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, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 000-28508

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 D02 T380
Ireland
(Address of Principal Executive Office and Zip Code)

+353-1-901-5201
(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*	AVDL	The Nasdaq Global Market
Ordinary Shares, nominal value $0.01 per share**	N/A	

*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 ☑ No ☐

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

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

Large accelerated filer	☐	Accelerated filer	☑
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 ☑

At May 4, 2022, 59,038,237 ordinary shares, nominal value $0.01 each, of the Company were outstanding.

TABLE OF CONTENTS

NOTE REGARDING TRADEMARKS

We own various trademark registrations and applications, and unregistered trademarks, including Avadel®, Micropump®, LiquiTime® and Medusa®. 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, LinkedIn 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.avadel.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, our LinkedIn posts or our Twitter posts are not incorporated into, and does not form a part of, this Quarterly Report.

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, (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 lead product candidate, FT218;
- Our ability to obtain regulatory approval of and successfully commercialize FT218, including any delays in approval;
- The ability of FT218, if approved, to gain market acceptance;
- Our ability to enter into strategic partnerships for the commercialization, manufacturing and distribution of FT218, if approved;
- Our dependence on a limited number of suppliers for the manufacturing of FT218 and certain raw materials used in FT218 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 size and market participation for FT218;
- Our ability to continue to service our Exchangeable Senior Notes due February 2023 (the "February 2023 Notes") and our Exchangeable Senior Notes due October 2023 (the "October 2023 Notes", together with the February 2023 Notes, 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 potential impact of COVID-19 on our business and future operating results;
- Our ability to hire and retain key members of our leadership team and other personnel; 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, 2022 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.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development expenses	$ 6,991	$ 3,852
Selling, general and administrative expenses	21,635	11,012
Restructuring income	—	(53)
Total operating expense	28,626	14,811
Operating loss	(28,626)	(14,811)
Investment and other (expense) income, net	(137)	610
Interest expense	(2,017)	(1,929)
Gain from release of certain liabilities	33	78
Loss before income taxes	(30,747)	(16,052)
Income tax benefit	(4,323)	(2,607)
Net loss	$ (26,424)	$ (13,445)
Net loss per share - basic	$ (0.45)	$ (0.23)
Net loss per share - diluted	(0.45)	(0.23)
Weighted average number of shares outstanding - basic	58,824	58,443
Weighted average number of shares outstanding - diluted	58,824	58,443

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2022	**2021**
Net loss	$ (26,424)	$ (13,445)
Other comprehensive loss, net of tax:		
Foreign currency translation loss	(185)	(718)
Net other comprehensive loss, net of income tax benefit (expense) of $330 and $(55), respectively	(917)	(537)
Total other comprehensive loss, net of tax	(1,102)	(1,255)
Total comprehensive loss	$ (27,526)	$ (14,700)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	March 31, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 60,873	$ 50,708
Marketable securities	62,608	106,513
Research and development tax credit receivable	2,387	2,443
Prepaid expenses and other current assets	34,873	32,826
Total current assets	160,741	192,490
Property and equipment, net	268	285
Operating lease right-of-use assets	2,410	2,652
Goodwill	16,836	16,836
Research and development tax credit receivable	1,237	1,225
Other non-current assets	39,635	33,777
Total assets	$ 221,127	$ 247,265
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 26,184	$ —
Current portion of operating lease liability	917	900
Accounts payable	6,048	7,679
Accrued expenses	9,432	7,151
Other current liabilities	1,442	5,270
Total current liabilities	44,023	21,000
Long-term debt	116,525	142,397
Long-term operating lease liability	1,500	1,707
Other non-current liabilities	3,847	3,917
Total liabilities	165,895	169,021
Shareholders' equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at March 31, 2022 and 488 issued and outstanding at December 31, 2021, respectively	5	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 59,032 issued and outstanding at March 31, 2022 and 58,620 issued and outstanding at December 31, 2021	590	586
Additional paid-in capital	553,859	549,349
Accumulated deficit	(474,180)	(447,756)
Accumulated other comprehensive loss	(25,042)	(23,940)
Total shareholders' equity	55,232	78,244
Total liabilities and shareholders' equity	$ 221,127	$ 247,265

See accompanying notes to unaudited condensed consolidated financial statements.

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

Three Months Ended March 31, 2022

	Ordinary shares		Preferred shares		Additional	Accumulated	Accumulated other comprehensive	Total shareholders'
	Shares	Amount	Shares	Amount	paid-in capital	deficit	loss	equity
Balance, December 31, 2021	58,620	$ 586	488	$ 5	$ 549,349	$ (447,756)	$ (23,940)	$ 78,244
Net loss	—	—	—	—	—	(26,424)	—	(26,424)
Other comprehensive loss	—	—	—	—	—	—	(1,102)	(1,102)
Exercise of stock options	275	3	—	—	1,903	—	—	1,906
Vesting of restricted shares	119	1	—	—	(1)	—	—	—
Employee share purchase plan share issuance	18	—	—	—	103	—	—	103
Stock-based compensation expense	—	—	—	—	2,505	—	—	2,505
Balance, March 31, 2022	59,032	$ 590	488	$ 5	$ 553,859	$ (474,180)	$ (25,042)	$ 55,232

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

Three Months Ended March 31, 2021

	Ordinary shares		Preferred shares		Additional paid-in	Accumulated	Accumulated other comprehensive	Total shareholders'
	Shares	Amount	Shares	Amount	capital	deficit	loss	equity
Balance, December 31, 2020	58,396	$ 583	488	$ 5	$ 566,916	$ (384,187)	$ (21,051)	$ 162,266
Impact of the adoption of ASU 2020-06	—	—	—	—	(26,699)	13,760	—	(12,939)
Net loss	—	—	—	—	—	(13,445)	—	(13,445)
Other comprehensive loss	—	—	—	—	—	—	(1,255)	(1,255)
Exercise of stock options	23	—	—	—	106	—	—	106
Vesting of restricted shares	61	1	—	—	(1)	—	—	—
Employee share purchase plan share issuance	8	—	—	—	43	—	—	43
Stock-based compensation expense	—	—	—	—	1,728	—	—	1,728
Balance, March 31, 2021	58,488	$ 584	488	$ 5	$ 542,093	$ (383,872)	$ (22,306)	$ 136,504

