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, 2023

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: 001-37977

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland	**98-1341933**
(State or Other Jurisdiction of Incorporation)	(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 every Interactive Data File required to be submitted 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, 2023, 89,367,975 ordinary shares, nominal value $0.01 each, of the Company were outstanding.

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NOTE REGARDING TRADEMARKS

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

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

Cautionary Disclosure Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”). Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but are not always, made through the use of words or phrases such as “may,” “will,” “could,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “potential,” “continue,” and similar expressions, or the negative of these terms, or similar expressions. Accordingly, these statements involve estimates, assumptions, risks and uncertainties which could cause actual results to differ materially from those expressed in them.

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

- Our ability to successfully launch and commercialize LUMRYZ (sodium oxybate) in the United States (“U.S.”) for the treatment of cataplexy or excessive daytime sleepiness (“EDS”) in adults with narcolepsy;
- Our plans with respect to our commercial infrastructure and marketing, market access and commercial activities;
- Our ability to maintain and receive additional regulatory approvals for LUMRYZ in any other jurisdictions outside the U.S., and any related restrictions, limitations, and/or warnings in the label of LUMRYZ;
- Our expectations regarding the rate and degree of market acceptance for LUMRYZ;
- Our ability to enter into strategic partnerships for the commercialization, manufacturing and distribution of LUMRYZ in the U.S.;
- Our reliance on a single product, 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, including commercialization of LUMRYZ in the U.S.;
- Our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness, issuance of equity, royalty-based financings, or through strategic financing or commercialization partnerships;
- Our expectations regarding the pricing and reimbursement of, and the extent to which patient assistance programs are utilized for, LUMRYZ;
- Our expectations about the potential market size and market participation for LUMRYZ;
- Our expectations regarding litigation related to LUMRYZ;
- Our expectations regarding our cash runway to support the commercial launch of LUMRYZ in the U.S.;
- Our ability to continue to service our remaining Exchangeable Senior Notes due October 2023 (the “October 2023 Notes”), including making the ongoing interest payments on the October 2023 Notes, settling exchanges of the October 2023 Notes in cash or completing any required repurchases of the October 2023 Notes;
- The potential impacts of COVID-19, inflation and rising interest rates 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 may 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 29, 2023 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,	
	2023	2022	2023	2022
Net product revenue	$ 1,496	$ —	$ 1,496	$ —
Cost of products sold	36	—	36	—
Gross profit	1,460	—	1,460	—
Operating expenses:				
Research and development expenses	4,223	4,541	8,053	11,532
Selling, general and administrative expenses	46,778	21,804	71,246	43,439
Restructuring expense	—	3,592	—	3,592
Total operating expense	51,001	29,937	79,299	58,563
Operating loss	(49,541)	(29,937)	(77,839)	(58,563)
Investment and other income, net	623	192	816	88
Interest expense	(2,295)	(3,506)	(5,554)	(5,523)
Loss on extinguishment of debt	(13,129)	—	(13,129)	—
Loss before income taxes	(64,342)	(33,251)	(95,706)	(63,998)
Income tax provision (benefit)	90	30,193	(490)	25,870
Net loss	$ (64,432)	$ (63,444)	$ (95,216)	$ (89,868)
Net loss per share – basic	$ (0.83)	$ (1.07)	$ (1.35)	$ (1.52)
Net loss per share – diluted	(0.83)	(1.07)	(1.35)	(1.52)
Weighted average number of shares outstanding - basic	77,246	59,037	70,603	58,931
Weighted average number of shares outstanding - diluted	77,246	59,037	70,603	58,931

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,	
	2023	2022	2023	2022
Net loss	$ (64,432)	$ (63,444)	$ (95,216)	$ (89,868)
Other comprehensive income (loss), net of tax:				
Foreign currency translation income (loss)	8	(657)	183	(842)
Net other comprehensive income (loss), net of income tax expense of $0, $330, $0 and $0, respectively	75	(629)	216	(1,546)
Total other comprehensive income (loss), net of tax	83	(1,286)	399	(2,388)
Total comprehensive loss	$ (64,349)	$ (64,730)	$ (94,817)	$ (92,256)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	June 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 49,985	$ 73,981
Marketable securities	110,525	22,518
Accounts receivable, net	1,775	—
Inventories	1,439	—
Research and development tax credit receivable	974	2,248
Prepaid expenses and other current assets	6,532	2,096
Total current assets	171,230	100,843
Property and equipment, net	715	839
Operating lease right-of-use assets	1,235	1,713
Goodwill	16,836	16,836
Research and development tax credit receivable	420	1,232
Other non-current assets	10,540	11,322
Total assets	$ 200,976	$ 132,785
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term debt	$ 20,851	$ 37,668
Current portion of operating lease liability	783	960
Accounts payable	11,786	7,890
Accrued expenses	17,582	7,334
Other current liabilities	500	1,941
Total current liabilities	51,502	55,793
Long-term debt	—	91,614
Long-term operating lease liability	490	780
Other non-current liabilities	5,792	5,743
Total liabilities	57,784	153,930
Shareholders' equity (deficit):		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 5,194 issued and outstanding at June 30, 2023 and 488 issued and outstanding at December 31, 2022	52	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 89,321 issued and outstanding at June 30, 2023 and 62,878 issued and outstanding at December 31, 2022	893	628
Additional paid-in capital	848,626	589,783
Accumulated deficit	(680,436)	(585,220)
Accumulated other comprehensive loss	(25,943)	(26,341)
Total shareholders' equity (deficit)	143,192	(21,145)
Total liabilities and shareholders' equity (deficit)	$ 200,976	$ 132,785

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Ordinary shares		Preferred shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total shareholders' equity (deficit)
	Shares	Amount	Shares	Amount				
Balance, December 31, 2022	62,878	$ 628	488	$ 5	$ 589,783	$ (585,220)	$ (26,341)	$ (21,145)
Net loss	—	—	—	—	—	(30,784)	—	(30,784)
Other comprehensive income	—	—	—	—	—	—	315	315
Issuance of common stock under at-the-market offering program, net of issuance costs	1,564	16	—	—	11,897	—	—	11,913
Amortization of deferred issuance costs	—	—	—	—	(16)	—	—	(16)
Vesting of restricted shares	22	—	—	—	—	—	—	—
Employee share purchase plan share issuance	14	—	—	—	29	—	—	29
Share-based compensation expense	—	—	—	—	1,522	—	—	1,522
Balance, March 31, 2023	64,478	$ 644	488	$ 5	$ 603,215	$ (616,004)	$ (26,026)	$ (38,166)
Net loss	—	—	—	—	—	(64,432)	—	(64,432)
Other comprehensive income	—	—	—	—	—	—	83	83
April 2023 public offering, net of issuance costs	12,205	122	4,706	47	133,982	—	—	134,151
Mandatory Exchange of April 2027 Notes, net of issuance costs	12,347	123	—	—	102,039	—	—	102,162
Exercise of stock options	291	4	—	—	1,746	—	—	1,750
Share-based compensation expense	—	—	—	—	7,644	—	—	7,644
Balance, June 30, 2023	89,321	$ 893	5,194	$ 52	$ 848,626	$ (680,436)	$ (25,943)	$ 143,192

