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: June 30, 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 filer	☑	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 August 4, 2022, 59,793,371 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™, LUMRYZ™, and MICROPUMP™. 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, LUMRYZ, also known as FT218;
- Our ability to obtain final regulatory approval from the U.S. Food and Drug Administration ("FDA") for and successfully commercialize LUMRYZ including any delays in approval;
- The ability of LUMRYZ, if granted final approval by the FDA, to gain market acceptance;
- Our ability to enter into strategic partnerships for the commercialization, manufacturing and distribution of LUMRYZ;
- Our dependence on a limited number of suppliers for the manufacturing of LUMRYZ and certain raw materials used in LUMRYZ 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 LUMRYZ, if granted final approval by the FDA;
- Our expectations regarding litigation related to LUMRYZ and the delisting of U.S. Patent No. 8731963 from the Orange Book;
- Our expectations regarding the timing and results of our cost structure optimization efforts, including the estimated charges and costs expected to be incurred and projected cost savings in connection with such cost structure optimization efforts;
- Our expectations regarding our cash runway lasting to a potential final FDA approval of our New Drug Application ("NDA") for LUMRYZ;
- 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 our subsequent filings 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development expenses	$ 4,541	$ 6,762	$ 11,532	$ 10,614
Selling, general and administrative expenses	21,804	15,174	43,439	26,186
Restructuring expense (income)	3,592	—	3,592	(53)
Total operating expense	29,937	21,936	58,563	36,747
Operating loss	(29,937)	(21,936)	(58,563)	(36,747)
Investment and other income, net	192	432	55	1,042
Interest expense	(3,506)	(1,930)	(5,523)	(3,859)
Gain from release of certain liabilities	—	88	33	166
Loss before income taxes	(33,251)	(23,346)	(63,998)	(39,398)
Income tax provision (benefit)	30,193	(3,765)	25,870	(6,372)
Net loss	$ (63,444)	$ (19,581)	$ (89,868)	$ (33,026)
Net loss per share – basic	$ (1.07)	$ (0.33)	$ (1.52)	$ (0.56)
Net loss per share – diluted	(1.07)	(0.33)	(1.52)	(0.56)
Weighted average number of shares outstanding - basic	59,037	58,488	58,931	58,465
Weighted average number of shares outstanding - diluted	59,037	58,488	58,931	58,465

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	$ (63,444)	$ (19,581)	$ (89,868)	$ (33,026)
Other comprehensive loss, net of tax:				
Foreign currency translation (loss) income	(657)	116	(842)	(602)
Net other comprehensive loss, net of income tax expense of $330, $78, $— and $133, respectively	(629)	(160)	(1,546)	(697)
Total other comprehensive loss, net of tax	(1,286)	(44)	(2,388)	(1,299)
Total comprehensive loss	$ (64,730)	$ (19,625)	$ (92,256)	$ (34,325)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	June 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 54,128	$ 50,708
Marketable securities	49,993	106,513
Research and development tax credit receivable	2,205	2,443
Prepaid expenses and other current assets	19,387	32,826
Total current assets	125,713	192,490
Property and equipment, net	252	285
Operating lease right-of-use assets	2,180	2,652
Goodwill	16,836	16,836
Research and development tax credit receivable	1,187	1,225
Other non-current assets	11,770	33,777
Total assets	$ 157,938	$ 247,265
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 26,241	$ —
Current portion of operating lease liability	932	900
Accounts payable	7,318	7,679
Accrued expenses	9,675	7,151
Other current liabilities	2,051	5,270
Total current liabilities	46,217	21,000
Long-term debt	108,074	142,397
Long-term operating lease liability	1,263	1,707
Other non-current liabilities	5,716	3,917
Total liabilities	161,270	169,021
Shareholders' (deficit) equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at June 30, 2022 and 488 issued and outstanding at December 31, 2021	5	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 59,038 issued and outstanding at June 30, 2022 and 58,620 issued and outstanding at December 31, 2021	590	586
Additional paid-in capital	560,025	549,349
Accumulated deficit	(537,624)	(447,756)
Accumulated other comprehensive loss	(26,328)	(23,940)
Total shareholders' (deficit) equity	(3,332)	78,244
Total liabilities and shareholders' (deficit) equity	$ 157,938	$ 247,265

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Ordinary shares		Preferred shares		Additional	Accumulated	Accumulated other comprehensive	Total shareholders'
	Shares	Amount	Shares	Amount	paid-in capital	deficit	loss	(deficit) 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
Net loss	—	—	—	—	—	(63,444)	—	(63,444)
Other comprehensive loss	—	—	—	—	—	—	(1,286)	(1,286)
Vesting of restricted shares	6	—	—	—	—	—	—	—
Change in fair value of October 2023 Notes conversion feature	—	—	—	—	5,508	—	—	5,508
Stock-based compensation expense	—	—	—	—	658	—	—	658
Balance, June 30, 2022	59,038	$ 590	488	$ 5	$ 560,025	$ (537,624)	$ (26,328)	$ (3,332)

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

	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
Net loss	—	—	—	—	—	(19,581)	—	(19,581)
Other comprehensive loss	—	—	—	—	—	—	(44)	(44)
Stock-based compensation expense	—	—	—	—	2,001	—	—	2,001
Balance, June 30, 2021	58,488	$ 584	488	$ 5	$ 544,094	$ (403,453)	$ (22,350)	$ 118,880

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

	Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (89,868)	$ (33,026)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	506	417
Amortization of debt discount and debt issuance costs	2,229	625
Change in deferred taxes	25,870	(6,228)
Stock-based compensation expense	3,163	3,729
Gain from release of certain liabilities	(33)	(166)
Other adjustments	1,239	757
Net changes in assets and liabilities		
Prepaid expenses and other current assets	13,305	(3,106)
Research and development tax credit receivable	30	3,078
Accounts payable & other current liabilities	(4,457)	176
Accrued expenses	2,559	1,199
Other assets and liabilities	(2,678)	(1,021)
Net cash used in operating activities	(48,135)	(33,566)
Cash flows from investing activities:		
Purchases of property and equipment	—	(26)
Proceeds from the disposition of the hospital products	—	16,500
Proceeds from sales of marketable securities	56,501	66,213
Purchases of marketable securities	(2,202)	(53,372)
Net cash provided by investing activities	54,299	29,315
Cash flows from financing activities:		
Payments for debt issuance costs	(4,803)	—
Proceeds from stock option exercises and employee share purchase plan	2,009	149
Net cash (used in) provided by financing activities	(2,794)	149
Effect of foreign currency exchange rate changes on cash and cash equivalents	50	(478)
Net change in cash and cash equivalents	3,420	(4,580)
Cash and cash equivalents at January 1,	50,708	71,722
Cash and cash equivalents at June 30,	$ 54,128	$ 67,142
Supplemental disclosures of cash flow information:		
Interest paid	$ 6,455	$ 3,234
Income taxes (refund) paid	$ (14,096)	$ 7

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, LUMRYZ, also known as FT218, is an investigational once-at-bedtime, extended-release formulation of sodium oxybate for the treatment of cataplexy or excessive daytime sleepiness ("EDS") in adults with narcolepsy. On July 18, 2022, the U.S. Food and Drug Administration ("FDA") granted tentative approval to LUMRYZ for this indication. Tentative approval indicates that LUMRYZ has met all required quality, safety, and efficacy standards necessary for approval in the U.S. The Company is primarily focused on obtaining final FDA approval of LUMRYZ.