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

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (26,424)	$ (13,445)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	259	218
Amortization of debt discount and debt issuance costs	312	312
Change in deferred taxes	(4,323)	(2,534)
Stock-based compensation expense	2,505	1,728
Gain from release of certain liabilities	(33)	(78)
Other adjustments	702	561
Net changes in assets and liabilities		
Prepaid expenses and other current assets	(2,058)	(3,736)
Research and development tax credit receivable	(19)	80
Accounts payable & other current liabilities	(5,613)	(3,789)
Accrued expenses	2,314	(2,112)
Other assets and liabilities	(1,667)	(618)
Net cash used in operating activities	(34,045)	(23,413)
Cash flows from investing activities:		
Purchases of property and equipment	—	(26)
Proceeds from the disposition of the hospital products	—	8,250
Proceeds from sales of marketable securities	44,341	40,736
Purchases of marketable securities	(2,090)	(37,769)
Net cash provided by investing activities	42,251	11,191
Cash flows from financing activities:		
Proceeds from stock option exercises and employee share purchase plan	2,009	149
Net cash provided by financing activities	2,009	149
Effect of foreign currency exchange rate changes on cash and cash equivalents	(50)	(477)
Net change in cash and cash equivalents	10,165	(12,550)
Cash and cash equivalents at January 1,	50,708	71,722
Cash and cash equivalents at March 31,	$ 60,873	$ 59,172
Supplemental disclosures of cash flow information:		
Interest paid	$ 5,531	$ 3,234
Income taxes paid	$ —	$ —

See accompanying notes to unaudited condensed consolidated financial statements

NOTE 1: Summary of Significant Accounting Policies

Nature of Operations. Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel," the "Company," "we," "our," or "us") is a biopharmaceutical company. The Company is registered as an Irish public limited company. The Company's headquarters are in Dublin, Ireland with operations in Dublin, Ireland and St. Louis, Missouri, United States ("U.S.").

The Company's lead product candidate, FT218, is an investigational once-nightly, extended-release formulation of sodium oxybate for the treatment of excessive daytime sleepiness ("EDS") or cataplexy in adults with narcolepsy. The Company is primarily focused on the development and potential United States ("U.S.") Food and Drug Administration ("FDA") approval of FT218. In December 2020, the Company submitted a New Drug Application ("NDA") to the FDA for FT218 to treat excessive daytime sleepiness or cataplexy in adults with narcolepsy. In February 2021, the NDA for FT218 was accepted by the FDA and was assigned a Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021. On October 15, 2021, the Company announced that the FDA informed Avadel that the review of the NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this Quarterly Report, the FDA's review of the Company's NDA for FT218 remains ongoing.

Outside of the Company's lead product candidate, the Company continues to evaluate opportunities to expand its product portfolio. As of the date of this Quarterly Report, the Company does not have any approved or commercialized products in its portfolio.

Basis of Presentation. The unaudited condensed consolidated balance sheet as of March 31, 2022, which is derived from the prior year 2021 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 U.S. ("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 2021 Annual Report on Form 10-K filed with the United States Securities and Exchange Commission ("SEC") on March 16, 2022.

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.

NOTE 2: 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, the Company uses 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, the Company may generally use one or each of the following techniques:

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

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

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

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

	As of March 31, 2022			As of December 31, 2021		
Fair Value Measurements:	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Marketable securities (see *Note 3*)						
Mutual and money market funds	$ 42,776	$ —	$ —	$ 78,098	$ —	$ —
Corporate bonds	—	13,912	—	—	16,479	—
Government securities - U.S.	—	3,988	—	—	9,471	—
Other fixed-income securities	—	1,932	—	—	2,465	—
Total assets	$ 42,776	$ 19,832	$ —	$ 78,098	$ 28,415	$ —

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, 2022 and December 31, 2021, respectively, there were no transfers in and out of Level 1, 2, or 3. During the three months ended March 31, 2022 and 2021, respectively, the Company did not recognize any allowances for credit losses.

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

Debt

The Company estimates the fair value of its $143,750 aggregate principal amount of its 4.50% exchangeable senior notes due February 2023 (the "February 2023 Notes") 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 (a Level 2 input). The estimated fair value of the February 2023 Notes at March 31, 2022 is $145,547. See *Note 4: Long-Term Debt* for additional information regarding the Company's debt obligations.

NOTE 3: Marketable Securities

The Company has investments in available-for-sale debt securities which are recorded at fair market value. The change in the fair value of available-for-sale debt investments is recorded as accumulated other comprehensive loss in shareholders' equity, net of income tax effects. As of March 31, 2022, the Company considered any decreases in fair value on its 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, 2022 and December 31, 2021, respectively:

	March 31, 2022			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Mutual and money market funds	$ 43,446	$ 341	$ (1,011)	$ 42,776
Corporate bonds	14,338	12	(438)	13,912
Government securities - U.S.	4,188	3	(203)	3,988
Other fixed-income securities	1,968	—	(36)	1,932
Total	$ 63,940	$ 356	$ (1,688)	$ 62,608

	December 31, 2021			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Mutual and money market funds	$ 78,331	$ 813	$ (1,046)	$ 78,098
Corporate bonds	16,478	94	(93)	16,479
Government securities - U.S.	9,530	39	(98)	9,471
Other fixed-income securities	2,473	2	(10)	2,465
Total	$ 106,812	$ 948	$ (1,247)	$ 106,513

The Company determines realized gains or losses on the sale of marketable securities on a specific identification method. The Company reflects these gains and losses as a component of investment and other (expense) income, net in the accompanying unaudited condensed consolidated statements of loss.

The Company recognized gross realized gains of $304 and $11 for the three months ended March 31, 2022 and 2021, respectively. These realized gains were offset by realized losses of $790 and $68 for the three months ended March 31, 2022 and 2021, respectively.

The following table summarizes the estimated fair value of the Company's 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, 2022:

	Maturities				
Marketable Debt Securities:	**Less than 1 Year**	**1-5 Years**	**5-10 Years**	**Greater than 10 Years**	**Total**
Corporate bonds	$ 3,878	$ 9,733	$ 301	$ —	$ 13,912
Government securities - U.S.	—	2,214	722	1,052	3,988
Other fixed-income securities	—	1,384	548	—	1,932
Total	$ 3,878	$ 13,331	$ 1,571	$ 1,052	$ 19,832

The Company has classified its investment in available-for-sale marketable securities as current assets in the 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 the Company's investment portfolio.

The following table shows the gross unrealized losses and fair value of the Company's available-for-sale debt securities at March 31, 2022. The unrealized losses in the table below are driven by factors other than credit risk. The Company does not intend to sell the investments and it is not more likely than not that it will be required to sell the investments before recovery of their amortized cost bases.