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

	Ordinary shares		Preferred shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total shareholders' equity (deficit)
	Shares	Amount	Shares	Amount				
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 CASH FLOWS
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (95,216)	$ (89,868)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,189	506
Amortization of debt discount and debt issuance costs	2,460	2,229
Changes in deferred taxes	—	25,870
Share-based compensation expense	9,166	3,163
Loss on extinguishment of debt	13,129	—
Other adjustments	42	1,206
Net changes in assets and liabilities		
Accounts receivable	(1,775)	—
Inventories	(1,439)	—
Prepaid expenses and other current assets	(4,400)	13,305
Research and development tax credit receivable	2,127	30
Accounts payable & other current liabilities	2,470	(4,457)
Accrued expenses	10,246	2,559
Other assets and liabilities	(255)	(2,678)
Net cash used in operating activities	(62,256)	(48,135)
Cash flows from investing activities:		
Proceeds from sales of marketable securities	25,618	56,501
Purchases of marketable securities	(113,460)	(2,202)
Net cash (used in) provided by investing activities	(87,842)	54,299
Cash flows from financing activities:		
Proceeds from April 2023 public offering, net of issuance costs	134,151	—
Payments for February 2023 Notes	(17,500)	—
Payments for debt issuance costs	(4,357)	(4,803)
Proceeds from issuance of shares off the at-the-market offering program	11,913	—
Proceeds from stock option exercises and employee share purchase plan	1,779	2,009
Net cash provided by (used in) financing activities	125,986	(2,794)
Effect of foreign currency exchange rate changes on cash and cash equivalents	116	50
Net change in cash and cash equivalents	(23,996)	3,420
Cash and cash equivalents at January 1,	73,981	50,708
Cash and cash equivalents at June 30,	$ 49,985	$ 54,128
Supplemental disclosures of cash flow information:		
Interest paid	$ 4,520	$ 6,455
Income taxes refund	$ —	$ (14,096)

See accompanying notes to unaudited condensed consolidated financial statements.

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

NOTE 1: Summary of Significant Accounting Policies

Nature of Operations. Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel," the "Company," "we," "our," or "us") is a 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.").

LUMRYZ, formally known as FT218, is an extended-release formulation of sodium oxybate indicated to be taken once at bedtime for the treatment of cataplexy or excessive daytime sleepiness ("EDS") in adults with narcolepsy. LUMRYZ was approved by the U.S. Food and Drug Administration ("FDA") on May 1, 2023. The FDA also granted Orphan Drug Exclusivity ("ODE") to LUMRYZ for a period of seven years until May 1, 2030. In June 2023, the Company commercially launched LUMRYZ in the U.S.

In approving LUMRYZ, the FDA approved a risk evaluation and mitigation strategy ("REMS") for LUMRYZ to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in narcolepsy outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of the drug. Under this REMS, healthcare providers, pharmacies, practitioners, or health care settings that dispense the drug must be specially certified and the drug must be dispensed to patients with documentation of safe use conditions.

As of the date of this Quarterly Report, the Company's only commercialized product is LUMRYZ. The Company continues to evaluate opportunities to expand its product portfolio.

Liquidity. The accompanying unaudited condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP") applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

On March 29, 2023, the Company and Avadel CNS Pharmaceuticals, LLC, an indirect wholly-owned subsidiary of the Company ("Avadel CNS") entered into a royalty purchase agreement ("RPA") with RTW Investments, L.P. that could provide the Company up to $75,000 of royalty financing in two tranches. The first tranche of $30,000 became available upon satisfaction of certain conditions which included the Company's first shipment of LUMRYZ. The second tranche is available to use, at the Company's election, upon achieving quarterly net revenue of $25,000. The second tranche will expire on August 31, 2024, if the quarterly net revenue target is not reached and if the Company does not elect to use it by that time. On August 1, 2023, the Company received the first tranche of $30,000.

At March 31, 2023, the Company had outstanding $117,375 aggregate principal amount of its 4.50% exchangeable senior notes due October 2023 (the "October 2023 Notes"). Over the course of April 3 and April 4, 2023, Avadel Finance Cayman Limited, a Cayman Islands exempted company and an indirect wholly-owned subsidiary of the Company (the "Issuer"), completed an exchange of $96,188 of its $117,375 October 2023 Notes for $106,268 of a new series 6.0% exchangeable notes due April 2027 (the "April 2027 Notes") (the "2023 Exchange Transaction"). The remaining $21,187 aggregate principal amount of the October 2023 Notes will mature on October 2, 2023.

On April 3, 2023, the Company completed the sale of 12,205 ordinary shares, nominal value $0.01 per share ("Ordinary Shares") in the form of American Depositary Shares ("ADSs") and 4,706 Series B Non-Voting Convertible Preferred Shares ("Series B Preferred Shares") in an underwritten public offering. The Company received proceeds, net of underwriter fees and issuance costs of $134,151.

On May 31, 2023 and in accordance with the terms of the Indenture of the April 2027 Notes (the "Indenture"), dated as of April 3, 2023, the Issuer exercised its option to exchange (the "Mandatory Exchange") $106,268 of aggregate principal amount of the April 2027 Notes, which represents all of the April 2027 Notes outstanding under the Indenture. The Mandatory Exchange consideration per one thousand dollars of principal Notes exchanged consisted of 116.1846 of the Company's American Depositary Shares (the "ADSs"), representing a corresponding number of the Company's ordinary shares, nominal value $0.01 per share, plus accrued and unpaid interest thereon. The aggregate amount of ADSs and cash in respect of accrued and unpaid interest delivered to holders of Notes in the Mandatory Exchange was 12,347 ADSs and $1,470, respectively. The Mandatory Exchange closed on June 26, 2023.

At-the-Market Offering Program

On February 5, 2020, the Company entered into an Open Market Sale Agreement[SM] (the “Sales Agreement”) with Jefferies LLC (“Jefferies”) with respect to an at-the-market offering program (“ATM Program”) under which the Company may offer and sell its ADSs (such ADSs sold under the ATM Program, “ATM ADSs”) through Jefferies as its sales agent. The Company agreed to pay Jefferies a commission up to 3.0% of the aggregate gross sales proceeds of such ATM ADSs. The initial aggregate offering price of the ATM Program was up to $50,000 of ADSs pursuant to its prospectus, dated February 14, 2020, included with the Company’s Registration Statement on Form S-3 (File No. 333-236258) (the “2020 Prospectus”). In August 2022, the Company filed an additional prospectus, dated September 12, 2022, included with the Company’s new Registration Statement on Form S-3 (File No. 333-267198) (the “2022 Prospectus”), in order to allocate up to $100,000 in additional ADSs to the ATM Program. The 2020 Shelf Registration expired on February 14, 2023.

Pursuant to the Sales Agreement, the Company issued and sold 1,564 ADSs during the six months ended June 30, 2023, resulting in net proceeds to the Company of approximately $11,913. The Company may offer and sell up to an additional $96,064 of ADSs under the ATM Program that remain available for sale pursuant to the 2022 Prospectus.

Basis of Presentation. The unaudited condensed consolidated balance sheet as of June 30, 2023, which is derived from the prior year 2022 audited consolidated financial statements, and the interim unaudited condensed consolidated financial statements presented herein, have been prepared in accordance with 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 2022 Annual Report on Form 10-K filed with the United States Securities and Exchange Commission (“SEC”) on March 29, 2023.

Reclassifications

Certain reclassifications are made to prior year amounts whenever necessary to conform with the current year presentation. Certain reclassifications have been made to balances within *Note 8: Other Assets and Liabilities* for the year ended December 31, 2022 to condense line items of the same nature into a single line.

During the three months ended June 30, 2023, we identified additional significant accounting policies as described below.

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

Product Sales

The Company sells products to specialty pharmacies and considers those specialty pharmacies to be its customers. Under ASC 606, revenue from product sales is recognized when the customer obtains control of the product, which occurs typically upon receipt by the customer. The Company’s gross product sales are subject to a variety of price adjustments to arrive at reported net product revenue. These adjustments include estimates of payment discounts, specialty pharmacy fees, patient assistance programs, rebates and product returns and are estimated based on contractual arrangements, historical trends, expected utilization of such products and other judgments and analysis.