A decision on final FDA approval of LUMRYZ is pending disposition of U.S. Patent No. 8731963 (the "REMS Patent"), which is listed in the FDA's Orange Book. The decision on final FDA approval could occur on or about the expiration of the REMS Patent on June 17, 2023 or sooner if the patent is earlier removed from the FDA's Orange Book or a court earlier determines that patent is not infringed, invalid or otherwise unenforceable. The FDA's tentative approval can be subject to change based on new information that may come to the FDA's attention between such time as the tentative approval and potential final approval. The Company cannot legally market LUMRYZ in the U.S. until final approval is granted by the FDA.

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 commercialized products in its portfolio.

Basis of Presentation. The unaudited condensed consolidated balance sheet as of June 30, 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 June 30, 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	$ 35,094	$ —	$ —	$ 78,098	$ —	$ —
Corporate bonds	—	9,403	—	—	16,479	—
Government securities - U.S.	—	3,766	—	—	9,471	—
Other fixed-income securities	—	1,730	—	—	2,465	—
Total assets	$ 35,094	$ 14,899	$ —	$ 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 June 30, 2022 and December 31, 2021, respectively, there were no transfers in and out of Level 3. During the three and six months ended June 30, 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 $26,375 aggregate principal amount of its 4.50% exchangeable senior notes due February 2023 (the "February 2023 Notes") and its $117,375 aggregate principal amount of its 4.50% exchangeable senior notes due October 2023 (the "October 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 values of the February 2023 Notes and the October 2023 Notes at June 30, 2022 are $25,320 and $91,846, respectively. 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' (deficit) equity, net of income tax effects. As of June 30, 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 June 30, 2022 and December 31, 2021, respectively:

	June 30, 2022			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Mutual and money market funds	$ 35,860	$ 293	$ (1,059)	$ 35,094
Corporate bonds	9,962	1	(560)	9,403
Government securities - U.S.	4,028	1	(263)	3,766
Other fixed-income securities	1,774	—	(44)	1,730
Total	$ 51,624	$ 295	$ (1,926)	$ 49,993

	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 income, net in the accompanying unaudited condensed consolidated statements of loss.

The Company recognized gross realized gains of $4 and $41 for the three months ended June 30, 2022 and 2021, respectively. These realized gains were offset by realized losses of $241 and $39 for the three months ended June 30, 2022 and 2021, respectively. We recognized gross realized gains of $308 and $52 for the six months ended June 30, 2022 and 2021, respectively. These realized gains were offset by realized losses of $1,031 and $107 for the six months ended June 30, 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 June 30, 2022:

	Maturities				
Marketable Debt Securities:	**Less than 1 Year**	**1-5 Years**	**5-10 Years**	**Greater than 10 Years**	**Total**
Corporate bonds	$ 785	$ 8,618	$ —	$ —	$ 9,403
Government securities - U.S.	—	2,129	665	972	3,766
Other fixed-income securities	—	1,503	227	—	1,730
Total	$ 785	$ 12,250	$ 892	$ 972	$ 14,899

The Company has classified its investment in available-for-sale marketable debt 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 June 30, 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	$ 8,040	$ 466	$ 1,119	$ 94	$ 9,159	$ 560
Government securities - U.S.	1,900	96	1,785	167	3,685	263
Other fixed-income securities	1,408	26	322	18	1,730	44
Total	$ 11,348	$ 588	$ 3,226	$ 279	$ 14,574	$ 867

NOTE 4: Long-Term Debt

Long-term debt is summarized as follows:

	June 30, 2022	December 31, 2021
Principal amount of 4.50% exchangeable senior notes due February 2023	$ 26,375	$ 143,750
Principal amount of 4.50% exchangeable senior notes due October 2023	117,375	—
Less: unamortized debt discount and issuance costs, net	(9,435)	(1,353)
Net carrying amount of debt	134,315	142,397
Less: current maturities, net of $134 unamortized debt discount and issuance costs	26,241	—
Long-term debt	$ 108,074	$ 142,397

For the three months ended June 30, 2022 and 2021, the total interest expense was $3,506 and $1,930, respectively, with coupon interest expense of $1,589 and $1,617 for each period, respectively, and the amortization of debt issuance costs and debt discount, totaling $1,917 and $313 for each period, respectively.

For the six months ended June 30, 2022 and 2021, the total interest expense was $5,523 and $3,859, respectively, with coupon interest expense of $3,206 and $3,234 for each period, respectively, and the amortization of debt issuance costs and debt discount of $2,229 and $625 for each period, respectively. Current period interest expense also includes $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 maintain a maturity date of February 1, 2023.

The Company accounted for the October 2023 Notes as a modification to the February 2023 Notes. The Company paid $4,804 in fees to note holders of the October 2023 Notes that will be amortized over the remaining term of the October 2023 Notes. The Company paid approximately $5,450 in fees to third parties that were expensed as part of the completed Exchange Transaction. Additionally, the fair value of the unseparated, embedded conversion feature increased by $5,508, which reduced the carrying amount of the convertible debt instrument as an unamortized debt discount, with a corresponding increase in additional paid-in capital. The $5,508 will be amortized over the remaining term of the October 2023 Notes as a component of interest expense.

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 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 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 provision was $30,193 for the three months ended June 30, 2022 resulting in an effective tax rate of (90.8)%. The income tax benefit was $3,765 for the three months ended June 30, 2021 resulting in an effective tax rate of 16.1%. The change in the effective income tax rate for the three months ended June 30, 2022, as compared to the prior period in 2021, is primarily due to the valuation allowances that were recorded against the deferred tax assets during the period.

The income tax provision was $25,870 for the six months ended June 30, 2022 resulting in an effective tax rate of (40.4)%. The income tax benefit was $6,372 for the six months ended June 30, 2021 resulting in an effective tax rate of 16.2%. The change in the effective income tax rate for the six months ended June 30, 2022, as compared to the prior period in 2021, is primarily due to the valuation allowances that were recorded against the deferred tax assets during this period.

