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

# FORM 10-Q

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

For the quarterly period ended: September 30, 2024

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**<br>**Dublin 2 D02 T380**<br>**Ireland** | N/A |
| (Address of Principal Executive Office and Zip Code) | (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 |
|---|---|---|
| Ordinary Shares, nominal value $0.01 per share | AVDL | 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 November 8, 2024, 96,361,528 ordinary shares, nominal value $0.01 each, of the Company were outstanding.

**TABLE OF CONTENTS**



NOTE REGARDING TRADEMARKS

We own various trademark registrations and applications, and unregistered trademarks, including, but not limited to, AVADEL™, LUMRYZ™ and RYZUP™. 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 X, formerly known as 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 X 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 commercialize LUMRYZ (sodium oxybate) in the United States ("U.S.") for the treatment of cataplexy or excessive daytime sleepiness ("EDS") in adults with narcolepsy and in the pediatric narcolepsy population seven years and older;
- 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 produce LUMRYZ or deliver sufficient quantities of such 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 including the incurrence of convertible or other indebtedness, issuance of equity or royalty-based financings, or through strategic financing or commercialization partnerships;
- Our expectations regarding the pricing and reimbursement and the extent to which patient financial 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 commercialization of LUMRYZ in the U.S.;
- The potential impacts of 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;
- The potential impacts due to global political instability and conflicts, such as terrorism, civil unrest, war and natural disasters in foreign countries on our business, financial condition and results of operations; 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 February 29, 2024 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Net product revenue | $ 50,025 | $ 7,014 | $ 118,707 | $ 8,510 |
| Cost of products sold | 6,155 | 117 | 10,465 | 153 |
| Gross profit | 43,870 | 6,897 | 108,242 | 8,357 |
| Operating expenses: | | | | |
| Research and development expenses | 3,803 | 2,849 | 10,922 | 10,902 |
| Selling, general and administrative expenses | 40,394 | 39,158 | 136,422 | 110,404 |
| Total operating expense | 44,197 | 42,007 | 147,344 | 121,306 |
| Operating loss | (327) | (35,110) | (39,102) | (112,949) |
| Investment and other income, net | 610 | 903 | 3,114 | 1,719 |
| Interest expense | (2,820) | (1,978) | (8,128) | (7,532) |
| Loss on extinguishment of debt | — | — | — | (13,129) |
| Loss before income taxes | (2,537) | (36,185) | (44,116) | (131,891) |
| Income tax provision (benefit) | 88 | 89 | (327) | (401) |
| Net loss | $ (2,625) | $ (36,274) | $ (43,789) | $ (131,490) |
| | | | | |
| Net loss per share - basic | $ (0.03) | $ (0.41) | $ (0.46) | $ (1.71) |
| Net loss per share - diluted | $ (0.03) | $ (0.41) | $ (0.46) | $ (1.71) |
| | | | | |
| Weighted average number of shares outstanding - basic | 96,300 | 89,380 | 94,720 | 76,931 |
| Weighted average number of shares outstanding - diluted | 96,300 | 89,380 | 94,720 | 76,931 |

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Net loss | $ (2,625) | $ (36,274) | $ (43,789) | $ (131,490) |
| Other comprehensive income (loss), net of tax: | | | | |
| Foreign currency translation income (loss) | 429 | (303) | 119 | (120) |
| Net other comprehensive (loss) income, net of income tax expense of $0, $0, $0, and $0, respectively | (16) | 295 | (754) | 511 |
| Total other comprehensive income (loss), net of tax | 413 | (8) | (635) | 391 |
| Total comprehensive loss | $ (2,212) | $ (36,282) | $ (44,424) | $ (131,099) |