Reserves for Variable Consideration

Revenues from product sales are recorded at the estimated net selling price, which includes reserves for estimated variable consideration to reduce gross product sales to net product revenue resulting from payment discounts, specialty pharmacy fees, patient assistance programs, rebates and product returns. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable if the amount is payable to the customer. The reserves are classified as a liability if the amount is payable to a party other than a customer. Where appropriate, these estimated reserves take into consideration relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, historical trends, current and expected patient demand and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates to reduce gross selling price to net selling price. The actual net selling price ultimately may differ from our estimates.

Inventories. Inventories consist of raw materials, work in process and finished products, which are stated at lower of cost or net realizable value, using the first-in, first- out ("FIFO") method. Raw materials used in the production of pre-clinical and clinical products are expensed as research and development ("R&D") costs when consumed. The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow-moving on a case by case basis.

The Company capitalizes inventory costs associated with products when future commercialization is considered probable and the future economic benefit is expected to be realized, which is typically when regulatory approval is obtained for a drug candidate. As such, the Company began capitalizing costs related to inventory in May 2023 upon FDA approval of LUMRYZ. Manufacturing costs associated with inventory purchased or produced prior to FDA approval were recorded as research and development expense in prior periods. Accordingly, cost of products sold in the near term will likely be lower than in later periods given the sales of pre-approval inventory will carry little to no manufacturing costs given such costs were previously expensed to research and development expense.

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: Revenue Recognition

The Company's source of net product revenue during the three and six months ended June 30, 2023 consists solely of sales of LUMRYZ.

For the three and six months ended June 30, 2023, three customers accounted for 100% of sales. The following table presents a summary of the percentage of total sales to customers:

	Three and Six Months Ended June 30,
Sales by Customer:	**2023**
Accredo	39 %
Caremark	42 %
Optum	19 %

The Company had no net product revenue during the three and six months ended June 30, 2022.

NOTE 3: 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, 2023			As of December 31, 2022		
Fair Value Measurements:	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Marketable securities (see *Note 4*)						
Mutual and money market funds	$ 17,408	$ —	$ —	$ 22,518	$ —	$ —
Government securities - U.S.	93,117	—	—	—	—	—
Total assets	$ 110,525	$ —	$ —	$ 22,518	$ —	$ —

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, 2023 and December 31, 2022, respectively, there were no transfers in and out of Level 3. During the three and six months ended June 30, 2023 and 2022, respectively, the Company did not recognize any allowances for credit losses.

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

Debt

The Company estimates the fair value of its $21,187 aggregate principal amount of its 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 value of the October 2023 Notes at June 30, 2023 is $31,622. See *Note 6: Long-Term Debt* for additional information regarding the Company’s debt obligations.

NOTE 4: Marketable Securities

The Company has investments in available-for-sale debt securities which are recorded at fair market value. The change in the fair value of available-for-sale debt investments is recorded as accumulated other comprehensive loss in shareholders' equity (deficit), net of income tax effects. As of June 30, 2023, 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, 2023 and December 31, 2022, respectively:

	June 30, 2023			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Mutual and money market funds	$ 19,513	$ —	$ (2,105)	$ 17,408
Government securities - U.S.	92,685	432	—	93,117
Total	$ 112,198	$ 432	$ (2,105)	$ 110,525

	December 31, 2022			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Mutual and money market funds	$ 24,407	$ —	$ (1,889)	$ 22,518
Total	$ 24,407	$ —	$ (1,889)	$ 22,518

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 immaterial gross realized gains and losses for the three and six months ended June 30, 2023 and for the three months ended June 30, 2022. The Company recognized gross realized gains of $308 for the six months ended June 30, 2022 which were offset by realized losses of $1,031 for the six months ended June 30, 2022.

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, 2023:

	Maturities				
Marketable Debt Securities:	**Less than 1 Year**	**1-5 Years**	**5-10 Years**	**Greater than 10 Years**	**Total**
Government securities - U.S.	$ 93,117	$ —	$ —	$ —	$ 93,117
Total	$ 93,117	$ —	$ —	$ —	$ 93,117

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 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.

NOTE 5: Inventories

The principal categories of inventories at June 30, 2023 is comprised of the following:

Inventory:		June 30, 2023
Raw materials and supplies	$	50
Work in process		799
Finished goods		590
Total	$	1,439

The Company had no capitalized inventories at December 31, 2022. The Company capitalizes inventory costs associated with products when future commercialization is considered probable and the future economic benefit is expected to be realized, which is typically when regulatory approval is obtained for a drug candidate. As such, the Company began capitalizing costs related to inventory in May 2023 upon FDA approval of LUMRYZ. Manufacturing costs associated with inventory purchased or produced prior to FDA approval were recorded as research and development expense in prior periods.

NOTE 6: Long-Term Debt

Long-term debt is summarized as follows:

		June 30, 2023		December 31, 2022
Principal amount of 4.50% exchangeable senior notes due October 2023	$	21,187	$	117,375
Principal amount of 4.50% exchangeable senior notes due February 2023		—		17,500
Less: unamortized debt discount and issuance costs, net		(336)		(5,593)
Net carrying amount of debt		20,851		129,282
Less: current maturities, net of $336 and $1,019 unamortized debt discount and issuance costs, respectively		(20,851)		(37,668)
Long-term debt	$	—	$	91,614

For the three months ended June 30, 2023 and 2022, the total interest expense was $2,295 and $3,506, respectively, with coupon interest expense of $1,708 and $1,589 for each period, respectively, and the amortization of debt issuance costs and debt discount, totaling $587 and $1,917 for each period, respectively.

For the six months ended June 30, 2023 and 2022, the total interest expense was $5,554 and $5,523, respectively, with coupon interest expense of $3,094 and $3,206 for each period, respectively, and the amortization of debt issuance costs and debt discount of $2,460 and $2,229 for each period, respectively.

February 2023 Notes

On February 16, 2018, the Issuer issued $125,000 aggregate principal amount of its 4.50% exchangeable senior notes due February 2023 (the “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 were the Company’s senior unsecured obligations and ranked 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.

October 2023 Notes

On April 5, 2022, the Issuer completed the exchange of $117,375 of its February 2023 Notes for a new series of its October 2023 Notes (the “2022 Exchange Transaction”). The remaining $26,375 aggregate principal amount of the February 2023 Notes were not exchanged and maintained a maturity date of February 1, 2023. On November 4, 2022, the Company repurchased $8,875 of its February 2023 Notes and on the maturity date of February 1, 2023, the Company repaid, with cash on hand, the remaining $17,500 aggregate principal amount of its February 2023 Notes.

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 are 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 2022 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 is amortized over the remaining term of the October 2023 Notes as a component of interest expense.

The October 2023 Notes are exchangeable at the option of the holders at an initial exchange rate of 92.6956 ADSs per $1 principal amount of 2023 Notes, which is equivalent to an initial exchange price of approximately $10.79 per ADS. Such an initial exchange price represents a premium of approximately 20% to the $8.99 per ADS closing price on The Nasdaq Global Market on February 13, 2018. Upon the exchange of any October 2023 Notes, the Issuer will pay a combination of cash and ADSs at the Issuer's election.

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.

April 2027 Notes

Over the course of April 3 and April 4, 2023, the Issuer completed an exchange of $96,188 of its $117,375 October 2023 Notes for $106,268 of new April 2027 Notes. The remaining $21,187 aggregate principal amount of the October 2023 Notes will mature on October 2, 2023. The Company accounted for the exchange of the October 2023 Notes for the April 2027 Notes as an extinguishment of $96,188 of its October 2023 Notes. The Company recorded a loss on the extinguishment of $13,129 as a result of the exchange.

On May 31, 2023 and in accordance with the terms of the Indenture the Company completed the Mandatory Exchange of $106,268 of aggregate principal amount of the April 2027 Notes, which represents all of the April 2027 Notes outstanding under the Indenture. The Mandatory Exchange consideration per one thousand dollars of principal Notes exchanged consisted of 116.1846 of ADSs representing a corresponding number of the Company's ordinary shares, nominal value $0.01 per share, plus accrued and unpaid interest thereon. The aggregate amount of ADSs and cash in respect of accrued and unpaid interest delivered to holders of Notes in the Mandatory Exchange was 12,347 ADSs and $1,470, respectively. The Mandatory Exchange closed on June 26, 2023.