The Company's cumulative loss position was significant negative evidence in assessing the need for a valuation allowance on its deferred tax assets. Given the weight of objectively verifiable historical losses from operations, the Company has recorded a full valuation allowance on its deferred tax assets. The Company will be able to reverse the valuation allowance when it has shown its ability to generate taxable income on a consistent basis in future periods. The valuation allowance that was recorded against the deferred tax assets during the three and six month ended June 30, 2022 does not have an impact on the Company's ability to utilize any net operating losses or other tax attributes to offset cash taxes payable as these items are still eligible to be used.

During the six months ended June 30, 2022, the Company received $14,096 of cash related to net operating loss carrybacks under the CARES Act for losses incurred during 2019, which were carried back to 2015.

NOTE 6: Other Assets and Liabilities

Various other assets and liabilities are summarized as follows:

Prepaid Expenses and Other Current Assets:	June 30, 2022	December 31, 2021
Income tax receivable	$ 15,026	$ 29,097
Prepaid and other expenses	3,881	3,179
Guarantee from Armistice	277	279
Other	203	271
Total	$ 19,387	$ 32,826

Other Non-Current Assets:	June 30, 2022	December 31, 2021
Right of use assets at contract manufacturing organizations	$ 10,600	$ 8,549
Guarantee from Armistice	633	771
Other	537	329
Deferred tax assets	—	24,128
Total	$ 11,770	$ 33,777

Accrued Expenses	June 30, 2022	December 31, 2021
Accrued restructuring	$ 3,628	$ 41
Accrued professional fees	3,188	2,678
Accrued compensation	1,592	3,167
Accrued outsource contract costs	1,267	1,048
Customer allowances	—	217
Total	$ 9,675	$ 7,151

Other Current Liabilities:	June 30, 2022	December 31, 2021
Accrued interest	$ 1,757	$ 4,920
Guarantee to Deerfield	278	280
Other	16	70
Total	$ 2,051	$ 5,270

Other Non-Current Liabilities:	June 30, 2022	December 31, 2021
Tax liabilities	$ 5,081	$ 3,143
Guarantee to Deerfield	635	774
Total	$ 5,716	$ 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 obligations 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 June 30,		Six Months Ended June 30,	
Net Loss Per Share:	**2022**	**2021**	**2022**	**2021**
Net loss	$ (63,444)	$ (19,581)	$ (89,868)	$ (33,026)
Weighted average shares:				
Basic shares	59,037	58,488	58,931	58,465
Effect of dilutive securities—employee and director equity awards outstanding, preferred shares and 2023 Notes	—	—	—	—
Diluted shares	59,037	58,488	58,931	58,465
Net loss per share - basic	$ (1.07)	$ (0.33)	$ (1.52)	$ (0.56)
Net loss per share - diluted	$ (1.07)	$ (0.33)	$ (1.52)	$ (0.56)

Potential ordinary shares of 22,455 and 15,586 were excluded from the calculation of weighted average shares for the three months ended June 30, 2022 and 2021, respectively, and potential ordinary shares of 19,042 and 15,426 were excluded from the calculation of weighted average shares for the six months ended June 30, 2022 and 2021 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 and six months ended June 30, 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 and six months ended June 30, 2022 and 2021, respectively, net of tax effects:

	Three Months Ended June 30,		Six Months Ended June 30,	
Accumulated Other Comprehensive Loss:	**2022**	**2021**	**2022**	**2021**
Foreign currency translation adjustment:				
Beginning balance	$ (24,040)	$ (23,345)	$ (23,855)	$ (22,627)
Net other comprehensive (loss) income	(657)	116	(842)	(602)
Balance at June 30,	$ (24,697)	$ (23,229)	$ (24,697)	$ (23,229)
Unrealized (loss) gain on marketable debt securities, net				
Beginning balance	$ (1,002)	$ 1,039	$ (85)	$ 1,576
Net other comprehensive loss, net of income tax expense of $330, $78, $ — and $133, respectively	(629)	(160)	(1,546)	(697)
Balance at June 30,	$ (1,631)	$ 879	$ (1,631)	$ 879
Accumulated other comprehensive loss at June 30,	$ (26,328)	$ (22,350)	$ (26,328)	$ (22,350)

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 June 30, 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 Jazz 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 ("Avadel CNS") will infringe at least one claim of U.S. 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 CNS'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 the Avadel Parties' 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.

On June 23, 2022, Avadel CNS filed a Renewed Motion for Judgment on the Pleadings, with respect to its counterclaim seeking to have U.S. Patent No. 8731963 (the "REMS Patent") de-listed from the Orange Book and seeking to have the motion resolved concurrent with the parties' *Markman* hearing on August 31, 2022. On July 7, 2022, Jazz filed a response it styled as Objections to Avadel CNS' Motion for Judgment on the Pleadings. On July 14, 2022, Avadel CNS' replied to Jazz' response, and on July 21, Avadel CNS requested oral argument on its delisting motion simultaneous with the *Markman* hearing.

Second Jazz 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 will

infringe at least one claim of U.S. 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 Jazz 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 will infringe at least one claim of U.S. 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 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.

On January 7, 2022, Avadel CNS 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.

Avadel Complaint

On April 14, 2022, Avadel CNS 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 the Avadel Plaintiffs' 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, for which the Jazz Parties claim ownership, to include former Avadel Plaintiffs' scientists.

On June 2, 2022, Jazz answered the Avadel Complaint. The Answer generally denies the allegations set forth in the Avadel Complaint and includes various affirmative defenses.

On July 8, 2022, Jazz filed a Motion for Judgment on the Pleadings seeking to have all Counts dismissed for failure to state a claim upon which relief can be granted. The Avadel Plaintiffs' response to that Motion was filed with the Court on July 29, 2022. Jazz's reply was filed with the Court on August 5, 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

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.

Deerfield Guarantee

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 $913 at June 30, 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 $910 at June 30, 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 June 30, 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: Restructuring Costs

2022 Corporate Restructuring Plan

In June 2022, the Company announced a plan to optimize its cost structure to reduce total quarterly cash operating expenses, excluding inventory purchases.

The Company's cost structure optimization efforts will include a nearly 50% reduction in its workforce by the end of August 2022 (the "2022 Corporate Restructuring Plan"). Restructuring charges of $3,592 associated with this plan, comprised primarily of severance related costs, were recorded in the three months ended June 30, 2022.

The following table sets forth activities for the Company's 2022 Corporate Restructuring Plan obligations as of June 30, 2022:

2022 Corporate Restructuring Plan Obligation:	**2022**
Balance of 2022 Corporate Restructuring Plan accrual at January 1,	$ —
Charges for employee severance, benefits and other costs	3,592
Balance of 2022 Corporate Restructuring Plan accrual at June 30,	$ 3,592

The 2022 Corporate Restructuring Plan liabilities of $3,592 are included in the unaudited condensed consolidated balance sheet in accrued expenses at June 30, 2022.