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

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

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| | *(Unaudited)* | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 28,582 | $ 31,167 |
| Marketable securities | 37,225 | 73,944 |
| Accounts receivable, net | 37,102 | 12,103 |
| Inventories | 16,097 | 10,380 |
| Prepaid expenses and other current assets | 8,252 | 6,608 |
| Total current assets | 127,258 | 134,202 |
| Property and equipment, net | 469 | 585 |
| Operating lease right-of-use assets | 1,930 | 2,591 |
| Goodwill | 16,836 | 16,836 |
| Other non-current assets | 11,760 | 10,484 |
| Total assets | $ 158,253 | $ 164,698 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Current portion of operating lease liability | $ 725 | $ 934 |
| Accounts payable | 7,917 | 11,433 |
| Accrued expenses | 33,907 | 24,227 |
| Other current liabilities | 234 | 261 |
| Total current liabilities | 42,783 | 36,855 |
| Long-term operating lease liability | 1,216 | 1,690 |
| Royalty financing obligation | 34,437 | 32,760 |
| Other non-current liabilities | 5,154 | 5,654 |
| Total liabilities | 83,590 | 76,959 |
| Shareholders' equity: | | |
| Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; zero issued and outstanding at September 30, 2024 and 5,194 issued and outstanding at December 31, 2023 | — | 52 |
| Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 96,338 issued and outstanding at September 30, 2024 and 89,825 issued and outstanding at December 31, 2023 | 963 | 898 |
| Additional paid-in capital | 886,787 | 855,452 |
| Accumulated deficit | (789,285) | (745,496) |
| Accumulated other comprehensive loss | (23,802) | (23,167) |
| Total shareholders' equity | 74,663 | 87,739 |
| Total liabilities and shareholders' equity | $ 158,253 | $ 164,698 |

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

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

| | Ordinary shares | | Preferred shares | | Additional | Accumulated | Accumulated other comprehensive | Total shareholders' |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | paid-in capital | deficit | loss | equity |
| **Balance, December 31, 2023** | 89,825 | $ 898 | 5,194 | $ 52 | $ 855,452 | $ (745,496) | $ (23,167) | $ 87,739 |
| Net loss | — | — | — | — | — | (27,342) | — | (27,342) |
| Other comprehensive loss | — | — | — | — | — | — | (589) | (589) |
| Issuance of common stock under at-the-market offering program, net of issuance costs | 640 | 6 | — | — | 9,244 | — | — | 9,250 |
| Amortization of deferred issuance costs | — | — | — | — | (3) | — | — | (3) |
| Conversion of preferred stock into ordinary shares | 5,194 | 52 | (5,194) | (52) | — | — | — | — |
| Exercise of stock options | 390 | 3 | — | — | 3,353 | — | — | 3,356 |
| Employee share purchase plan share issuance | 48 | 1 | — | — | 583 | — | — | 584 |
| Share-based compensation expense | — | — | — | — | 5,389 | — | — | 5,389 |
| **Balance, March 31, 2024** | 96,097 | $ 960 | — | $ — | $ 874,018 | $ (772,838) | $ (23,756) | $ 78,384 |
| Net loss | — | — | — | — | — | (13,822) | — | (13,822) |
| Other comprehensive income | — | — | — | — | — | — | (459) | (459) |
| Exercise of stock options | 107 | 1 | — | — | 722 | — | — | 723 |
| Share-based compensation expense | — | — | — | — | 5,462 | — | — | 5,462 |
| **Balance, June 30, 2024** | 96,204 | $ 961 | — | $ — | $ 880,202 | $ (786,660) | $ (24,215) | $ 70,288 |
| Net loss | — | — | — | — | — | (2,625) | — | (2,625) |
| Other comprehensive income | — | — | — | — | — | — | 413 | 413 |
| Exercise of stock options | 69 | 1 | — | — | 399 | — | — | 400 |
| Employee share purchase plan share issuance | 65 | 1 | — | — | 776 | — | — | 777 |
| Share-based compensation expense | — | — | — | — | 5,410 | — | — | 5,410 |
| **Balance, September 30, 2024** | 96,338 | $ 963 | — | $ — | $ 886,787 | $ (789,285) | $ (23,802) | $ 74,663 |