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 October 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.

Royalty Financing Agreement

On March 29, 2023, the Company and Avadel CNS entered into the RPA with RTW Investments, L.P. that could provide the Company up to $75,000 of royalty financing in two tranches. The first tranche of $30,000 became available upon satisfaction of certain conditions which included the Company's first shipment of LUMRYZ. The second tranche is available to use, at the Company's election, upon achieving quarterly net revenue of $25,000. The second tranche will expire on August 31, 2024, if the quarterly net revenue target is not reached and if the Company does not elect to use it by that time. On August 1, 2023, the Company received the first tranche of $30,000.

NOTE 7: Income Taxes

The income tax provision was $90 for the three months ended June 30, 2023, resulting in an effective tax rate of (0.1)%. 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 change in the effective income tax rate for the three months ended June 30, 2023, as compared to the prior period in 2022, is primarily driven by the valuation allowances recorded against net deferred tax assets established in the second quarter of 2022.

The income tax benefit was $490 for the six months ended June 30, 2023, resulting in an effective tax rate of 0.5%. 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 change in the effective income tax rate for the six months ended June 30, 2023, as compared to the prior period in 2022, is primarily driven by the valuation allowances recorded against net deferred tax assets established in the second quarter of 2022.

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 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 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.

NOTE 8: Other Assets and Liabilities

Various other assets and liabilities are summarized as follows:

Prepaid Expenses and Other Current Assets:	**June 30, 2023**	**December 31, 2022**
Prepaid and other expenses	$ 5,716	$ 1,523
Other	747	504
Income tax receivable	69	69
Total	$ 6,532	$ 2,096

Other Non-Current Assets:	**June 30, 2023**	**December 31, 2022**
Right of use assets at contract manufacturing organizations, net	$ 10,098	$ 10,686
Other	442	636
Total	$ 10,540	$ 11,322

Accrued Expenses	**June 30, 2023**	**December 31, 2022**
Accrued professional fees	$ 12,662	$ 4,040
Accrued compensation	4,405	1,613
Reserves for variable consideration	280	—
Accrued outsource contract costs	182	1,208
Accrued restructuring	53	473
Total	$ 17,582	$ 7,334

Other Current Liabilities:	**June 30, 2023**	**December 31, 2022**
Other	$ 275	$ 292
Accrued interest	225	1,649
Total	$ 500	$ 1,941

Other Non-Current Liabilities:	**June 30, 2023**	**December 31, 2022**
Tax liabilities	$ 5,420	$ 5,246
Other	372	497
Total	$ 5,792	$ 5,743

NOTE 9: 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.

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:	**2023**	**2022**	**2023**	**2022**
Net loss	$ (64,432)	$ (63,444)	$ (95,216)	$ (89,868)
Weighted average shares:				
Basic shares	77,246	59,037	70,603	58,931
Effect of dilutive securities—employee and director equity awards outstanding, preferred shares and 2023 Notes	—	—	—	—
Diluted shares	77,246	59,037	70,603	58,931
Net loss per share - basic	$ (0.83)	$ (1.07)	$ (1.35)	$ (1.52)
Net loss per share - diluted	$ (0.83)	$ (1.07)	$ (1.35)	$ (1.52)

Potential ordinary shares of 2,212 and 22,455 were excluded from the calculation of weighted average shares for the three months ended June 30, 2023 and 2022, respectively, and potential ordinary shares of 6,813 and 19,042 were excluded from the calculation of weighted average shares for the six months ended June 30, 2023 and 2022 because their effect was considered to be anti-dilutive. For the three and six months ended June 30, 2023 and 2022, 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 10: Comprehensive Loss

The following table shows the components of accumulated other comprehensive loss for the three and six months ended June 30, 2023 and 2022, respectively, net of tax effects:

	Three Months Ended June 30,		Six Months Ended June 30,	
Accumulated Other Comprehensive Loss:	**2023**	**2022**	**2023**	**2022**
Foreign currency translation adjustment:				
Beginning balance	$ (24,277)	$ (24,040)	$ (24,452)	$ (23,855)
Net other comprehensive income (loss)	8	(657)	183	(842)
Balance at June 30,	$ (24,269)	$ (24,697)	$ (24,269)	$ (24,697)
Unrealized loss on marketable debt securities, net				
Beginning balance	$ (1,749)	$ (1,002)	$ (1,890)	$ (85)
Net other comprehensive income (loss), net of income tax expense of $0, $330, $0 and $0, respectively	75	(629)	216	(1,546)
Balance at June 30,	$ (1,674)	$ (1,631)	$ (1,674)	$ (1,631)
Accumulated other comprehensive loss at June 30,	$ (25,943)	$ (26,328)	$ (25,943)	$ (26,328)

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 11: Commitments and Contingencies

Litigation

The Company is subject to potential liabilities generally incidental to its business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The 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, 2023 and December 31, 2022, 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 against Jazz seeking to have U.S. Patent No. 8731963 (the "REMS Patent") delisted 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 styled as Objections to Avadel CNS' Motion for Judgment on the Pleadings. On July 14, 2022, Avadel CNS replied to Jazz's response, and on July 21, 2022, Avadel CNS requested oral argument on its delisting motion simultaneous with the *Markman* hearing. On August 24, 2022, the Court ordered Jazz to respond substantively to Avadel CNS' motion, which Jazz did on August 26, 2022. Avadel CNS filed its reply on August 28, 2022.

On August 23, 2022, the *Markman* hearing was postponed. On September 7, 2022, the case was reassigned to a new judge, and the *Markman* hearing was held on October 25, 2022. At the *Markman* hearing, Avadel CNS reiterated its request for an expedited hearing on the Renewed Motion for Judgment on the Pleadings for the delisting of the REMS Patent. On October 28, 2022, the Court granted Avadel CNS' request and scheduled the hearing for November 15, 2022.

The Court held the *Markman* hearing on November 15, 2022 and issued a claim construction ruling on November 18, 2022. Also on November 18, 2022 the Court granted Avadel's Renewed Motion for Judgment on the Pleadings and ordered Jazz to request delisting of the REMS Patent from the Orange Book. On November 22, 2022, Jazz appealed that decision and on December 14, 2022, the Federal Circuit issued a stay of the delisting order until further notice. Oral argument was held February 14, 2023. On February 24, 2023, the United States Court of Appeals for the Federal Court affirmed the previous ruling from the Court, ordering the delisting of the REMS Patent from the Orange Book, which has since occurred. On March 7, 2023, in response to a joint stipulation filed by the parties, the Court issued an order dismissing Jazz's infringement claims against the Avadel Parties relating to the REMS Patent as well as Avadel Parties' noninfringement and invalidity counterclaims relating to the REMS Patent.

On March 15, 2023, the parties submitted a Stipulation and Proposed Order Modifying the Case Schedule to accommodate additional claim construction proceedings. That stipulation remains pending before the Court. On April 26, 2023 the parties filed their Supplemental Joint Claim Construction Brief.

On July 3, 2023, the Court issued a modified scheduling order establishing a new trial date of February 26, 2024.

On July 21, 2023, in response to a Court order, the parties submitted a Stipulation and Proposed Order Modifying the Case Schedule with an updated proposed schedule to accommodate additional claim construction proceedings. On August 4, 2023, the Court entered a modified version of the parties' proposed schedule. The parties' Second Supplemental Joint Claim Construction Brief is due October 9, 2023, and a Markman hearing is set for October 25, 2023.

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.

On September 7, 2022, the case was reassigned to a new judge.

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.