NOTE 11: Subsequent Events

Fourth Jazz Complaint

On July 15, 2022, Jazz filed another formal complaint (the "Fourth Complaint") initiating a lawsuit in the Court against Avadel CNS. In the Fourth Complaint, Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS will infringe at least one claim of the REMS Patent, which was asserted in the First Complaint. The FDA required Avadel CNS to file a Paragraph IV certification against the REMS Patent, which Avadel CNS did under protest. Avadel CNS provided the required notice of its Paragraph IV certification to Jazz, and Jazz reasserted the REMS Patent in a separate action following receipt of

that notice. The Fourth Complaint further includes typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses.

Administrative Procedure Act Complaint

On July 21, 2022, Avadel CNS filed an Administrative Procedure Act suit against the FDA, the U.S. Department of Health and Human Services, the Secretary of Health and Human Services and the Commissioner of Food and Drugs in the United States District Court for the District of Columbia (the "DC Court") related to the NDA for LUMRYZ (sodium oxybate). This suit alleges that the FDA's decision requiring Avadel CNS to file a patent certification concerning the REMS Patent was arbitrary, capricious and contrary to law and asks the DC Court to vacate the FDA's decision and order the FDA to take final action on the LUMRYZ NDA. On July 28, 2022, the DC Court granted Jazz's unopposed motion to intervene in the case to defend the FDA's decision. The DC Court also entered an expedited briefing schedule governing Avadel CNS's motion for preliminary injunction or, in the alternative, summary judgment, and the FDA's and Jazz's oppositions to that motion and anticipated cross-motions for summary judgment. Under the DC Court's schedule, the final briefs will be filed on September 14, 2022, and the parties were instructed to prepare for a hearing tentatively scheduled for September 30, 2022, which may be modified depending on the DC Court's schedule.

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, LUMRYZ, also known as FT218, is an investigational once-at-bedtime, extended-release formulation of sodium oxybate for the treatment of cataplexy or excessive daytime sleepiness ("EDS") in adults with narcolepsy. We are primarily focused on obtaining final United States ("U.S.") Food and Drug Administration ("FDA") approval of LUMRYZ.

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 commercialized products in our portfolio.

LUMRYZ

LUMRYZ is an investigational once-at-bedtime formulation of sodium oxybate that uses our proprietary controlled release drug-delivery technology for the treatment of cataplexy or EDS 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 cataplexy or EDS 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 July 18, 2022, the FDA granted tentative approval to LUMRYZ for the treatment of cataplexy or EDS in adults suffering from narcolepsy. Tentative approval indicates that LUMRYZ has met all required quality, safety, and efficacy standards necessary for approval in the U.S.

A decision on final FDA approval of LUMRYZ is pending disposition of U.S. Patent No. 8731963 (the "REMS Patent"), which is listed in the FDA's Orange Book. The decision on final FDA approval could occur on or about the expiration of the REMS Patent on June 17, 2023 or sooner if the patent is earlier removed from the FDA's Orange Book or a court earlier determines that the REMS Patent is not infringed, invalid or otherwise unenforceable. The FDA's tentative approval can be subject to change based on new information that may come to the FDA's attention between such time as the tentative approval and potential final approval. We cannot legally market LUMRYZ in the U.S. until final approval is granted by the FDA.

With respect to clinical data generated for LUMRYZ, we conducted a Phase 3 clinical trial of LUMRYZ, the REST-ON trial, which was a randomized, double-blind, placebo-controlled study that enrolled 212 patients who received at least one dose of LUMRYZ or placebo, and was conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient and 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-at-bedtime LUMRYZ, 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-at-bedtime LUMRYZ 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 LUMRYZ discontinued the trial due to adverse reactions.

In January 2018, the FDA granted LUMRYZ orphan drug designation for the treatment of narcolepsy, which makes LUMRYZ potentially eligible for certain development and commercial incentives, including potential U.S. market exclusivity for up to seven years. Additionally, several LUMRYZ-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 LUMRYZ as a potential treatment for cataplexy or EDS in patients with narcolepsy (the "RESTORE study"). The RESTORE study is examining the long-term safety and maintenance of efficacy of LUMRYZ 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-at-bedtime LUMRYZ, 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 LUMRYZ 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. LUMRYZ 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 ("ESS"), 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. LUMRYZ 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 ("NT1") or Type 2 ("NT2"). Additionally, a post-hoc analysis showed that LUMRYZ 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 LUMRYZ 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-at-bedtime, 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 LUMRYZ 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 LUMRYZ.

In addition, the results of a discrete choice experiment ("DCE") were presented, which confirmed that once-at-bedtime 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-at-bedtime) 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 study, which showed that

LUMRYZ has generally been well-tolerated, with some patients receiving therapy for more than 18 months. No new safety signals have been observed as of July 10, 2022.

Additional peer-reviewed publications have included the improvement on DNS, the first DCE and a Plain Language Summary reviewing sodium oxybate and cardiovascular health, which did not identify a signal of cardiovascular disease in the twenty years that sodium oxybate has been available. At the annual SLEEP Congress in June 2022, nine posters were presented, including five post-hoc analyses from REST-ON of the following:

- Analysis showing a low number-needed-to-treat to achieve effectiveness across all three evaluated doses, as well as effect sizes, showing a moderate-to-high effect for improving MWT, ESS, and number of cataplexy attacks;
- Confirmation via various statistical methods to handle missing data that LUMRYZ improved EDS and cataplexy symptoms versus placebo;
- Confirmation of benefit for NT1 and NT2 for DNS and ESS;
- Confirmation of benefit for subgroups taking stimulants and those without stimulants for DNS and ESS; and
- Early efficacy (Week 1 and Week 2) for ESS, refreshing nature of sleep and quality of sleep.

In addition, interim data from RESTORE were presented demonstrating that a high proportion of patients switching from twice-nightly sodium oxybate formulations had difficulty in taking the second dose, with a high proportion (92.5%) stating a preference for the once-at-bedtime dosing regimen and that most participants (62%) switching from twice-nightly sodium oxybate formulations had a stable dose equal to their starting dose; participants not currently taking sodium oxybate formulations or oxybate naive reached a stable dose with 2–4 dose titrations within 4 weeks.

We believe LUMRYZ has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standards of care for cataplexy or EDS in patients with narcolepsy.