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

| | Ordinary shares | | Preferred shares | | Additional paid-in | Accumulated | Accumulated other comprehensive | Total shareholders' |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | capital | deficit | loss | equity (deficit) |
| **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 |
| Net loss | — | — | — | — | — | (36,274) | — | (36,274) |
| Other comprehensive loss | — | — | — | — | — | — | (8) | (8) |
| Mandatory Exchange of April 2027 Notes, net of issuance costs | — | — | — | — | (350) | — | — | (350) |
| Exercise of stock options | 44 | — | — | — | 261 | — | — | 261 |
| Employee share purchase plan share issuance | 33 | — | — | — | 201 | — | — | 201 |
| Share-based compensation expense | — | — | — | — | 3,127 | — | — | 3,127 |
| **Balance, September 30, 2023** | 89,398 | $ 893 | 5,194 | $ 52 | $ 851,865 | $ (716,710) | $ (25,951) | $ 110,149 |

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2024** | **2023** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (43,789) | $ (131,490) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 2,013 | 1,784 |
| Amortization of debt discount and debt issuance costs | — | 2,796 |
| Share-based compensation expense | 16,261 | 12,293 |
| Loss on extinguishment of debt | — | 13,129 |
| Other adjustments | (1,052) | (349) |
| Net changes in assets and liabilities | | |
| Accounts receivable | (24,999) | (6,239) |
| Inventories | (5,255) | (5,286) |
| Prepaid expenses and other current assets | (1,615) | (3,203) |
| Accounts payable & other current liabilities | (3,516) | 3,837 |
| Accrued expenses | 9,680 | 10,621 |
| Other assets and liabilities | (2,508) | 1,625 |
| Net cash used in operating activities | (54,780) | (100,482) |
| | | |
| **Cash flows from investing activities:** | | |
| Proceeds from sales of marketable securities | 298,829 | 125,498 |
| Purchases of marketable securities | (261,962) | (203,519) |
| Net cash provided by (used in) investing activities | 36,867 | (78,021) |
| | | |
| **Cash flows from financing activities:** | | |
| Proceeds from April 2023 public offering, net of issuance costs | — | 134,149 |
| Payments for February 2023 Notes | — | (17,500) |
| Payments for debt issuance costs | — | (4,357) |
| Proceeds from royalty purchase agreement | — | 30,000 |
| Proceeds from issuance of shares off the at-the-market offering program | 9,250 | 11,913 |
| Proceeds from stock option exercises and employee share purchase plan | 5,840 | 2,241 |
| Net cash provided by financing activities | 15,090 | 156,446 |
| | | |
| Effect of foreign currency exchange rate changes on cash and cash equivalents | 238 | (113) |
| | | |
| Net change in cash and cash equivalents | (2,585) | (22,170) |
| Cash and cash equivalents at January 1, | 31,167 | 73,981 |
| Cash and cash equivalents at September 30, | $ 28,582 | $ 51,811 |
| | | |
| Supplemental disclosures of cash flow information: | | |
| Interest paid | $ 3,305 | $ 4,520 |

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

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

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

LUMRYZ 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 and in the pediatric narcolepsy population seven years and older.

LUMRYZ was approved by the U.S. Food and Drug Administration ("FDA") on May 1, 2023 for the treatment of cataplexy or EDS in adults with narcolepsy. The FDA also granted Orphan Drug Exclusivity ("ODE") to LUMRYZ for treatment of cataplexy or EDS in adults with narcolepsy for a period of seven years until May 1, 2030. In June 2023, the Company commercially launched LUMRYZ in the U.S for the treatment of cataplexy or EDS in adults living with narcolepsy. LUMRYZ was approved by the FDA for use in the treatment of cataplexy or EDS in the pediatric narcolepsy population seven years and older on October 16, 2024, and was granted ODE through October 16, 2031.

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 who prescribe the drug must be specially certified; pharmacies that dispense the drug must be specially certified; and the drug must be dispensed only to patients who have enrolled in the LUMRYZ REMS and completed all REMS requirements, including 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.