On September 7, 2022, the case was reassigned to a new judge.

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, consistent with its Renewed Motion for Judgment on the Pleadings for the delisting of the REMS Patent from the Orange Book, which was later ordered to be delisted in the above First Jazz Complaint action. 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.

On September 7, 2022, the case was reassigned to a new judge.

On September 21, 2022, Jazz served the Fourth Complaint. On October 21, 2022, Avadel CNS timely filed its Answer and Counterclaims (the “Fourth Avadel Answer”) with the Court in response to the Fourth Complaint. The Fourth Avadel Answer generally denies the allegations set forth in the Fourth 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 for i) a declaratory judgment of non-infringement of the patent-in-suit, ii) a declaratory judgment of invalidity/unenforceability of the patent-in-suit, iii) delisting of the patent-in-suit from the Orange Book; iv) monopolization under the Sherman Antitrust Act of 1890 (the “Sherman Act”); and v) attempted monopolization under the Sherman Act.

On December 9, 2022, Jazz filed a Motion to Dismiss Avadel’s Antitrust Counterclaims. Avadel filed its opposition brief on December 27, 2022, and Jazz filed its reply brief on January 6, 2022. On January 11, 2023, Avadel filed a request for oral argument on the motion, which is still pending.

On March 6, 2023, the parties filed a stipulation of dismissal, dismissing Jazz’s claims with respect to the REMS Patent and Avadel CNS’s related non-infringement and invalidity counterclaims. The Court entered that stipulation on March 7, 2023.

On May 19, 2023, the Court issued a scheduling order establishing timing for litigation events including i) completion of fact discovery by March 14, 2024, and ii) a deadline for case dispositive motions of September 20, 2024.

On June 29, 2023, Jazz filed a Motion to Stay the case, pending resolution of its Motion to Dismiss. Briefing on that Motion to Stay is scheduled to close on August 10, 2023.

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. On February 2, 2023, the Court held a hearing on Jazz's Motion for Judgment on the Pleadings.

On September 7, 2022, the case was reassigned to a new judge.

On February 2, 2023, the Court held a hearing on Jazz's Motion for Judgment on the Pleadings.

On July 18, 2023, the Court denied Jazz's Motion for Judgment on the Pleadings.

Jazz's Administrative Procedure Act Complaint

On June 22, 2023, Jazz 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 (the "Federal Defendants") in the United States District Court for the District of Columbia (the "DC Court") related to the NDA for LUMRYZ. This suit alleges that the FDA's approval of LUMRYZ was an unlawful agency action and asks the DC Court to set aside FDA's approval of LUMRYZ. On June 28, 2023, the DC Court granted Avadel CNS's unopposed motion to intervene in the case to defend the FDA's decision.

Material Commitments

Other than commitments disclosed in *Note 11: Contingent Liabilities and Commitments* to the Company's consolidated financial statements included in the 2022 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 Capital L.P. ("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 its pediatric assets, including four pediatric commercial stage assets – Karbinal™ ER, Cefaclor, Flexichamber™ and AcipHex® Sprinkle™ ("FSC products"), to Cerecor, Inc. ("Cerecor"), the Company guaranteed to Deerfield a quarterly royalty payment of 15% on net sales of the FSC products through February 6, 2026 ("FSC Product Royalties"), in an aggregate amount of up to approximately $10,300. 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 $639 at June 30, 2023. 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, 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 $633 at June 30, 2023. This asset is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield noted above.

NOTE 12: Subsequent Events

On March 29, 2023, the Company and Avadel CNS entered into the RPA with RTW Investments, L.P. that could provide the Company up to $75,000 of royalty financing in two tranches. The first tranche of $30,000 became available upon satisfaction of certain conditions which included the Company's first shipment of LUMRYZ. On August 1, 2023, the Company received the first tranche of $30,000.

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 29, 2023 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. LUMRYZ, formerly known as FT218, is an extended-release formulation of sodium oxybate indicated to be taken once at bedtime for the treatment of cataplexy or excessive daytime sleepiness ("EDS") in adults with narcolepsy.

As of the date of this Quarterly Report, LUMRYZ is the only commercialized product in our portfolio. We continue to evaluate opportunities to expand our product portfolio.

LUMRYZ

LUMRYZ was approved by the United States ("U.S.") Food and Drug Administration ("FDA") in May 2023 for the treatment of cataplexy or EDS in adults with narcolepsy. In approving LUMRYZ, the FDA approved a risk evaluation and mitigation strategy ("REMS") for LUMRYZ to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in narcolepsy outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of the drug. Under this REMS, healthcare providers must be specially certified, pharmacies, practitioners, or health care settings that dispense the drug must be specially certified and the drug must be dispensed to patients with documentation of safe use conditions. Additionally, with its approval, the FDA also granted seven years of orphan drug exclusivity to LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy due to a finding of clinical superiority of LUMRYZ relative to currently marketed oxybate treatments. In particular, FDA found that LUMRYZ makes a major contribution to patient care over currently marketed, twice-nightly oxybate treatments by providing a once-nightly dosing regimen that avoids nocturnal arousal to take a second dose. The orphan exclusivity will continue until May 1, 2030. In June 2023 we announced the U.S. commercial launch of LUMRYZ for the treatment of cataplexy or EDS in adults living with narcolepsy.

Thirteen LUMRYZ-related U.S. patents have been issued having expiration dates spanning from mid-2037 to early-2042, 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.

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's 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.

Additionally, our open-label extension ("OLE")/switch study of LUMRYZ as a potential treatment for cataplexy or EDS in patients with narcolepsy ("RESTORE") 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. An interim safety analysis from the ongoing RESTORE study showed that LUMRYZ has generally been well-tolerated, with some patients receiving therapy for more than 18 months. 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 does titrations within four weeks.

A discrete choice experiment ("DCE") showed 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.

Additional peer-reviewed publications have included data on 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 which support the following:

- 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 maintenance of wakefulness test, the Epworth Sleepiness Scare ("ESS"), and number of cataplexy attacks;
- Confirmation via various statistical methods to handle missing data that LUMRYZ improved cataplexy and EDS symptoms versus placebo;
- Confirmation of benefit for NT1 and NT2 for disturbed nocturnal sleep ("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.

At the 2023 SLEEP meeting, additional LUMRYZ data, including post-hoc analyses from the pivotal trial, interim data from the open-label study and real-world evidence regarding sodium oxybate utilization and co-morbidities was presented.

A second DCE among clinicians was published in May 2023, showing the dosing regimen was the most important driver of choice, with once-nightly preferred. Post-hoc analyses of NT1 and NT2 were also published, demonstrating consistent improvements regardless of narcolepsy type.

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

Key Business Trends and Highlights

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

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

- **Competition and Technological Change**: Competition in the pharmaceutical and biotechnology industry continues to be intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing niche branded or generic specialty pharmaceutical products or drug delivery platforms. Furthermore, major technological changes can happen quickly in the pharmaceutical and biotechnology industries. Such rapid technological change, or the development by our competitors of technologically improved or differentiated products, could render our 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.

- **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 generate revenues sufficient to generate positive cash flow from the commercialization of LUMRYZ. Similar to other businesses in our industry and at our stage of development, we will continue to rely on external sources of capital to fund our business. The process of raising capital and the 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.

- **Continuing Net Loss from Operations**: LUMRYZ is the only commercialized product in our portfolio, and we will incur substantial expenses to continue our commercial launch of LUMRYZ.

Impact of COVID-19

We continue to actively monitor the impact of COVID-19. 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 vaccination efforts, future developments and impact on our operations remain uncertain and cannot be predicted with confidence, including the duration of the COVID-19 pandemic, new variants of the virus, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that governments, or we, may direct, which may result in extending continued business disruptions.