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. We believe there could be 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 LUMRYZ receives final FDA approval, we anticipate LUMRYZ 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**: We have a recent history of generating losses from operations and expect to continue generating losses until we are able to launch LUMRYZ, if final FDA approval is obtained, and generate revenues sufficient to generate positive cash flow from operations. Similar to other businesses in our industry and at our stage of development, we will continue in the medium term to rely on external sources of capital to fund our business. 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 us.

- **Net Loss from Operations in 2022**: We do not have any 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 LUMRYZ.

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 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 LUMRYZ, if final FDA approval is obtained. 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.

2022 Corporate Restructuring Plan

In June 2022, we announced a plan to optimize our cost structure to reduce total quarterly cash operating expenses to between $12,000 and $14,000, excluding inventory purchases. The reduction in cash operating expenses, together with cash, cash equivalents and marketable securities currently on hand, is expected to extend our cash runway to the FDA's decision regarding final approval of LUMRYZ, which could occur in June 2023 or possibly sooner.

Our cost structure optimization efforts included a nearly 50% reduction in our workforce (the "2022 Corporate Restructuring Plan"). As a result of the 2022 Corporate Restructuring Plan, we recorded an aggregate restructuring charge of $3,592, comprised primarily of severance related costs, during the three months ended June 30, 2022. See *Note 10: Restructuring Costs* to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information.

Financial Highlights

Highlights of our consolidated results for the three and six months ended June 30, 2022 are as follows:

- Operating loss was $29,937 and $58,563 for the three and six months ended June 30, 2022, respectively, compared to operating loss of $21,936 and $36,747 for the three and six months ended June 30, 2021, respectively. Selling, general and administrative expenses increased during the six months ended June 30, 2022 by $17,253, driven by the increased

legal and compensation spend of approximately $6,200 and $4,600, respectively, as well as approximately $5,450 of debt issuance costs expensed in the three months ended June 30, 2022 as part of the exchange of $117,375 of our February 2023 Notes for a new series of Exchangeable Senior Notes due October 2, 2023 (the "Exchange Transaction").

- Net loss was $63,444 and $89,868 for the three and six months ended June 30, 2022, respectively, compared to net loss of $19,581 and $33,026 in the same periods last year, respectively.

- Diluted net loss per share was $1.07 and $1.52 for the three and six months ended June 30, 2022, respectively, compared to diluted net loss per share of $0.33 and $0.56 in the same period last year, respectively.

- Cash and marketable securities decreased $53,100 to $104,121 at June 30, 2022, from $157,221 at December 31, 2021. The decrease in cash during the six months ended June 30, 2022 was driven primarily by cash used in operating activities of $48,135, which included the receipt of approximately $14,100 of refund claims associated with the carry-back of 2019 losses, as well as approximately $6,500 of interest payments, approximately $5,450 of fees paid to third parties that were expensed as part of the completed Exchange Transaction and approximately $4,800 of insurance premiums. The decrease in cash was also due to the payment of approximately $4,800 in fees to note holders of the October 2023 Notes that will be amortized as interest expense over the remaining term of the October 2023 Notes.

Critical Accounting Estimates

Our 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 on 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 June 30, 2022 and 2021, respectively:

Comparative Statements of Loss	Three Months Ended June 30, 2022	2021	Change 2022 vs. 2021 $	%
Operating expenses:				
Research and development expenses	$ 4,541	$ 6,762	$ (2,221)	(32.8)%
Selling, general and administrative expenses	21,804	15,174	6,630	43.7 %
Restructuring expense	3,592	—	3,592	100.0 %
Total operating expense	29,937	21,936	8,001	36.5 %
Operating loss	(29,937)	(21,936)	(8,001)	(36.5)%
Investment and other income, net	192	432	(240)	(55.6)%
Interest expense	(3,506)	(1,930)	(1,576)	(81.7)%
Gain from release of certain liabilities	—	88	(88)	(100.0)%
Loss before income taxes	(33,251)	(23,346)	(9,905)	(42.4)%
Income tax provision (benefit)	30,193	(3,765)	33,958	901.9 %
Net loss	$ (63,444)	$ (19,581)	$ (43,863)	(224.0)%
Net loss per share - diluted	$ (1.07)	$ (0.33)	$ (0.74)	(224.2)%

The following is a summary of our financial results (in thousands, except per share amounts) for the six months ended June 30, 2022 and 2021, respectively:

Comparative Statements of Loss	Six Months Ended June 30, 2022	2021	Change 2022 vs. 2021 $	%
Operating expenses:				
Research and development expenses	$ 11,532	$ 10,614	$ 918	8.6 %
Selling, general and administrative expenses	43,439	26,186	17,253	65.9 %
Restructuring expense (income)	3,592	(53)	3,645	6,877.4 %
Total operating expense	58,563	36,747	21,816	59.4 %
Operating loss	(58,563)	(36,747)	(21,816)	(59.4)%
Investment and other income, net	55	1,042	(987)	(94.7)%
Interest expense	(5,523)	(3,859)	(1,664)	(43.1)%
Gain from release of certain liabilities	33	166	(133)	(80.1)%
Loss before income taxes	(63,998)	(39,398)	(24,600)	(62.4)%
Income tax provision (benefit)	25,870	(6,372)	32,242	506.0 %
Net loss	$ (89,868)	$ (33,026)	$ (56,842)	(172.1)%
Net loss per share - diluted	$ (1.52)	$ (0.56)	$ (0.96)	(171.4)%

Research and Development Expenses:	Three Months Ended June 30, 2022	2021	Change 2022 vs. 2021 $	%
Research and development expenses	$ 4,541	$ 6,762	$ (2,221)	(32.8)%

Research and development expenses decreased $2,221 or 32.8% during the three months ended June 30, 2022 as compared to the same period in the prior year. This decrease was driven by lower active pharmaceutical ingredients (“API”) purchases during the current period of approximately $1,900 and the reversal of share-based compensation expense of approximately $300 for employees affected by the 2022 Corporate Restructuring Plan.

Research and Development Expenses:	Six Months Ended June 30, 2022	2021	Change 2022 vs. 2021 $	%
Research and development expenses	$ 11,532	$ 10,614	$ 918	8.6 %

Research and development expenses increased $918 or 8.6% during the six months ended June 30, 2022 as compared to the same period in the prior year. This increase was driven by higher API purchases of $1,200, the majority of which were purchased in the three months ended March 31, 2022, partially offset by the reversal of share-based compensation expense of approximately $300 for employees affected by the 2022 Corporate Restructuring Plan.