The adequacy of the Company's cash resources depends on the outcome of certain business conditions including the cost of the Company's ongoing LUMRYZ commercialization activities, the Company's cost structure, and other factors set forth in "Risk Factors" within Part I, Item 1A of the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on February 29, 2024 (the "Annual Report on Form 10-K").

*Ordinary Shares*

Effective April 15, 2024, the Company's ordinary shares, nominal value $0.01 per share ("ordinary shares"), became directly listed on the Nasdaq Stock Market. The Company caused a mandatory exchange of its American Depositary Shares ("ADSs") for the underlying ordinary shares on a one-for-one basis. Accordingly, the Bank of New York Mellon ("BNY Mellon"), as Depositary for the ADSs, issued a notice of termination of its American Depository Receipt program ("ADR Program") of ADSs to the registered holders of ADSs according to the requirements under the deposit agreement dated January 3, 2017 (the "Deposit Agreement") among the Company, BNY Mellon and holders of ADSs. The Deposit Agreement terminated on July 15, 2024.

*At-the-Market Offering Program*

On May 8, 2024, the Company entered into an Open Market Sale Agreement℠ (the "Sales Agreement") with Jefferies LLC ("Jefferies") pursuant to which the Company may offer and sell its ordinary shares, from time to time, with respect to an at-the-market offering program ("ATM Program") under which Jefferies will act as sales agent. The Sales Agreement provides that Jefferies will be entitled to aggregate compensation for its services of an amount up to 3.0% of the gross proceeds of any ordinary shares sold through Jefferies under the Sales Agreement. The Sales Agreement replaces the Company's previous Open Market Sale Agreement℠ with Jefferies, dated February 4, 2020 (the "ADS Sales Agreement"), which provided for the sale of ADSs by the Company. The Company terminated the ADS Sales Agreement upon effectiveness of the Sales Agreement

following the mandatory exchange of the ADSs and the direct listing of the ordinary shares on the Nasdaq Stock Market on April 15, 2024.

The ordinary shares will be offered and sold pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-267198), filed with the SEC on August 31, 2022, as amended, and declared effective by the SEC on September 12, 2022, as supplemented by the prospectus supplement dated May 8, 2024 (the "Prospectus Supplement"). The Company may offer and sell ordinary shares having an aggregate offering price of up to $100,000 under the Prospectus Supplement.

Prior to termination, the Company issued and sold 640 ordinary shares pursuant to the ADS Sales Agreement during the three months ended March 31, 2024, resulting in net proceeds to the Company of approximately $9,250. The Company has not issued or sold ordinary shares pursuant to the ADS Sales Agreement or the Sales Agreement subsequent to March 31, 2024.

*Preferred Shares*

In March 2024, 5,194 Series A Non-Voting Convertible Preferred Shares and Series B Non-Voting Convertible Preferred Shares ("Series B Preferred Shares") were converted to 5,194 ordinary shares at the option of the holders. Accordingly, there were no preferred shares issued and outstanding at September 30, 2024.

***Basis of Presentation.*** The unaudited condensed consolidated balance sheet as of September 30, 2024 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 Annual Report on Form 10-K.

Certain prior year amounts have been reclassified within the notes to the unaudited condensed consolidated financial statements to condense line items of the same nature to conform with the current year presentation.

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.

***Newly Issued Climate-Related Disclosure Rule.*** In March 2024, the SEC issued a final rule requiring public companies to disclose climate-related information in their registration statements and annual reports. For large accelerated filers, the initial disclosure rules are effective for annual periods for the year ending December 31, 2025. In April 2024, the SEC voluntarily stayed the final rule pending the completion of judicial review by the Court of Appeals for the Eighth Circuit. The Company is monitoring the development of litigation related to the SEC's rule, and is currently evaluating the effects of the final rule on its disclosures, processes and procedures.

**NOTE 2: Revenue Recognition**

The Company's source of net product revenue during the three and nine months ended September 30, 2024 and 2023 consists solely of sales of LUMRYZ in the U.S.