Financial Highlights

Highlights of our consolidated results for the three and six months ended June 30, 2023 are as follows:

- Net product revenue was $1,496 during the three and six months ended June 30, 2023. LUMRYZ was approved by the FDA on May 1, 2023 and we began shipping product to our customers in June 2023.

- Operating loss was $49,541 and $77,839 for the three and six months ended June 30, 2023, respectively, compared to operating loss of $29,937 and $58,563 for the three and six months ended June 30, 2022, respectively. Selling, general and administrative expenses increased during the three months ended June 30, 2023 by $24,974 compared to the three months ended June 30, 2022 driven by higher legal fees of $6,900, higher marketing and market research activities of $5,500, higher costs associated with the commercial launch of LUMRYZ of $2,600, higher compensation costs of $3,000, and an increase in regulatory expenses of $800. Selling, general, and administrative expense also includes a $7,800 cumulative adjustment for certain compensation awards tied to the achievement of performance conditions, which became probable in the period. Selling, general and administrative expenses increased during the six months ended June 30, 2023 by $27,807 compared to the six months ended June 30, 2022, driven by higher legal fees of $8,600, higher marketing and market research activities of $3,900, higher costs associated with the commercial launch of LUMRYZ of $3,500, and higher compensation costs of $2,600 due to increased headcount. Selling, general, and administrative expense in the six months ended June 30, 2023 includes a $7,800 cumulative adjustment for certain compensation awards tied to the achievement of performance conditions, which became probable in the period. We also incurred costs related to financing activities of approximately $1,300 in the current period. Research and development expenses decreased $3,479 during the six months ended June 30, 2023 compared to the six months ended June 30, 2022, primarily driven by lower API purchases of $3,300.

- Net loss was $64,432 and $95,216 for the three and six months ended June 30, 2023, respectively, compared to net loss of $63,444 and $89,868 in the same periods last year, respectively.

- Diluted net loss per share was $0.83 and $1.35 for the three and six months ended June 30, 2023, respectively, compared to diluted net loss per share of $1.07 and $1.52 in the same period last year, respectively.

- Cash, cash equivalents and marketable securities increased $64,011 to $160,510 at June 30, 2023, from $96,499 at December 31, 2022. The increase in cash during the six months ended June 30, 2022 was driven primarily by net cash provided by financing activities of $125,986 from net proceeds of $134,151 received in exchange for issuing 12,205 ordinary shares and 4,706 Series B Preferred Shares in the April 3, 2023 public offering and net proceeds of $11,913 from the sale of ADSs through the ATM Program, offset by payments for the February 2023 Notes of $17,500, debt issuance costs of $4,357 and cash used in operating activities of $62,256.

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 Form 10-K for the year ended December 31, 2022 (the “2022 Form 10-K”). During the three months ended June 30, 2023, we identified additional significant accounting policies as described in Note 1 of our unaudited condensed consolidated financial statements of this Quarterly Report on Form 10-Q. 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. During the three months ended June 30, 2023, we have identified the following to be an additional critical accounting estimate because it had a material impact, or it has the potential to have a material impact, on our consolidated financial statements and because it requires us to make significant judgments, assumptions or estimates.

Revenue. We sell products to specialty pharmacies and consider those specialty pharmacies to be our customers. Under ASC 606, revenue from product sales is recognized when the customer obtains control of the product, which occurs typically upon receipt by the customer. Our gross product sales are subject to a variety of price adjustments to arrive at reported net product revenue. These adjustments include estimates of payment discounts, specialty pharmacy fees, patient assistance programs, rebates and product returns and are estimated based on contractual arrangements, historical trends, expected utilization of such products and other judgments and analysis.

Product Sales

Revenue from product sales are recognized when the customer obtains control of our product and our performance obligations are met, which occurs typically upon receipt of delivery to the customer. As is customary in the pharmaceutical industry, our gross product sales are subject to a variety of price adjustments in arriving at reported net product revenue. These adjustments include estimates of payment discounts, specialty pharmacy fees, patient assistance programs, rebates and product returns and are estimated based on contractual arrangements, historical trends, expected utilization of such products and other judgments and analysis.

Reserves for Variable Consideration

Revenues from product sales are recorded at the estimated net selling price, which includes reserves for estimated variable consideration to reduce gross product sales to net product revenue resulting from payment discounts, specialty pharmacy fees, patient assistance programs, rebates and product returns. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable if the amount is payable to the customer. The reserves are classified as a liability if the amount is payable to a party other than a customer. Where appropriate, these estimated reserves take into consideration relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, historical trends, current and expected patient demand and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates to reduce gross selling price to net selling price. The actual net selling price ultimately may differ from our estimates.

Payment Discounts and Specialty Pharmacy Fees

Payment discounts and specialty pharmacy fees represent the estimated obligations resulting from contractual commitments with our customers. We offer customers discounts off of list price and fees for the distribution of our products. Reserves for these discounts and fees are established in the same period that the related revenue is recognized, resulting in a reduction of gross product sales and accounts receivable.

Patient Assistance Programs

We offer certain patient assistance programs. We have multiple programs to assist patients, including patient assistance programs, a free product program, and co-pay assistance programs. We estimate a reserve for these programs primarily based on expected utilization by patients. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of gross product sales.

Rebates

Rebates represent the estimated obligations resulting from agreements with payors. We estimate a reserve for rebates based on contractual rates, estimates regarding our expectations of future utilization rates and channel inventory data. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of gross product sales.

Product Returns

We maintain a returns policy that offers customers a right to return product within a defined period before and after the expiration date of that product. We record the estimate of product returns as a reduction of gross product sales in the period the related product revenue was recognized.

Except as set forth above, there have been no material changes in our critical accounting estimates from those disclosed in the “Critical Accounting Estimates” section of the Management’s Discussion & Analysis in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 29, 2023.

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, 2023 and 2022, respectively:

Comparative Statements of Loss	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Change 2023 vs. 2022 $	Change 2023 vs. 2022 %
Net product revenue	$ 1,496	$ —	$ 1,496	n/a
Cost of products sold	36	—	36	n/a
Gross profit	1,460	—	1,460	
Operating expenses:				
Research and development expenses	4,223	4,541	(318)	(7.0)%
Selling, general and administrative expenses	46,778	21,804	24,974	114.5 %
Restructuring expense	—	3,592	(3,592)	(100.0)%
Total operating expense	51,001	29,937	21,064	70.4 %
Operating loss	(49,541)	(29,937)	(19,604)	(65.5)%
Investment and other income, net	623	192	431	224.5 %
Interest expense	(2,295)	(3,506)	1,211	34.5 %
Loss on extinguishment of debt	(13,129)	—	(13,129)	n/a
Loss before income taxes	(64,342)	(33,251)	(31,091)	(93.5)%
Income tax provision	90	30,193	(30,103)	99.7 %
Net loss	$ (64,432)	$ (63,444)	$ (988)	(1.6)%
Net loss per share - diluted	$ (0.83)	$ (1.07)	$ 0.24	22.4 %

The following is a summary of our financial results (in thousands, except per share amounts) for the six months ended June 30, 2023 and 2022, respectively:

Comparative Statements of Loss	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Change 2023 vs. 2022 $	Change 2023 vs. 2022 %
Net product revenue	$ 1,496	$ —	$ 1,496	n/a
Cost of products sold	36	—	36	n/a
Gross profit	1,460	—	1,460	n/a
Operating expenses:				
Research and development expenses	8,053	11,532	(3,479)	(30.2)%
Selling, general and administrative expenses	71,246	43,439	27,807	64.0 %
Restructuring expense	—	3,592	(3,592)	(100.0)%
Total operating expense	79,299	58,563	20,736	35.4 %
Operating loss	(77,839)	(58,563)	(19,276)	(32.9)%
Investment and other income, net	816	88	728	827.3 %
Interest expense	(5,554)	(5,523)	(31)	(0.6)%
Loss on extinguishment of debt	(13,129)	—	(13,129)	n/a
Loss before income taxes	(95,706)	(63,998)	(31,708)	(49.5)%
Income tax (benefit) provision	(490)	25,870	(26,360)	101.9 %
Net loss	$ (95,216)	$ (89,868)	$ (5,348)	(6.0)%
Net loss per share - diluted	$ (1.35)	$ (1.52)	$ 0.17	11.2 %

Gross Margin:	Three and Six Months Ended June 30, 2023	2022	Change 2023 vs. 2022 $	%
Net product revenue	$ 1,496	$ —	$ 1,496	n/a
Cost of products sold	36	—	36	n/a
Gross margin	$ 1,460	$ —	$ 1,460	n/a
Gross margin as a percentage of net product revenue	98 %	n/a	98 %	n/a

Net product revenue was $1,496 during the three and six months ended June 30, 2023. LUMRYZ was approved by the FDA on May 1, 2023 and we began shipping product to our customers in June 2023. Gross margin as a percentage of net product revenue was 98%, driven by the sale of inventory that was expensed as research and development prior to FDA approval.