Selling, General and Administrative Expenses:	Three Months Ended June 30, 2022	2021	Change 2022 vs. 2021 $	%
Selling, general and administrative expenses	$ 21,804	$ 15,174	$ 6,630	43.7 %

Selling, general and administrative expenses increased $6,630 or 43.7% during the three months ended June 30, 2022 as compared to the same period in the prior year, driven by debt issuance costs of approximately $5,100 related to the Exchange Transaction and higher legal and payroll and benefits costs of approximately $3,200 and $2,800, respectively. Compensation costs were offset by the reversal of approximately $2,300 of previously recorded compensation costs related to share based compensation and bonuses from employees affected by the 2022 Corporate Restructuring Plan. These costs were partially offset by lower marketing and market research activities of approximately $2,000 and lower consulting spend of approximately $300 incurred as we began to reduce our commercial spend during the three months ended June 30, 2022.

Selling, General and Administrative Expenses:	Six Months Ended June 30, 2022	2021	Change 2022 vs. 2021 $	%
Selling, general and administrative expenses	$ 43,439	$ 26,186	$ 17,253	65.9 %

Selling, general and administrative expenses increased $17,253 or 65.9% during the six months ended June 30, 2022 as compared to the same period in the prior year, driven by compensation and higher legal costs of approximately $6,900 and $6,200, respectively, debt issuance costs of approximately $5,450 related to the Exchange Transaction and higher marketing costs of approximately $2,300. Compensation costs were partially offset by the reversal of approximately $2,300 of previously recorded compensation costs related to share based compensation and bonuses from employees affected by the 2022 Corporate Restructuring Plan. The increase in selling, general and administrative expense was also offset by lower other commercial-related activities of approximately $800 and lower other professional fees of approximately $600.

Restructuring Expense	Three Months Ended June 30, 2022	2021	Change 2022 vs. 2021 $	%
Restructuring expense	$ 3,592	$ —	$ 3,592	100.0 %

Restructuring expense increased $3,592 or 100.0% during the three months ended June 30, 2022 as compared to the same period in the prior year, driven by the 2022 Corporate Restructuring Plan, which was announced in June 2022. See *Note 10: Restructuring Costs* to our unaudited condensed consolidated financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q for further details for further details.

Restructuring Expense (Income)	Six Months Ended June 30, 2022	2021	Change 2022 vs. 2021 $	%
Restructuring expense (income)	$ 3,592	$ (53)	$ 3,645	6,877.4 %

Restructuring expense (income) increased $3,645 or 6,877.4% during the six months ended June 30, 2022 as compared to the same period in the prior year, driven by the 2022 Corporate Restructuring Plan, which was announced in June 2022. See *Note 10: Restructuring Costs* to our unaudited condensed consolidated financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q for further details for further details.

	Three Months Ended June 30,		Change 2022 vs. 2021	
Investment and Other Income, net	**2022**	**2021**	**$**	**%**
Investment and other income, net	$ 192	$ 432	$ (240)	(55.6)%

Investment and other income, net decreased $240 or 55.6% during the three months ended June 30, 2022 as compared to the same period in the prior year. This decrease was driven by lower interest income on our marketable securities of approximately $300 and higher net realized losses on our marketable securities of approximately $200, partially offset by higher foreign currency gains of approximately $200.

	Six Months Ended June 30,		Change 2022 vs. 2021	
Investment and Other Income, net	**2022**	**2021**	**$**	**%**
Investment and other income, net	$ 55	$ 1,042	$ (987)	(94.7)%

Investment and other income, net decreased $987 or 94.7% during the six months ended June 30, 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 $600 and lower interest received on our marketable securities of approximately $400.

	Three Months Ended June 30,		Change 2022 vs. 2021	
Interest Expense	**2022**	**2021**	**$**	**%**
Interest expense	$ (3,506)	$ (1,930)	$ (1,576)	81.7 %

Interest expense increased $1,576 or 81.7% during the three months ended June 30, 2022 as compared to the same period in the prior year. Interest expense increased by approximately $900 due to non-cash amortization of the $5,500 of debt discount related to the change in the fair value of the conversion feature of the October 2023 Notes. In addition, interest expense increased by $700 due to non-cash amortization of the $4,800 of debt issuance fees paid to note holders that participated in the Exchange Transaction in April 2022. These fees will be amortized over the life of the October 2023 Notes. See *Note 4: Long-Term Debt* to our unaudited condensed consolidated financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q for further details for further details.

	Six Months Ended June 30,		Change 2022 vs. 2021	
Interest Expense	**2022**	**2021**	**$**	**%**
Interest expense	$ (5,523)	$ (3,859)	$ (1,664)	43.1 %

Interest expense increased $1,664 or 43.1% during the six months ended June 30, 2022 as compared to the same period in the prior year. Interest expense increased by approximately $900 due to non-cash amortization of the $5,500 of debt discount related to the change in the fair value of the conversion feature of the October 2023 Notes. In addition, interest expense increased by $700 due to amortization of the $4,800 of debt issuance fees paid to note holders that participated in the Exchange Transaction in April 2022. These fees will be amortized over the life of the October 2023 Notes. See *Note 4: Long-Term Debt* to our unaudited condensed consolidated financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q for further details for further details.

Income Tax Provision (Benefit):	Three Months Ended June 30, 2022	2021	Change 2022 vs. 2021 $	%
Income tax provision (benefit)	$ 30,193	$ (3,765)	$ 33,958	901.9 %
Percentage of loss before income taxes	(90.8)%	16.1 %		

The income tax provision was $30,193 for the three months ended June 30, 2022 resulting in an effective tax rate of (90.8)%. The income tax benefit was $3,765 for the three months ended June 30, 2021 resulting in an effective tax rate of 16.1%. The income tax provision for the three months ended June 30, 2022 is primarily driven by the valuation allowances recorded against our deferred tax assets during the three months ended June 30, 2022.

Income Tax Provision (Benefit):	Six Months Ended June 30, 2022	2021	Change 2022 vs. 2021 $	%
Income tax provision (benefit)	$ 25,870	$ (6,372)	$ 32,242	506.0 %
Percentage of loss before income taxes	(40.4)%	16.2 %		

The income tax provision was $25,870 for the six months ended June 30, 2022 resulting in an effective tax rate of (40.4)%. The income tax benefit was $6,372 for the six months ended June 30, 2021 resulting in an effective tax rate of 16.2%. The income tax provision for the six months ended June 30, 2022 is primarily driven by the valuation allowances recorded against our deferred tax assets during the three months ended June 30, 2022.

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:	Six Months Ended June 30, 2022	2021	Change 2022 vs. 2021 $	%
Operating activities	$ (48,135)	$ (33,566)	$ (14,569)	(43.4)%
Investing activities	54,299	29,315	24,984	85.2 %
Financing activities	(2,794)	149	(2,943)	(1,975.2)%

Operating Activities

Net cash used in operating activities was $48,135 and $33,566 for the six months ended June 30, 2022 and 2021, respectively. Net cash used in operating activities for the six months ended June 30, 2022 was driven by net loss of $89,868, partially offset by favorable non-cash adjustments of $32,974 and favorable changes in working capital of $8,759. For the six months ended June 30, 2021, net cash used in operating activities was driven by net loss of $33,026 and an $866 unfavorable change in non-cash adjustments. The June 30, 2022 net favorable change in working capital was driven by the receipt of $14,096 of refund claims associated with the carryback of 2019 losses during the six months ended June 30, 2022.