For the three and nine months ended September 30, 2024 and 2023, three customers accounted for 100% of sales. The following table presents a summary of the percentage of total gross sales to customers:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| **Sales by Customer:** | **2024** | **2023** | **2024** | **2023** |
| Caremark | 43 % | 41 % | 46 % | 41 % |
| Accredo | 39 % | 38 % | 37 % | 38 % |
| Optum | 18 % | 21 % | 17 % | 21 % |

**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. 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 Measurement*, 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 September 30, 2024 | | | As of December 31, 2023 | | |
|---|---|---|---|---|---|---|
| **Fair Value Measurements:** | **Level 1** | **Level 2** | **Level 3** | **Level 1** | **Level 2** | **Level 3** |
| Marketable securities (see *Note 4*) | | | | | | |
| Government securities - U.S. | $ 37,225 | $ — | $ — | $ 73,944 | $ — | $ — |
| Total assets | $ 37,225 | $ — | $ — | $ 73,944 | $ — | $ — |

A review of fair value hierarchy classifications is conducted on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification for certain financial assets or liabilities. During the periods ended September 30, 2024 and December 31, 2023, there were no transfers in and out of Level 3. During the three and nine months ended September 30, 2024 and 2023, 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 unaudited condensed consolidated balance sheets at carrying value, which approximates fair value due to their short-term nature.

*Royalty Financing Obligation*

As of September 30, 2024, the carrying value of the royalty financing obligation under the Royalty Purchase Agreement ("RPA") approximated its fair value and was measured using the estimates of forecasted net product revenue based on 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 (Level 3 inputs). See *Note 6: Royalty Financing Obligation* for additional information regarding the Company's royalty financing obligation.

**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, net of income tax effects. As of September 30, 2024, 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 September 30, 2024 and December 31, 2023:

| | September 30, 2024 | | | |
|---|---|---|---|---|
| **Marketable Securities:** | **Adjusted Cost** | **Unrealized Gains** | **Unrealized Losses** | **Fair Value** |
| Government securities - U.S. | $ 37,025 | $ 200 | $ — | $ 37,225 |
| Total | $ 37,025 | $ 200 | $ — | $ 37,225 |

| | December 31, 2023 | | | |
|---|---|---|---|---|
| **Marketable Securities:** | **Adjusted Cost** | **Unrealized Gains** | **Unrealized Losses** | **Fair Value** |
| Government securities - U.S. | $ 72,990 | $ 954 | $ — | $ 73,944 |
| Total | $ 72,990 | $ 954 | $ — | $ 73,944 |

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

The Company recognized gross realized gains of $331 and no gross realized losses for three months ended September 30, 2024. The Company recognized gross realized gains of $1,438 and no gross realized losses for the nine months ended September 30, 2024.

The Company recognized gross realized gains of $268 and gross realized losses of $283 for the three months ended September 30, 2023. The Company recognized gross realized gains of $269 and gross realized losses of $344 for the nine months ended September 30, 2023.

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 September 30, 2024:

| | Maturities | | | | |
|---|---|---|---|---|---|
| **Marketable Debt Securities:** | **Less than 1 Year** | **1-5 Years** | **5-10 Years** | **Greater than 10 Years** | **Total** |
| Government securities - U.S. | $ 37,225 | $ — | $ — | $ — | $ 37,225 |
| Total | $ 37,225 | $ — | $ — | $ — | $ 37,225 |

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

**NOTE 5: Inventories**

The principal categories of inventories were comprised of the following:

| Inventory: | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Raw materials and supplies | $ 4,048 | $ 5,291 |
| Work in process | 3,117 | 2,037 |
| Finished goods | 8,932 | 3,052 |
| Total | $ 16,097 | $ 10,380 |

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: Royalty Financing Obligation**

On March 29, 2023, the Company and Avadel CNS Pharmaceuticals, LLC entered into the RPA with RTW Investments, L.P. ("RTW") 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 became available to use, at the Company's election, when the Company achieved quarterly net revenue of $25,000 prior to the quarter ending June 30, 2024. The Company allowed the second tranche to expire on August 31, 2024 and paid a one-time commitment fee of $2,000 to RTW in accordance with the terms of the RPA.