Research and Development Expenses:	Three Months Ended June 30, 2023	2022	Change 2023 vs. 2022 $	%
Research and development expenses	$ 4,223	$ 4,541	$ (318)	(7.0)%

Research and development expenses decreased $318 or 7.0% during the three months ended June 30, 2023 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 $700. The decrease in research and development expense was offset by a $500 cumulative adjustment for certain compensation awards tied to the achievement of performance conditions, which became probable in the period.

Research and Development Expenses:	Six Months Ended June 30, 2023	2022	Change 2023 vs. 2022 $	%
Research and development expenses	$ 8,053	$ 11,532	$ (3,479)	(30.2)%

Research and development expenses decreased $3,479 or 30.2% during the six months ended June 30, 2023 as compared to the same period in the prior year. This decrease was driven by lower API purchases of $3,300 and lower pre-commercial product related costs of $300, the majority of which were purchased in the three months ended March 31, 2022. The decrease in research and development expense was offset by a $500 cumulative adjustment for certain compensation awards tied to the achievement of performance conditions, which became probable in the period.

Selling, General and Administrative Expenses:	Three Months Ended June 30, 2023	2022	Change 2023 vs. 2022 $	%
Selling, general and administrative expenses	$ 46,778	$ 21,804	$ 24,974	114.5 %

Selling, general and administrative expenses increased $24,974 or 114.5% during the three months ended June 30, 2023 as compared to the same period in the prior year. This increase was driven by higher legal fees of $6,900, higher marketing and market research activities of $5,500, higher costs associated with the commercial launch of LUMRYZ of $2,600, higher compensation costs of $3,000, and an increase in regulatory expenses of $800. Selling, general, and administrative expense also includes a $7,800 cumulative adjustment for certain compensation awards tied to the achievement of performance conditions, which became probable in the period.

In the prior period, we incurred costs of approximately $5,100 related to the exchange of $117,375 of our February 2023 Notes for a new series of its October 2023 Notes that did not recur in the current period. In the prior period, we realized benefit from the reversal of approximately $2,300 of previously recorded compensation costs for employees affected by the 2022 Corporate Restructuring Plan that did not recur in the current period.

Selling, General and Administrative Expenses:	Six Months Ended June 30, 2023	2022	Change 2023 vs. 2022 $	%
Selling, general and administrative expenses	$ 71,246	$ 43,439	$ 27,807	64.0 %

Selling, general and administrative expenses increased $27,807 or 64.0% during the six months ended June 30, 2023 as compared to the same period in the prior year. This increase was driven by higher legal fees of $8,600, higher marketing and market research activities of $3,900, higher costs associated with the commercial launch of LUMRYZ of $3,500, and higher compensation costs of $2,600 due to increased headcount. Selling, general, and administrative expense in the six months ended June 30, 2023 includes a $7,800 cumulative adjustment for certain compensation awards tied to the achievement of performance conditions, which became probable in the period. We also incurred costs related to financing activities of approximately $1,300 in the current period.

In the prior period, we incurred costs of approximately $5,450 related to the exchange of $117,375 of our February 2023 Notes for a new series of its October 2023 Notes that did not recur in the current period. In the prior period, we realized benefit from the reversal of approximately $2,300 of previously recorded compensation costs for employees affected by the 2022 Corporate Restructuring Plan that did not recur in the current period.

Investment and Other Income, net:	Three Months Ended June 30, 2023	2022	Change 2023 vs. 2022 $	%
Investment and other income, net	$ 623	$ 192	$ 431	224.5 %

Investment and other income, net increased $431 or 224.5% during the three months ended June 30, 2023 as compared to the same period in the prior year. This increase was driven by higher interest income of approximately $400.

Investment and Other Income, net:	Six Months Ended June 30, 2023	2022	Change 2023 vs. 2022 $	%
Investment and other income, net	$ 816	$ 88	$ 728	827.3 %

Investment and other income, net increased $728 or 827.3% during the six months ended June 30, 2023 as compared to the same period in the prior year. This increase was driven by higher net realized losses during the six months ended June 30, 2022 of approximately $700.

Interest Expense:	Three Months Ended June 30, 2023	2022	Change 2023 vs. 2022 $	%
Interest expense	$ (2,295)	$ (3,506)	$ 1,211	(34.5)%

Interest expense decreased $1,211 or 34.5% during the three months ended June 30, 2023 as compared to the same period in the prior year. This decrease was driven by a $1,300 decrease in amortization of debt discount and debt issuance costs as a result of the extinguishment of $96,188 of our October 2023 Notes. See *Note 6: 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.

Loss on extinguishment of debt:	Three and Six Months Ended June 30, 2023	2022	Change 2023 vs. 2022 $	%
Loss on extinguishment of debt	$ (13,129)	$ —	$ (13,129)	n/a

Over the course of April 3 and April 4, 2023, we completed an exchange of $96,188 of our $117,375 October 2023 Notes for $106,268 of new April 2027 Notes. We accounted for the exchange of the October 2023 Notes for the April 2027 Notes as an extinguishment of $96,188 of our October 2023 Notes. We recorded a loss on the extinguishment of $13,129 as a result of the exchange. See *Note 6: 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.

	Three Months Ended June 30,		Change 2023 vs. 2022	
Income Tax Provision:	**2023**	**2022**	**$**	**%**
Income tax provision	$ 90	$ 30,193	$ (30,103)	99.7 %
Percentage of loss before income taxes	(0.1)%	(90.8)%		

The income tax provision was $90 for the three months ended June 30, 2023 resulting in an effective tax rate of (0.1)%. 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 change in the effective tax rate for the three months ended June 30, 2023 when compared to the same period in 2022, is primarily driven by the valuation allowances recorded against net deferred tax assets established in the second quarter of 2022.

	Six Months Ended June 30,		Change 2023 vs. 2022	
Income Tax (Benefit) Provision:	**2023**	**2022**	**$**	**%**
Income tax (benefit) provision	$ (490)	$ 25,870	$ (26,360)	101.9 %
Percentage of loss before income taxes	0.5 %	(40.4)%		

The income tax benefit was $490 for the six months ended June 30, 2023 resulting in an effective tax rate of 0.5%. 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 change in the effective tax rate for the six months ended June 30, 2023 when compared to the same period in 2022, is primarily driven by the valuation allowances recorded against net deferred tax assets established in the second quarter of 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:

	Six Months Ended June 30,		Change 2023 vs. 2022	
Net cash (used in) provided by:	**2023**	**2022**	**$**	**%**
Operating activities	$ (62,256)	$ (48,135)	$ (14,121)	(29.3)%
Investing activities	(87,842)	54,299	(142,141)	(261.8)%
Financing activities	125,986	(2,794)	128,780	(4,609.2)%

Operating Activities

Net cash used in operating activities was $62,256 and $48,135 for the six months ended June 30, 2023 and 2022, respectively. Net cash used in operating activities for the six months ended June 30, 2023 was driven by net loss of $95,216, offset by favorable changes in working capital of $6,974 driven by an increase in accrued expenses and favorable non-cash adjustments of $25,986 due to the loss on extinguishment of debt and share-based compensation expense. For the six months ended June 30, 2022, net cash used in operating activities 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.

