K, filed on March 16, 2020)](http://www.sec.gov/Archives/edgar/data/1012477/000101247720000007/a123119ex-1040.htm) |
| 31.1\* |  | [Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act](exhibit311q12020.htm) |
| 31.2\* |  | [Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act](exhibit312q12020.htm) |
| 32.1\*\* |  | [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](exhibit321q12020.htm) |
| 32.2\*\* |  | [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](exhibit322q12020.htm) |
| 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.

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**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.

|  |  |  |
| --- | --- | --- |
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|  |  |  |
|  | **AVADEL PHARMACEUTICALS PLC** | |
|  | (Registrant) | |
|  |  |  |
| Date: May 11, 2020 | By: | /s/ Thomas S. McHugh |
|  |  | Thomas S. McHugh |
|  |  | *Senior Vice President and Chief Financial Officer* |
|  |  | *(Duly Authorized Officer* and *Principal Financial and Accounting Officer)* |

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