Marketable Debt Securities:	Less than 12 months		Greater than 12 months		Total	
	Fair value	Unrealized Losses	Fair value	Unrealized Losses	Fair value	Unrealized Losses
Corporate bonds	$ 11,041	$ 360	$ 1,137	$ 78	$ 12,178	$ 438
Government securities - U.S.	1,975	73	1,892	130	3,867	203
Other fixed-income securities	1,811	36	—	—	1,811	36
Total	$ 14,827	$ 469	$ 3,029	$ 208	$ 17,856	$ 677

NOTE 4: Long-Term Debt

Long-term debt is summarized as follows:

	March 31, 2022	December 31, 2021
Principal amount of 4.50% exchangeable senior notes due 2023	$ 143,750	$ 143,750
Less: unamortized debt discount and issuance costs, net	(1,041)	(1,353)
Net carrying amount of debt	142,709	142,397
Less: current maturities, net of $191 unamortized debt discount and issuance costs	26,184	—
Long-term debt	$ 116,525	$ 142,397

For the three months ended March 31, 2022 and 2021, the total interest expense was $2,017 and $1,929, respectively, with coupon interest expense of $1,617 for each period and the amortization of debt issuance costs and debt discount of $312 for each period. Current period interest expense also included $88 of additional interest expense owed to be in compliance with certain terms of the February 2023 Notes indenture and is not applicable to future periods.

On February 16, 2018, Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of the Company (the "Issuer"), issued $125,000 aggregate principal amount of its February 2023 Notes in a private placement (the "Offering") to qualified institutional buyers pursuant to Rule 144A under the Securities Act. In connection with the Offering, the Issuer granted the initial purchasers of the February 2023 Notes a 30-day option to purchase up to an additional $18,750 aggregate principal amount of the February 2023 Notes, which was fully exercised on February 16, 2018. Net proceeds received by the Company, after issuance costs and discounts, were approximately $137,560. The February 2023 Notes are the Company's senior unsecured obligations and rank equally in right of payment with all of the Company's existing and future senior unsecured indebtedness and effectively junior to any of the Company's existing and future secured indebtedness, to the extent of the value of the assets securing such indebtedness.

On April 5, 2022, the Issuer completed the exchange of $117,375 of its February 2023 Notes for a new series of its Exchangeable Senior Notes due October 2, 2023 (the "October 2023 Notes", together with the February 2023 Notes, the "2023 Notes") (the "Exchange Transaction"). The remaining $26,375 aggregate principal amount of the February 2023 Notes were not exchanged and will maintain a maturity date of February 1, 2023. Due to the Exchange Transaction, $117,375 of the February 2023 Notes will be classified as long-term debt as of March 31, 2022.

The 2023 Notes will be exchangeable at the option of the holders at an initial exchange rate of 92.6956 ADSs per $1 principal amount of 2023 Notes (so long as the principal amount of such holder's 2023 Notes not exchanged is at least $200), which is equivalent to an initial exchange price of approximately $10.79 per ADS. Upon the exchange of any 2023 Notes, the Issuer will pay or cause to be delivered, as the case may be, cash, ADSs or a combination of cash and ADSs, at the Issuer's election.

February 2023 Notes

Holders of the February 2023 Notes may convert their February 2023 Notes, at their option, only under the following circumstances prior to the close of business on the business day immediately preceding August 1, 2022, under the circumstances and during the periods set forth below and regardless of the conditions described below, on or after August 1, 2022 and prior to the close of business on the business day immediately preceding the maturity date:

- Prior to the close of business on the business day immediately preceding August 1, 2022, a holder of the February 2023 Notes may surrender all or any portion of its February 2023 Notes for exchange at any time during the five business day period immediately after any five consecutive trading day period (the "Measurement Period") in which the trading price per $1 principal amount of February 2023 Notes, as determined following a request by a holder of the

2023 Notes, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the ADSs and the exchange rate on each such trading day.

- If a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs prior to the close of business on the business day immediately preceding August 1, 2022, regardless of whether a holder of the February 2023 Notes has the right to require the Company to repurchase the February 2023 Notes, or if Avadel is a party to a merger event that occurs prior to the close of business on the business day immediately preceding August 1, 2022, all or any portion of a the holder's February 2023 Notes may be surrendered for exchange at any time from or after the date that is 95 scheduled trading days prior to the anticipated effective date of the transaction (or, if later, the earlier of (x) the business day after the Company gives notice of such transaction and (y) the actual effective date of such transaction) until 35 trading days after the actual effective date of such transaction or, if such transaction also constitutes a fundamental change, until the related fundamental change repurchase date.

- Prior to the close of business on the business day immediately preceding August 1, 2022, a holder of the February 2023 Notes may surrender all or any portion of its February 2023 Notes for exchange at any time during any calendar quarter commencing after the calendar quarter ending on June 30, 2018 (and only during such calendar quarter), if the last reported sale price of the ADSs for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the exchange price on each applicable trading day.

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

October 2023 Notes

Holders of the October 2023 Notes may convert their October 2023 Notes, at their option, only under the following circumstances prior to the close of business on the business day immediately preceding May 1, 2023, under the circumstances and during the periods set forth below and regardless of the conditions described below, on or after May 1, 2023 and prior to the close of business on the business day immediately preceding the maturity date:

- Prior to the close of business on the business day immediately preceding May 1, 2023, a holder of the October 2023 Notes may surrender all or any portion of its October 2023 Notes for exchange at any time during the five business day period immediately after any five consecutive trading day period (the "Measurement Period") in which the trading price per $1 principal amount of October 2023 Notes, as determined following a request by a holder of the October 2023 Notes, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the ADSs and the exchange rate on each such trading day.

- If a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs prior to the close of business on the business day immediately preceding May 1, 2023, regardless of whether a holder of the October 2023 Notes has the right to require the Company to repurchase the October 2023 Notes, or if Avadel is a party to a merger event that occurs prior to the close of business on the business day immediately preceding May 1, 2023, all or any portion of a the holder's October 2023 Notes may be surrendered for exchange at any time from or after the date that is 95 scheduled trading days prior to the anticipated effective date of the transaction (or, if later, the earlier of (x) the business day after the Company gives notice of such transaction and (y) the actual effective date of such transaction) until 35 trading days after the actual effective date of such transaction or, if such transaction also constitutes a fundamental change, until the related fundamental change repurchase date.

- Prior to the close of business on the business day immediately preceding May 1, 2023, a holder of the October 2023 Notes may surrender all or any portion of its October 2023 Notes for exchange at any time during any calendar quarter commencing after the calendar quarter ending on March 31, 2022 (and only during such calendar quarter), if the last reported sale price of the ADSs for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the exchange price on each applicable trading day.

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

The Company, at its option, may redeem for cash all of the October 2023 Notes if the last reported sale price (as defined by the indenture) of the ADSs has been at least 130% of the Exchange Price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending on, and including, the trading day immediately preceding the date on which the Company provides notice to redeem the October 2023 Notes.

The Company considered the guidance in ASC 815-15, *Embedded Derivatives*, to determine if this instrument contains an embedded feature that should be separately accounted for as a derivative. ASC 815 provides for an exception to this rule when convertible notes, as host instruments, are deemed to be conventional, as defined by ASC 815-40. The Company determined that this exception applies due, in part, to the Company's ability to settle the 2023 Notes in cash, ADSs or a combination of cash and ADSs, at the Company's option. The Company has therefore applied the guidance provided by ASC 470-20, *Debt with Conversion and Other Options*, as amended by ASU 2020-06.