Investing Activities

Net cash used in investing activities was $87,842 for the six months ended June 30, 2023. Net cash provided by investing activities was $54,299 for the six months ended June 30, 2022. Net cash used in investing activities for the six months ended

June 30, 2023 was due to net purchases of marketable securities over proceeds received from the excess of sales of $87,842 as a result of investing the proceeds of our financing activities. 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.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2023 of $125,986 was a result of net proceeds of $134,151 received in exchange for issuing 12,205 ordinary shares and 4,706 Series B Preferred Shares in the April 3, 2023 public offering and net proceeds of $11,913 from the sale of ADSs through the ATM Program, offset by payments for the February 2023 Notes of $17,500 and debt issuance costs of $4,357. Net cash used in financing activities for the six months ended June 30, 2022 of $2,794 related to payment of $4,803 of debt issuance fees associated with the completed exchange of $117,375 of its February 2023 Notes for a new series of its Exchangeable Senior Notes due October 2, 2023, partially offset by $2,009 of proceeds from stock option exercises and employee share purchase plan issuances.

Risk Management

The adequacy of our cash resources depends on the outcome of certain business conditions including the cost of our LUMRYZ commercial launch plans, our cost structure, and other factors set forth in “Risk Factors” within Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC on March 29, 2023. To complete the LUMRYZ 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.

We believe our existing cash, cash equivalents and marketable securities provides sufficient capital to meet our operating, debt service and capital requirements for the next twelve months following the date of this Quarterly Report.

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, 2023 and December 31, 2022, 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 11: Commitments and Contingencies - Litigation* to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

We are subject to interest rate risk as a result of 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' equity (deficit). 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, 2023 would have had an immaterial impact on net loss for the three and six months ended June 30, 2023.

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 consolidated statements of loss. As of June 30, 2023, 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, 2023.

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 products. 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, 2023. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future (especially if inflation rates continue to rise) due to an impact on the costs to conduct clinical trials, the costs to commercially launch LUMRYZ, labor costs we incur to attract and retain qualified personnel, and other operational costs. Inflationary costs could adversely affect our business, financial condition and results of operations.

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, 2023, 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, 2023.

Other Changes in Internal Controls

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, 2023 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 11: Commitments and Contingencies - Litigation* to the Company's unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q is incorporated by reference herein.

ITEM 1A. RISK FACTORS.

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, 2022 filed with the SEC on March 29, 2023.

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.

During the three months ended June 30, 2023, none of the Company's directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934) adopted, terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

ITEM 6. EXHIBITS.

Exhibit No.	Description
10.1‡*	Fourth Amendment to Sublease Agreement, dated as of May 31, 2023, between Avadel Management Corporation and R.G. Brinkmann Company
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, 2023	By:	*/s/ Gregory J. Divis* Gregory J. Divis *Chief Executive Officer* *(Duly Authorized Officer* and *Principal Executive Officer)*
Date: August 9, 2023	By:	*/s/ Thomas S. McHugh* Thomas S. McHugh *Senior Vice President and Chief Financial Officer* *(Duly Authorized Officer* and *Principal Financial and Accounting Officer)*

FOURTH AMENDMENT TO SUBLEASE AGREEMENT

This Fourth Amendment to Sublease Agreement (this "Fourth Amendment"), is made and entered into effective as of the 31st day of May, 2023 (the "Effective Date"), by and between Avadel Management Corporation, a Delaware corporation (f/k/a Eclat Pharmaceuticals LLC) (hereinafter called "Sublessor") and R.G. Brinkmann Company d/b/a Brinkmann Constructors, a Missouri corporation (collectively, hereinafter called "Subtenant").

WITNESSETH:

WHEREAS, Sublessor and Subtenant are parties to that certain Sublease Agreement dated April 30, 2019, as amended by that certain First Amendment to Sublease Agreement dated February 6, 2020, as amended by that certain Second Amendment to Sublease Agreement dated May 10, 2021, and as further amended by that certain Third Amendment to Sublease Agreement dated April 13, 2022 (collectively, the "Sublease") for the Subleased Premises located at Suite 190, 16640 Chesterfield Grove Road, Chesterfield, Missouri 63 005 consisting of approximately 4,164 square feet of space and as more particularly described in the Sublease; and

WHEREAS, Sublessor and Subtenant desire to amend the Sublease as provided herein.

NOW, THEREFORE, in consideration of the foregoing, and for other good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, Sublessor and Subtenant do hereby agree as follows:

1. Capitalized Terms. Capitalized terms used in this Fourth Amendment, to the extent not otherwise defined herein, shall have the same meaning as in the Sublease.

2. Term. Notwithstanding anything to the contrary contained therein, the Term of the Sublease shall be extended to expire on April 30, 2025.

3. Rent. Notwithstanding anything to the contrary contained herein, from June 1, 2023 through May 31, 2024, Subtenant shall pay to Sublessor as gross rent under this Sublease the sum of $10,454.00 per month (approx. $30.12/sf annual rent). From June 1, 2024 through April 30, 2025, the monthly gross rent paid by Subtenant to Sublessor under this Sublease shall be increased from the amount set forth in the previous sentence by the Consumer Price Index (CPI).

4. Execution. For purposes of executing this Fourth Amendment, a document (or signature page thereto) signed and transmitted by facsimile machine or email is to be treated as an original document. The signature of any party thereon, for purposes hereof, is to be considered as an original signature, and the documents transmitted is to be considered to have the same binding effect as an original signature on an original document. At the request of any party, any facsimile or email document is to be re-executed in original form by the parties who executed the facsimile or email document. No party may raise the use of a facsimile machine or email or the fact that any signature was transmitted through the use of a facsimile or email as a defense to the enforcement of this Fourth Amendment or any amendment or other document executed in compliance with this Paragraph.

5. Counterparts. This Fourth Amendment may be executed by the parties on any number of separate counterparts, and all such counterparts so executed constitute one agreement binding on all the parties notwithstanding that all the parties are not signatories to the same counterpart.

6. Entire Agreement. This Fourth Amendment constitutes the entire agreement among the parties pertaining to the subject matter hereof and supersedes all prior agreements, letters of intent, understandings, negotiations and discussions of the parties, whether oral or written.

7. Successors and Assigns. All provisions of this Fourth Amendment are binding upon, inure to the benefit of, and are enforceable by or against, the parties and their respective heirs, executors, administrators or other legal representatives and permitted successors and assigns.

8. Conflict. In the event of any conflict between the terms of this Fourth Amendment and the terms of the original Sublease, the terms of this Fourth Amendment shall control.

9. Full Force and Effect. As modified by this instrument, the Sublease remains in full force and effect.

[signature page follows]

IN WITNESS WHEREOF, the parties hereto have hereunto executed this Fourth Amendment as of the Effective Date.

SUBLESSOR:
Avadel Management Corporation, a Delaware corporation
By: /s/ Jerad G. Seurer
Name: Jerad G. Seurer
Title: Director

SUBTENANT:
R.G. Brinkmann Company d/b/a Brinkmann Constructors, a Missouri corporation
By: /s/ Brian D. Satterthwaite
Name: Brian D. Satterthwaite
Title: CEO

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, 2023	/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, 2023

/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, 2023 (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 (15 U.S.C. 78m or 78*o*(d)), 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, 2023

/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, 2023 (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 (15 U.S.C. 78m or 78*o*(d)), 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, 2023

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