Investing Activities

Net cash provided by investing activities was $54,299 and $29,315 for the six months ended June 30, 2022 and 2021, respectively. Net cash provided by investing activities for the six months ended June 30, 2022 was due to net proceeds received from the excess of sales over purchases of marketable securities of $54,299. Net cash provided by investing activities for the six months ended June 30, 2021 was driven by proceeds from the disposition of the hospital products of $16,500, as well as net proceeds received from the excess of sales over purchases of marketable securities of $12,841.

Financing Activities

Net cash used in financing activities for the six months ended June 30, 2022 was $2,794 related to payment of $4,803 of debt issuance fees associated with the Exchange Transaction, partially offset by $2,009 of proceeds from stock option exercises and employee share purchase plan ("ESPP") issuances. Net cash provided by financing activities for the six months ended June 30, 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 LUMRYZ clinical development, commercial launch plans and the FDA's decision regarding final approval of LUMRYZ, 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 LUMRYZ 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.

In June 2022, we announced a plan to optimize our cost structure to reduce total quarterly cash operating expenses to between $12,000 and $14,000, excluding inventory purchases. Cash, cash equivalent and marketable securities balances as of June 30, 2022, income tax receivable balances as of June 30, 2022 and unused available financing sources, such as sales of ADSs through our 2020 Open Market Sale Agreement™, together with the reduction in cash operating expenses, are expected to provide us with the flexibility to meet our liquidity needs through June 30, 2023, including operating requirements related to potential final FDA approval of LUMRYZ.

We have a recent history of generating losses from operations and expect to continue generating losses until we are able to launch LUMRYZ, if granted final approval by the FDA, and generate revenues sufficient to generate positive cash flow from operations. Similar to other businesses in our industry and at our stage of development, we will continue in the medium term to rely on external sources of capital to fund its 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.

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 June 30, 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 11: Subsequent Events* 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 our portfolio of marketable securities. The primary objectives of our investment policy are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and competitive yield. Although our investments are subject to market risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or certain types of investment. Our investment policy allows us to maintain a portfolio of cash equivalents and marketable securities in a variety of instruments, including U.S. federal government and federal agency securities, European Government bonds, corporate bonds or commercial paper issued by U.S. or European corporations, money market instruments, certain

qualifying money market mutual funds, certain repurchase agreements, tax-exempt obligations of states, agencies, and municipalities in the U.S and Europe, and equities. 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' (deficit) 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 June 30, 2022 would have had an immaterial impact on net loss for the three and six months ended June 30, 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 income, net in the condensed consolidated statements of loss. As of June 30, 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 three and six months ended June 30, 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 three and six months ended June 30, 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 June 30, 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 Securities Exchange Act of 1934, as amended) were effective as of June 30, 2022.

Material Weakness

Remediation of Previously Reported Material Weakness

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 implemented measures in the first quarter of 2022 to remediate the control deficiency contributing to the material weakness. Specifically, management implemented a remediation plan that included:

- 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.

- A review of all Company contractual and debt agreements for potential terms or tentative conditions that could impact the calculation of interest expense similar to those terms underlying the control deficiency alongside the Exchange Transaction on April 5, 2022, noting none.

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.

As of June 30, 2022, management evaluated the design and operational effectiveness of the remediation activities and concluded that that we have sufficient evidence that the previously reported material weakness pertaining to the February 2023 Notes indenture has been remediated as of June 30, 2022.

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 June 30, 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 11: Subsequent Events* 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.

Risks Related to Our Lead Product Candidate, Future Product Candidates Clinical Development and Commercialization

We cannot be certain that our lead product candidate or future product candidates will receive marketing approval. Without marketing approval, we will not be able to commercialize our lead product candidate or future product candidates.

We have devoted significant financial resources and business efforts to the development of our lead product candidate. We cannot be certain that our lead product candidate or future product candidates will receive marketing approval.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the U.S. and by comparable regulatory authorities in other countries. We are not permitted to market our lead product candidate or future product candidates in the U.S. until we receive approval of an NDA by the FDA. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. An NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. For example, we submitted an NDA to the FDA for LUMRYZ, also known as FT218, for the treatment of cataplexy or EDS in adults with narcolepsy to the FDA in December 2020 through the Section 505(b)(2) regulatory pathway. In February 2021, the FDA assigned LUMRYZ a PDUFA target action date of October 15, 2021.

In October 2021, the FDA notified us that its review was still ongoing and action would not be taken by the PDUFA date. On May 24, 2022, we were notified by the FDA that the LUMRYZ NDA patent statement pertaining to the REMS Patent was deemed inappropriate. As such, the FDA requested the Company add a certification to the REMS Patent to its NDA. On June 29, 2022, we announced that we had submitted a Paragraph IV patent certification pertaining to the REMS Patent to LUMRYZ's NDA. On July 15, 2022, Jazz filed a patent infringement suit in the U.S. District of Delaware asserting that LUMRYZ will infringe at least one claim of that patent. The filing of that lawsuit triggers a regulatory stay on FDA approval of LUMRYZ. On July 18, 2022, we received tentative approval from the FDA for LUMRYZ for the treatment of cataplexy or EDS in adults suffering from narcolepsy. As such, we anticipate a decision regarding the final approval of LUMRYZ from the FDA on or about the expiration of the REMS Patent on June 17, 2023 or sooner if the patent is earlier removed from the FDA's Orange Book or a court earlier determines the patent is not infringed, invalid or otherwise unenforceable. Our receipt of tentative approval does not mean we will receive final FDA approval for the LUMRYZ NDA in a timely manner or at all. In addition, a drug product that is granted tentative approval, like LUMRYZ, may be subject to additional review before final approval. The FDA's tentative approval of LUMRYZ was based on information available to the FDA at the time of the tentative approval letter (i.e., information in the application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to the FDA's attention. We cannot legally market LUMRYZ in the U.S. until we obtain final approval from the FDA. Any delay or setback in obtaining final approval or the commercialization of our lead product candidate will adversely affect our business.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that we cannot rely on the Section 505(b)(2) regulatory pathway or other pathways we have selected, as applicable, for our product candidate;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of our product candidate for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the U.S., including any findings that the clinical and other benefits of our product candidate outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for our product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously approved drugs with the same conditions of approval as our product candidate, as applicable;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidate;
- may audit some or all of our clinical research study sites to determine the integrity of our data and may reject any or all of such data;
- may approve our lead product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our lead product candidate.

Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling and/or require expensive and time-consuming clinical trials and/or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for the approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions.

We have submitted an NDA for LUMRYZ in the U.S. and will evaluate filing potentially elsewhere. We have determined, following FDA consultation, that the 505(b)(2) approval pathway, which permits an NDA applicant to rely on the FDA's previous findings of safety or effectiveness and data from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, is the appropriate pathway for a LUMRYZ NDA. There can be no assurances, however, that the 505(b)(2) approval pathway in the U.S., or similar approval pathways outside of the U.S., will be available for our product candidate or that the FDA or other regulatory authorities will approve our product candidate through an application based on such pathways.

Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the U.S. or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidate.

Risks Related to Regulation

We will need to obtain regulatory approval of any proposed product names for our product candidates, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA or other regulatory authorities in jurisdictions where we may seek approval regardless of whether we have secured a trademark registration from the USPTO or similar protection in other jurisdictions. The FDA and other regulatory authorities each typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA or other regulatory authorities in jurisdictions where we may seek approval may object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA or other regulatory authorities in jurisdictions where we may seek approval objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. There is no guarantee that we will be able to use the same proprietary name for our product candidates in each jurisdiction where we market our products, if approved. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA or other regulatory authorities. The FDA has tentatively accepted our proprietary name for our lead product candidate, LUMRYZ. Final acceptance of a proposed proprietary name occurs as part of the final approval of the drug product. We may be unable to build a successful brand identity for a new proprietary name or trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Related to our Reliance on Third Parties

The commercialization of LUMRYZ, if granted final approval by the FDA, will require us to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

Following the completion of our reduction in workforce, which was announced in June 2022, we expect to employ approximately 35 full-time employees. If LUMRYZ is finally approved by the FDA, we expect to expand our full-time employee base to advance the commercialization of LUMRYZ. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to recognize and/or grow revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize LUMRYZ, if finally approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Risks Related to Our Business and Industry

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, LUMRYZ, if finally approved, would adversely affect sales of our product candidate. For example, in the future, we expect LUMRYZ 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.

Our cost structure optimization efforts, including a reduction in workforce, announced in June 2022, may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In June 2022, we announced a reduction in workforce of nearly 50 percent in connection with cost structure optimization efforts. We may not realize, in full or in part, the anticipated benefits and cost savings from our cost structure optimization efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. We also cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our cost structure optimization efforts may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale.

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

In June 2022, we announced our cost structure optimization efforts to reduce our quarterly cash operating expenses through a reduction in workforce of nearly 50 percent. We had previously carried out a workforce reduction in February 2019. Our management may determine we need to take further restructuring actions to achieve additional cost savings, to generate additional capital needed for our business strategy, or for other purposes. Certain restructuring scenarios that management consider could require obtaining the consent of third parties, such as holders of our Exchangeable Senior Notes due February 2023 (the "February 2023 Notes"). For example, the voluntary bankruptcy filing by Avadel Specialty Pharmaceuticals LLC ("Specialty Pharma") in February 2019 required the consent of holders of a majority in principal amount of our February 2023 Notes in order to avoid a default under the Indenture governing such February 2023 Notes. While we were successful in obtaining that consent, there can be no assurance we will be successful in obtaining additional consents in the future from such holders or from other third parties whose consents may be required. Failure to obtain these third-party consents would prevent us from taking additional restructuring actions, which could have a material adverse effect on our cash flow, financial resources and ability to successfully pursue our business strategy.

Risks Related to Our Intellectual Property

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidates.

The LUMRYZ NDA was submitted under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) NDA enables the applicant to reference published literature for which the applicant does not have a right of reference and the FDA's previous findings of safety and effectiveness for a previously approved drug.

For 505(b)(2) NDAs, the patent certification and related provisions of the Hatch-Waxman Amendments apply. Accordingly, if the applicant relies for approval on the safety or effectiveness information for a previously approved drug, referred to as a listed drug, the applicant is required to include patent certifications in its 505(b)(2) NDA regarding any applicable patents covering the listed drug. If there are applicable patents listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, and the applicant seeks to obtain approval prior to the expiration of one or more of those patents, the applicant is required to submit a Paragraph IV certification indicating their belief that the relevant patents are invalid or unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) application. Otherwise, the 505(b)(2) NDA cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug. On May 24, 2022, we were notified by the FDA that the LUMRYZ NDA patent statement pertaining to the REMS Patent was deemed inappropriate. On June 29, 2022, we announced that we had submitted a Paragraph IV certification pertaining to the REMS Patent to LUMRYZ's NDA. On July 15, 2022, Jazz filed a patent infringement suit in the U.S. District of Delaware asserting that LUMRYZ will infringe at least one claim of that patent. The filing of that lawsuit triggers a regulatory stay on final FDA approval of LUMRYZ. As such, we anticipate the FDA's decision regarding final approval on or about the expiration of the REMS Patent on June 17, 2023 or sooner if the patent is earlier removed from the FDA's Orange Book or a court earlier determines the patent is not infringed, invalid or otherwise unenforceable. There can be no assurance that we will not be required to submit a Paragraph IV certification in respect of any future product candidates for which we seek approval under Section 505(b)(2).

Following any Paragraph IV certification that may be required, an applicant will be required to provide notice of that certification to the NDA holder and patent owner. Under the Hatch-Waxman Amendments, the patent owner may file a patent infringement lawsuit after receiving such notice. If a patent infringement lawsuit is filed within 45 days of the patent owner's or NDA holder's receipt of notice (whichever is later), a one-time, automatic stay of the FDA's ability to approve the 505(b)(2) NDA is triggered, which typically extends for 30 months unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) NDA will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the listed drug, or for any other drug with the same protected conditions of approval as our product, has expired. The FDA also may require us to perform one or more additional clinical trials or measurements to support the change from the listed drug, which could be time consuming and could substantially delay our achievement of regulatory approval. The FDA also may reject any future 505(b)(2) NDAs and require us to submit traditional NDAs under Section 505(b)(1), which would require extensive data to establish safety and effectiveness of the product for the proposed use and could cause delay and additional costs. In addition, the FDA could reject any future 505(b)(2) application and require us to submit a Section 505(b)(1) NDA or a Section 505(j) ANDA if, before the submission of our 505(b)(2) application, the FDA approves an application for a product that is pharmaceutically equivalent to ours and determines that our product is inappropriate for review through the 505(b)(2) pathway. These factors, among others, may limit our ability to commercialize our product candidates successfully.

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
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: August 9, 2022

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

Date: August 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: August 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: August 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 June 30, 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: August 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 June 30, 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: August 9, 2022

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