NOTE 5: Income Taxes

The income tax benefit was $4,323 for the three months ended March 31, 2022 resulting in an effective tax rate of 14.1%. The income tax benefit was $2,607 for the three months ended March 31, 2021 resulting in an effective tax rate of 16.2%. The increase in the income tax benefit for the three months ended March 31, 2022, when compared to the same period in 2021, is primarily due to an increase in net operating losses recognized in the United States.

NOTE 6: Other Assets and Liabilities

Various other assets and liabilities are summarized as follows:

Prepaid Expenses and Other Current Assets:	**March 31, 2022**	**December 31, 2021**
Income tax receivable	$ 29,122	$ 29,097
Prepaid and other expenses	5,317	3,179
Guarantee from Armistice	278	279
Other	156	271
Total	$ 34,873	$ 32,826

Other Non-Current Assets:	**March 31, 2022**	**December 31, 2021**
Deferred tax assets	$ 28,578	$ 24,128
Right of use assets at contract manufacturing organizations	10,082	8,549
Guarantee from Armistice	702	771
Other	273	329
Total	$ 39,635	$ 33,777

Accrued Expenses	**March 31, 2022**	**December 31, 2021**
Accrued professional fees	$ 7,063	$ 2,678
Accrued compensation	1,755	3,167
Accrued outsource contract costs	574	1,048
Accrued restructuring	40	41
Customer allowances	—	217
Total	$ 9,432	$ 7,151

Other Current Liabilities:	March 31, 2022	December 31, 2021
Accrued interest	$ 1,094	$ 4,920
Guarantee to Deerfield	279	280
Other	69	70
Total	$ 1,442	$ 5,270

Other Non-Current Liabilities:	March 31, 2022	December 31, 2021
Tax liabilities	$ 3,143	$ 3,143
Guarantee to Deerfield	704	774
Total	$ 3,847	$ 3,917

NOTE 7: 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 per share is calculated by dividing net loss - diluted 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 the Company's preferred shares, the exercise of outstanding equity compensation awards, and ordinary shares expected to be issued under the Company's Employee Share Purchase Plan ("ESPP").

The Company has a choice to settle the conversion obligation under the 2023 Notes in cash, shares or any combination of the two. The Company utilizes 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 the Company's ordinary shares and reflects the elimination of the interest expense related to the 2023 Notes.

The dilutive effect of the stock options, restricted stock units, preferred shares and ordinary shares expected to be issued under the Company's ESPP has been calculated using the treasury stock method. The dilutive effect of the performance share unit awards ("PSUs") will be calculated using the treasury stock method, if and when the contingent vesting condition is achieved.

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:	2022	2021
Net loss	$ (26,424)	$ (13,445)
Weighted average shares:		
Basic shares	58,824	58,443
Effect of dilutive securities—employee and director equity awards outstanding, preferred shares and 2023 Notes	—	—
Diluted shares	58,824	58,443
Net loss per share - basic	$ (0.45)	$ (0.23)
Net loss per share - diluted	$ (0.45)	$ (0.23)

Potential ordinary shares of 17,696 and 15,275 were excluded from the calculation of weighted average shares for the three months ended March 31, 2022 and 2021, respectively, because either their effect was considered to be anti-dilutive or they were related to shares from PSUs for which the contingent vesting condition had not been achieved. For the three months ended March 31, 2022 and 2021, the effects of dilutive securities were entirely excluded from the calculation of net loss per share as a net loss was reported in these periods.

NOTE 8: Comprehensive Loss

The following table shows the components of accumulated other comprehensive loss for the three months ended March 31, 2022 and 2021, respectively, net of tax effects:

	Three Months Ended March 31,	
Accumulated Other Comprehensive Loss:	**2022**	**2021**
Foreign currency translation adjustment:		
Beginning balance	$ (23,855)	$ (22,627)
Net other comprehensive loss	(185)	(718)
Balance at March 31,	$ (24,040)	$ (23,345)
Unrealized (loss) gain on marketable debt securities, net		
Beginning balance	$ (85)	$ 1,576
Net other comprehensive loss, net of income tax benefit (expense) of $330 and $(55), respectively	(917)	(537)
Balance at March 31,	$ (1,002)	$ 1,039
Accumulated other comprehensive loss at March 31,	$ (25,042)	$ (22,306)

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 9: Commitments and Contingencies

Litigation

The Company is subject to potential liabilities generally incidental to the Company's 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, 2022 and December 31, 2021, 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 consolidated financial position, results of operations, cash flows or liquidity.

First Complaint

On May 12, 2021, Jazz Pharmaceuticals, Inc. ("Jazz") filed a formal complaint (the "First Complaint") initiating a lawsuit in the United States District Court for the District of Delaware (the "Court") against Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Management Corporation, Avadel Legacy Pharmaceuticals, LLC, Avadel Specialty Pharmaceuticals, LLC, and Avadel CNS Pharmaceuticals, LLC (collectively, the "Avadel Parties"). In the First Complaint, Jazz alleges the sodium oxybate product ("Proposed Product") described in the NDA owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 8731963, 10758488, 10813885, 10959956 and/or 10966931 (collectively, the "patents-in-suit"). The First Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses.

On June 3, 2021, the Avadel Parties timely filed their Answer and Counterclaims (the "Avadel Answer") with the Court in response to the First Complaint. The Avadel Answer generally denies the allegations set forth in the First Complaint, includes numerous affirmative defenses (including, but not limited to, non-infringement and invalidity of the patents-in-suit), and asserts a number of counterclaims seeking i) a declaratory judgment of non-infringement of each patent-in-suit, and ii) a declaratory judgment of invalidity of each patent-in-suit.

On June 18, 2021, Jazz filed its Answer ("Jazz Answer") with the Court in response to the Avadel Answer. The Jazz Answer generally denies the allegations set forth in the Avadel Answer and sets forth a single affirmative defense asserting that Avadel has failed to state a claim for which relief can be granted.

On June 21, 2021, the Court issued an oral order requiring the parties to i) confer regarding proposed dates to be included in the Court's scheduling order for the case, and ii) submit a proposed order, including a proposal for the length and timing of trial, to the Court by no later than July 21, 2021.

On July 30, 2021, the Court issued a scheduling order establishing timing for litigation events including i) a claim construction hearing date of August 2, 2022, and ii) a trial date of October 30, 2023.

On October 18, 2021, consistent with the scheduling order, Jazz filed a status update with the Court indicating that Jazz did not intend to file a preliminary injunction with the Court at this time. Jazz further indicated that it would provide the Court with an update regarding whether preliminary injunction proceedings may be necessary after receiving further information regarding the FDA's action on Avadel's NDA.

On January 4, 2022, the Court entered an agreed order dismissing this case with respect to Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, and Avadel Management Corporation. A corresponding order was entered in the two below cases on the same day.

On February 25, 2022, Jazz filed an amended Answer to Avadel's Counterclaims ("the Jazz First Amended Answer"). The Jazz First Amended Answer is substantially similar to the Jazz Answer except insofar as it adds an affirmative defense for judicial estoppel and unclean hands. Corresponding amended Answers were filed in the two below cases on the same day.

Second Complaint

On August 4, 2021, Jazz filed another formal complaint (the "Second Complaint") initiating a lawsuit in the Court against the Avadel Parties. In the Second Complaint, Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 11077079. The Second Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses.

On September 9, 2021, the Avadel Parties timely filed their Answer and Counterclaims (the "Second Avadel Answer") with the Court in response to the Second Complaint. The Second Avadel Answer generally denies the allegations set forth in the Second Complaint, includes numerous affirmative defenses (including, but not limited to, non-infringement and invalidity of the patent-in-suit), and asserts a number of counterclaims seeking i) a declaratory judgment of non-infringement of the patent-in-suit, and ii) a declaratory judgment of invalidity of the patent-in-suit.

On October 22, 2021, the Court issued an oral order stating that this case should proceed on the same schedule as the case filed on May 12, 2021

Third Complaint

On November 10, 2021, Jazz filed another formal complaint (the "Third Complaint") initiating a lawsuit in the Court against the Avadel Parties. In the Third Complaint, Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 11147782. The Third Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses. This case will proceed on the same schedule as the cases associated with the First and Second Complaints above.

On January 7, 2022, Avadel CNS Pharmaceuticals LLC timely filed its Answer and Counterclaims (the "Third Avadel Answer") with the Court in response to the Third Complaint. The Third Avadel Answer generally denies the allegations set forth in the Third Complaint, includes numerous affirmative defenses (including, but not limited to, non-infringement and invalidity of the patent-in-suit), and asserts a number of counterclaims seeking i) a declaratory judgment of non-infringement of the patent-in-suit, and ii) a declaratory judgment of invalidity/unenforceability of the patent-in-suit.

On December 21, 2021, the Court entered a revised schedule for the First, Second and Third Complaints, setting a new claim construction date of August 31, 2022.

Material Commitments

Other than commitments disclosed in *Note 15: Contingent Liabilities and Commitments* to the Company's consolidated financial statements included in the 2021 Annual Report on Form 10-K, there were no other material commitments outside of the normal course of business.

Guarantees

Deerfield Guarantee

The fair values of the Company's guarantee to Deerfield and the guarantee received by the Company from Armistice Capital Master Fund, Ltd. largely offset and when combined are not material.

In connection with the Company's February 2018 divestiture of the Company's pediatric assets, the Company 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 the Company's explicit guarantee to Deerfield, the Company recorded the guarantee in accordance with ASC 460. The balance of this guarantee liability was $983 at March 31, 2022. This liability is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

Armistice Guarantee

In connection with the Company's February 2018 divestiture of the pediatric assets, Armistice Capital Master Fund, Ltd., the majority shareholder of Cerecor, Inc., guaranteed to the Company the FSC Product Royalties. The Company recorded the guarantee in accordance with ASC 460. The balance of this guarantee asset was $980 at March 31, 2022. This asset 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, 2022, the Company did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

NOTE 10: Subsequent Events

Exchange Transaction Closing

On April 5, 2022, Avadel completed the exchange of $117,375 of its February 2023 Notes for a new series of its Exchangeable Senior Notes due October 2, 2023. The remaining $26,375 aggregate principal amount of the February 2023 Notes were not exchanged and will maintain a maturity date of February 1, 2023. The Company paid $4,804 in fees paid to noteholders of the October 2023 Notes and $5,449 in fees paid to third parties as part of the completed Exchange Transaction. See *Note 4: Long-Term Debt* for additional information regarding the Company's debt obligations.

Jazz Litigation

On April 14, 2022, Avadel CNS Pharmaceuticals LLC and Avadel Pharmaceuticals plc (collectively the "Avadel Plaintiffs") filed a formal complaint (the "Avadel Complaint") initiating a lawsuit in the Court against Jazz and Jazz Pharmaceuticals Ireland Ltd. (collectively, the "Jazz Parties"). In the Avadel Complaint, the Avadel Plaintiffs allege that the Jazz Parties breached certain confidential disclosure agreements and misappropriated certain of Avadel's trade secrets. The Avadel Complaint further includes typical relief requests such as injunctive relief, monetary damages and attorneys' fees, costs and expenses, as well as seeking correction of inventorship of certain Jazz patents to include former Avadel scientists.

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, 2022 and Part II, Item 1A in this Quarterly Report on Form 10-Q for a discussion of additional important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this Quarterly Report.

Overview

General Overview

Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel," the "Company," "we," "our," or "us") is a biopharmaceutical company. Our lead product candidate, FT218, is an investigational once-nightly, extended-release formulation of sodium oxybate for the treatment of excessive daytime sleepiness ("EDS") or cataplexy in adults with narcolepsy. We are primarily focused on the development and potential United States ("U.S.") Food and Drug Administration ("FDA") approval of FT218. In December 2020, we submitted a New Drug Application ("NDA") to the FDA for FT218 to treat excessive daytime sleepiness or cataplexy in adults with narcolepsy. In February 2021, the NDA for FT218 was accepted by the FDA and was assigned a Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021. On October 15, 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this Quarterly Report, the FDA's review of our NDA for FT218 remains ongoing.

Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio. As of the date of this Quarterly Report, we do not have any approved or commercialized products in our portfolio.

FT218

FT218 is a once-nightly formulation of sodium oxybate that uses our Micropump controlled release drug-delivery technology for the treatment of EDS or cataplexy in adults suffering from narcolepsy. Sodium oxybate is the sodium salt of gamma hydroxybutyrate, an endogenous compound and metabolite of the neurotransmitter gamma-aminobutyric acid. Immediate release sodium oxybate is approved in the U.S. for the treatment of EDS or cataplexy in patients with narcolepsy and is approved in Europe for the treatment of cataplexy in patients with narcolepsy. Since 2002, sodium oxybate has only been available as a formulation that must be taken twice nightly, first at bedtime, and then again 2.5 to 4 hours later.

On December 16, 2020, we announced the submission of our NDA to the FDA for FT218. On February 26, 2021, the FDA notified us of formal acceptance of the NDA and assigned a PDUFA target action date of October 15, 2021. On October 15, 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date. As of the date of this Quarterly Report, the FDA's review of our NDA for FT218 remains ongoing.

We conducted a Phase 3 clinical trial of FT218, the REST-ON trial, which was a randomized, double-blind, placebo-controlled study that enrolled 212 patients who received at least one dose of FT218 or placebo, and was 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 9 g of once-nightly FT218, the highest dose administered in the trial, demonstrated statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test ("MWT"), clinical global impression-improvement ("CGI-I"), and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g also demonstrated statistically significant and clinically meaningful improvement on all three co-primary endpoints compared to

placebo. We observed the 9 g 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% and enuresis 9%), and 3.9% of the patients who received 9 g of FT218 discontinued the trial due to adverse reactions.

In January 2018, the FDA granted FT218 orphan drug designation for the treatment of narcolepsy, which makes FT218 potentially eligible for certain development and commercial incentives, including potential U.S. market exclusivity for up to seven years. Additionally, several FT218-related U.S. patents have been issued, and there are additional patent applications currently in development and/or pending at the U.S. Patent and Trademark Office ("USPTO"), as well as foreign patent offices.

In July 2020, we announced that the first patient was dosed in our open-label extension ("OLE")/switch study of FT218 as a potential treatment for EDS or cataplexy in patients with narcolepsy. The OLE/switch study is examining the long-term safety and maintenance of efficacy of FT218 in patients with narcolepsy who participated in the REST-ON study, as well as dosing and preference data for patients switching from twice-nightly sodium oxybate to once-nightly FT218, regardless of whether they participated in REST-ON. In May 2021, inclusion criteria were expanded to allow for oxybate naïve patients to enter the study.

New secondary endpoints from the REST-ON trial were presented at the American Academy of Neurology, beginning April 17, 2021. The first poster described FT218 improvements in disturbed nocturnal sleep ("DNS"), defined in REST-ON as the number of shifts from stages N1, N2, N3, and rapid eye movement ("REM") sleep to wake and from stages N2, N3, and REM sleep to stage N1. FT218 also decreased the number of nocturnal arousals as measured on polysomnography. Improvements in DNS were further supported by post-hoc analyses demonstrating increased time in deep sleep (N3, also known as slow wave sleep), and less time in N1. A second poster described the statistically significant improvements in the Epworth Sleepiness Scale, both the quality of sleep and the refreshing nature of sleep, and a decrease in sleep paralysis. These clinically relevant improvements were observed for all doses, beginning at week 3, for the lowest 6 g dose, compared to placebo. FT218 did not demonstrate significant improvement for hypnagogic hallucinations compared to placebo.

Additional data supportive of the efficacy findings in REST-ON were presented at the 35th Annual Meeting of the Associated Professional Sleep Societies, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, also known as SLEEP 2021, beginning June 10, 2021. New data included post-hoc analyses demonstrating endpoints improvements, regardless of concomitant stimulant use, in both narcolepsy Type 1 or Type 2. Additionally, a post-hoc analysis showed that FT218 was associated with decreased body mass index compared to placebo, which may be relevant as people with narcolepsy often have co-morbid obesity. In August 2021, the primary results from the REST-ON trial were published by Kushida et al. in the journal SLEEP.

New data was presented at the American College of Chest Physicians annual meeting ("CHEST"), beginning October 17, 2021, including additional post-hoc analyses from the REST-ON trial, demonstrating a greater proportion of patients receiving FT218 experienced reductions in weekly cataplexy attacks and improvement in mean sleep latency compared to placebo, as well as the results of a discrete choice experiment, indicating that the overall driver of patient preference between sodium oxybate treatments is a once-nightly, versus twice-nightly, formulation.

New data was presented at World Sleep 2022 congress, which was held March 11 through 16, 2022 in Rome, Italy. A total of eight posters were presented, including five new post-hoc analyses from the REST-ON trial. Most notably, the post-hoc analyses showed that FT218 demonstrated improvement in subjective measures of daytime sleepiness, sleep quality and refreshing nature of sleep as early as week 1 with the 4.5 g starting dose, with even greater improvement at week 2 soon after starting the 6 g dose compared to placebo. Additional post-hoc analyses, stratified by narcolepsy type, as well as concomitant stimulant use, or without stimulants, demonstrated positive results that are generally consistent with previously reported positive endpoints from REST-ON and add to the existing body of evidence for FT218.

In addition, the results of a discrete choice experiment ("DCE") were presented, which confirmed that once-nightly dosing, when compared to twice-nightly dosing, was the most important attribute driving both patient and clinician preference for overall oxybate product choice, as well as patient quality of life and reduction of patient anxiety/stress; dosing frequency (twice-nightly versus once-nightly) was also viewed as a more important attribute as compared to other attributes assessed, including sodium content. Accompanying the DCE was a background survey for both patients and clinicians, which showed that dosing frequency was noted as a significant stressor by both patients and clinicians. The World Sleep 2022 presentations also included the first presentation of an interim safety analysis from the ongoing RESTORE OLE/switch study, which showed that FT218 has generally been well-tolerated, with some patients receiving therapy for more than 18 months, and no new safety signals have been observed.

We believe FT218 has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standards of care for EDS or cataplexy in patients with narcolepsy, which are twice-nightly oxybate formulations.

Micropump Drug-Delivery Technology

Our Micropump drug-delivery technology allows for the controlled 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.

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 other pharmaceutical and biotechnology companies. 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 products, product candidates, or 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 pharmaceutical 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. As such, we expect to see generic competition for our products in the future. If approved, we anticipate FT218 may face competition from manufacturers of generic twice-nightly sodium oxybate formulations, who have reached settlement agreements with the current marketer, which allows for entry of an authorized generic in 2023, or earlier under certain circumstances. For example, Hikma Pharmaceuticals PLC is expected to launch a generic version of sodium oxybate in 2023 or earlier, depending on certain circumstances. Beyond 2023, there are other potential future competitive products and additional generic twice-nightly sodium oxybate formulations that could impact the marketplace.

- **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, expensive and/or dilutive and, as a result, could create liquidity challenges for the Company.

- **Net Loss from Operations in 2022**: We do not have any approved or commercialized products in our portfolio. We will incur substantial expenses to further the clinical development of and continue our preparations for the commercial launch of FT218, if approved.

Impact of COVID-19

Since early 2020, we have seen the profound impact that the coronavirus ("COVID-19") pandemic is having on human health, the global economy and society at large. We have continued to actively monitor the COVID-19 pandemic, as well as new variants of the virus and recent increases in case numbers, and have taken measures to mitigate the potential impacts to our

employees and business, such as continuing to offer a work from home policy. We believe the ongoing impact of COVID-19 and measures to prevent its spread could impact our business in a number of ways, including: i) possibly delaying our ongoing RESTORE OLE/switch study, ii) disruptions to our supply chain and third parties; iii) allowing our employees to work from home for an extended period of time; and iv) hindering sales efforts for FT218, if approved. An extended period of global supply chain and economic disruption could materially affect our business, results of operations, access to sources of liquidity and financial condition. Despite progress in vaccination efforts, future developments and impact on our operations remain uncertain and cannot be predicted with confidence, including the duration of the COVID-19 pandemic, new variants of the virus, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that governments, or we, may direct, which may result in extending continued business disruptions.

Financial Highlights

Highlights of our consolidated results for the three months ended March 31, 2022 are as follows:

- Operating loss was $28,626 for the three months ended March 31, 2022, compared to operating loss of $14,811 for the three months ended March 31, 2021. Selling, general and administrative expenses increased in the current period by $10,623, driven by the Company's continued commercial preparations and launch readiness activities for the potential approval of FT218.

- Net loss was $26,424 for the three months ended March 31, 2022, compared to net loss of $13,445 in the same period last year.

- Diluted net loss per share was $0.45 for the three months ended March 31, 2022, compared to diluted net loss per share of $0.23 in the same period last year.

- Cash and marketable securities decreased $33,740 to $123,481 at March 31, 2022, from $157,221 at December 31, 2021. The decrease in cash during the quarter was driven primarily by cash used in operating activities of $34,045, which included approximately $5,500 of interest payments and approximately $4,800 of insurance policy payments.

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, 2021 (the "2021 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 Management's Discussion & Analysis in our 2021 Form 10-K.

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, 2022 and 2021, respectively:

	Three Months Ended March 31,		Change 2022 vs. 2021	
Comparative Statements of Loss	**2022**	**2021**	**$**	**%**
Operating expenses:				
Research and development expenses	$ 6,991	$ 3,852	$ 3,139	81.5 %
Selling, general and administrative expenses	21,635	11,012	10,623	96.5 %
Restructuring income	—	(53)	53	100.0 %
Total operating expense	28,626	14,811	13,815	93.3 %
Operating loss	(28,626)	(14,811)	(13,815)	(93.3)%
Investment and other (expense) income, net	(137)	610	(747)	(122.5)%
Interest expense	(2,017)	(1,929)	(88)	(4.6)%
Gain from release of certain liabilities	33	78	(45)	(57.7)%
Loss before income taxes	(30,747)	(16,052)	(14,695)	(91.5)%
Income tax benefit	(4,323)	(2,607)	(1,716)	(65.8)%
Net loss	$ (26,424)	$ (13,445)	$ (12,979)	(96.5)%
Net loss per share - diluted	$ (0.45)	$ (0.23)	$ (0.22)	(95.7)%

	Three Months Ended March 31,		Change 2022 vs. 2021	
Research and Development Expenses:	**2022**	**2021**	**$**	**%**
Research and development expenses	$ 6,991	$ 3,852	$ 3,139	81.5 %

Research and development expenses increased $3,139 or 81.5% during the three months ended March 31, 2022 as compared to the same period in the prior year. This increase was driven by higher active pharmaceutical ingredients (“API”) purchases during the current period of approximately $3,100.

	Three Months Ended March 31,		Change 2022 vs. 2021	
Selling, General and Administrative Expenses:	**2022**	**2021**	**$**	**%**
Selling, general and administrative expenses	$ 21,635	$ 11,012	$ 10,623	96.5 %

Selling, general and administrative expenses increased $10,623 or 96.5% during the three months ended March 31, 2022 as compared to the same period in the prior year, driven by the our continued commercial preparations and launch readiness activities for potential approval of FT218. These activities included an increase in marketing and market research activities of approximately $3,400. Compensation costs increased by approximately $3,700 due to an increase in headcount, primarily in commercial and medical affairs. Other professional fees increased by approximately $3,500.

	Three Months Ended March 31,		Change 2022 vs. 2021	
Investment and Other (Expense) Income, net	**2022**	**2021**	**$**	**%**
Investment and other (expense) income, net	$ (137)	$ 610	$ (747)	(122.5)%

Investment and other (expense) income, net decreased $747 or 122.5% during the three months ended March 31, 2022 as compared to the same period in the prior year. This decrease was driven by higher net realized losses on our marketable securities of approximately $500 and lower foreign currency gains of approximately $300.

Income Tax Benefit:	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021	Change 2022 vs. 2021 $	Change 2022 vs. 2021 %
Income tax benefit	$ (4,323)	$ (2,607)	$ (1,716)	(65.8)%
Percentage of loss before income taxes	14.1 %	16.2 %		

The income tax benefit was $4,323 for the three months ended March 31, 2022 resulting in an effective tax rate of 14.1%. The income tax benefit was $2,607 for the three months ended March 31, 2021 resulting in an effective tax rate of 16.2%. The increase in the income tax benefit for the three months ended March 31, 2022 as compared to the prior period in 2021 is primarily due to an increase in net operating losses recognized in the United States.

Liquidity and Capital Resources

Our 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:

Net cash (used in) provided by:	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021	Change 2022 vs. 2021 $	Change 2022 vs. 2021 %
Operating activities	$ (34,045)	$ (23,413)	$ (10,632)	(45.4)%
Investing activities	42,251	11,191	31,060	277.5 %
Financing activities	2,009	149	1,860	1,248.3 %

Operating Activities

Net cash used in operating activities was $34,045 and $23,413 for the three months ended March 31, 2022 and 2021, respectively. Net cash used in operating activities for the three months ended March 31, 2022 was driven by net loss of $26,424 and unfavorable changes in working capital of $7,043, offset by favorable non-cash adjustments of $578. For the three months ended March 31, 2021, net cash used in operating activities was driven by net loss of $13,445 and a $10,175 unfavorable change in working capital. The March 31, 2022 net unfavorable change in working capital was less than the March 31, 2021 net unfavorable change in working capital mainly due to timing of receipt and payment of trade payables and accrued expenses associated with continued commercial preparations and launch readiness activities for potential approval of FT218.

Investing Activities

Net cash provided by investing activities was $42,251 and $11,191 for the three months ended March 31, 2022 and 2021, respectively. Net cash provided by investing activities for the three months ended March 31, 2022 was due to net proceeds received from the excess of sales over purchases of marketable securities of $42,251. Net cash provided by investing activities for the three months ended March 31, 2021 was driven by proceeds from the disposition of the hospital products of $8,250, as well as higher net proceeds received from the excess of sales over purchases of marketable securities.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2022 was $2,009 related to proceeds from stock option exercises and employee share purchase plan (“ESPP”) issuances. Net cash provided by financing activities for the three months ended March 31, 2021 of $149 related to proceeds from stock option exercises and ESPP issuances.

Risk Management

The adequacy of our cash resources depends on the outcome of certain business conditions including the cost of our FT218 clinical development and commercial launch plans, our cost structure, and other factors set forth in “Risk Factors” within Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC on March 16, 2022. To complete the FT218 clinical development and commercial launch plans 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 impacts of COVID-19 and inflation, which may have a material adverse impact on our business.

If available to us, raising additional capital may be accomplished through one or more public or private debt or equity financings, royalty financings or collaborations or partnering arrangements. Any equity financing would be dilutive to our shareholders.

Cash, cash equivalent and marketable security balances as of March 31, 2022 and unused financing sources are expected to provide us with the flexibility to meet our liquidity needs through March 31, 2023, including operating requirements related to the commercial launch of FT218.

Other Matters

Litigation

We are 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. We accrue 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, 2022 and December 31, 2021, 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 our consolidated financial position, results of operations, cash flows or liquidity. For information regarding legal proceedings we are involved in, see *Note 9: Commitments and Contingencies - Litigation and Note 10: Subsequent Events - Jazz Litigation* to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

We are 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.

Foreign Exchange Risk

We are exposed to foreign currency exchange risk as the functional currency financial statements of a non-U.S. subsidiary is translated to U.S. dollars. The assets and liabilities of this non-U.S. subsidiary having a functional currency other than the U.S. dollar is translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders' equity. The reported results of this non-U.S. subsidiary will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposure is related to one subsidiary that has functional currencies denominated in euro. A 10% strengthening/weakening in the rates used to translate the results of our non-U.S. subsidiaries that have functional currencies denominated in euro as of March 31, 2022 would have had an immaterial impact on net loss for the quarter ended March 31, 2022.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the

resulting gains and losses are reported in investment and other (expense) income, net in the condensed consolidated statements of loss. As of March 31, 2022, our primary exposure is to transaction risk related to euro net monetary assets and liabilities held by subsidiaries with a U.S. dollar functional currency. Realized and unrealized foreign exchange gains resulting from transactional exposure were immaterial for the quarter ended March 31, 2022.

Inflation Risk

Inflation generally affects us by increasing our costs of labor and supplies and the costs of our third-parties we rely on for the development, manufacture and supply of our product candidates. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the quarter ended March 31, 2022.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure 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, 2022, 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 Quarterly Report on 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 Exchange Act were not effective due to the material weakness in our internal control over financial reporting described below.

Material Weakness

Remediation Plans

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, management had identified a material weakness in the Company's internal controls over financial reporting specifically related to its February 2023 Notes indenture. The Company is committed to maintaining a strong internal control environment and have implemented measures designed to ensure that the control deficiency contributing to the material weakness is remediated. In the first quarter of 2022, management implemented a remediation plan that included the adoption of additional control procedures surrounding timely and periodic evaluation of all terms of the Company's debt agreements and the associated calculation of interest expense in accordance with the terms of any such debt agreement. Management believes these additional internal controls and procedures will ensure the completeness and accuracy of the calculation and timely payment of interest expense, classification of debt and compliance with terms of the Company's debt agreements.

With the Exchange Transaction on April 5, 2022, the Company performed the evaluation of all terms of the Company's updated debt agreements. The material weakness will be fully remediated when the Company has determined, through testing, that these controls have operated effectively for a sufficient period of time.

Other Changes in Internal Controls

Other than the above noted remediation activity, 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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

The information contained in *Note 9: Commitments and Contingencies - Litigation* and *Note 10: Subsequent Events - Jazz Litigation* to the Company's unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q 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, 2021 filed with the SEC on March 16, 2022.

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

Competition in the pharmaceutical and biotechnology industry is intense and is expected to increase. We compete with other pharmaceutical and biotechnology companies.

The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, FT218, if approved, would adversely affect sales of our product candidate. For example, in the future, we expect FT218 to face competition from manufacturers of generic twice-nightly sodium oxybate formulations who have reached settlement agreements with the current brand product marketer. Hikma Pharmaceuticals is expected to launch an authorized generic version of twice-nightly sodium oxybate in 2023 or earlier, depending on certain circumstances. There are other potential future competitive products that could impact the marketplace who have reached settlement agreements with the current brand product marketer, which allows for entry of other authorized generics in 2023 and other generic products in 2026, or earlier for both under certain circumstances. Beyond generics, there are other potential future competitive products that could impact the narcolepsy treatment marketplace.

If the FDA approves a competitor's application for a product candidate before our application for a similar product candidate, and grants such competitor a period of exclusivity, the FDA may take the position that it cannot approve our 505(b)(2) application for a similar product candidate until the exclusivity period expires. Additionally, even if our 505(b)(2) application for a product candidate is approved first, and we receive a period of statutory marketing exclusivity, we may still be subject to competition from other companies with approved products or approved 505(b)(2) NDAs for different conditions of use that would not be restricted by a grant of exclusivity to us.

Many of our competitors have substantially greater financial, technological, manufacturing, marketing, managerial and research and development resources and experience than we do. Furthermore, acquisitions of competing companies by large pharmaceutical companies could enhance our competitors' resources. Accordingly, our competitors may be able to develop, obtain regulatory approval and gain market share for their products more rapidly than us.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit No.	Description
4.1	Indenture, dated as of April 4, 2022, by and between Avadel Finance Cayman Limited, the Company and The Bank of New York Mellon, as Trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-37977) filed with the SEC on April 5, 2022)
4.2	Form of 4.50% Exchangeable Senior Note due 2023 (included in Exhibit 4.1, which is incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-37977) filed with the SEC on April 5, 2022)
10.1	Form of Exchange Agreement by and between Avadel Finance Cayman Limited, the Company and certain holders of the February 2023 Notes (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37977) filed with the SEC on March 16, 2022)
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act
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
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
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

AVADEL PHARMACEUTICALS PLC
(Registrant)

Date: May 9, 2022

By: /s/ Gregory J. Divis
Gregory J. Divis
Chief Executive Officer
(Duly Authorized Officer and *Principal Executive Officer)*

Date: May 9, 2022

By: /s/ Thomas S. McHugh
Thomas S. McHugh
Senior Vice President and Chief Financial Officer
(Duly Authorized Officer and *Principal Financial and Accounting Officer)*

Exhibit 31.1

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

I, Gregory J. Divis, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 9, 2022

/s/ Gregory J. Divis
Gregory J. Divis
Chief Executive Officer

Exhibit 31.2

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

I, Thomas S. McHugh, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 9, 2022

/s/ Thomas S. McHugh
Thomas S. McHugh
Senior Vice President and Chief Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc (the "Company") for the period ended March 31, 2022 (the "Report"), the undersigned hereby certifies in his capacity as Chief Executive Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2022

/s/ Gregory J. Divis
Gregory J. Divis
Chief Executive Officer

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc (the "Company") for the period ended March 31, 2022 (the "Report"), the undersigned hereby certifies in his capacity as Chief Financial Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 9, 2022

/s/ Thomas S. McHugh
Thomas S. McHugh
Senior Vice President and Chief Financial Officer