On August 1, 2023, the Company received the first tranche of $30,000. The Company is required to make quarterly royalty payments calculated as 3.75% of worldwide net product revenue of LUMRYZ, up to a total payback of $75,000.

The RPA is recorded as a royalty financing obligation on the unaudited condensed consolidated balance sheets based on the Company's evaluation of the terms of the RPA. The accounts receivable and inventory balances of LUMRYZ are pledged as collateral for the RPA. There are no subjective acceleration clauses or provisions, and there are no covenants in violation or other clauses that would cause the full amount of the royalty financing obligation to be callable. As such, the RPA is recorded as a long-term obligation on the unaudited condensed consolidated balance sheets.

The Company imputes interest using the effective interest method and records interest expense based on the unamortized royalty financing obligation. The Company's estimate of the interest rate under the RPA is based primarily on forecasted net revenue and the calculated amounts and timing of net royalty payments to reach the total payback of $75,000. As of September 30, 2024 and December 31, 2023 the effective interest rate is estimated as 30.4%. The Company will account for changes in the imputed interest rate resulting from changes in forecasted net product revenue using the prospective method.

The following table shows the activity within the royalty financing obligation account:

| Royalty Financing Obligation: | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Royalty financing obligation – beginning balance | $ 33,490 | $ — |
| Receipt of the first tranche of the royalty financing obligation | — | 30,000 |
| Accretion of imputed interest expense on royalty financing obligation | 8,128 | 3,743 |
| Less: royalty payments made to RTW | (3,305) | (253) |
| Less: one-time payment for expiration of second tranche | (2,000) | — |
| Royalty financing obligation – ending balance | 36,313 | 33,490 |
| Less: royalty payable to RTW classified within accrued expenses | (1,876) | (730) |
| Royalty financing obligation, non-current | $ 34,437 | $ 32,760 |

The accretion of imputed interest expense is reflected as interest expense in the unaudited condensed consolidated statements of loss. For the three months ended September 30, 2024 and 2023, the total interest expense related to the royalty financing obligation was $2,820 and $1,404, respectively. For the nine months ended September 30, 2024 and 2023, the total interest expense related to the royalty financing obligation was $8,128 and $1,404, respectively.

**NOTE 7: Income Taxes**

The income tax provision was $88 for the three months ended September 30, 2024 resulting in an effective tax rate of (3.5)%. The income tax provision was $89 for the three months ended September 30, 2023 resulting in an effective tax rate of (0.2)%.

The income tax benefit was $327 for the nine months ended September 30, 2024 resulting in an effective tax rate of 0.7%. The income tax benefit was $401 for the nine months ended September 30, 2023 resulting in an effective tax rate of 0.3%. The change in the effective income tax rate for the nine months ended September 30, 2024, as compared to the prior period in 2023, is primarily driven by the release of uncertain tax positions due to the expiration of their statute of limitations in the current period compared to a state tax refund received during the first quarter of the prior period.

The Company's cumulative loss position was significant negative evidence in assessing the need for a valuation allowance on its deferred tax assets. Given the weight of objectively verifiable historical losses from operations, the Company has 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: | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Prepaid and other expenses | $ 6,306 | $ 4,373 |
| Other | 1,946 | 2,235 |
| Total | $ 8,252 | $ 6,608 |

| Other Non-Current Assets: | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Right of use assets at contract manufacturing organizations | $ 11,361 | $ 9,905 |
| Other | 399 | 579 |
| Total | $ 11,760 | $ 10,484 |

| Accrued Expenses: | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Accrued professional fees | $ 14,694 | $ 11,961 |
| Reserves for variable consideration | 11,599 | 4,044 |
| Accrued compensation | 5,738 | 7,492 |
| Royalty payable to RTW | 1,876 | 730 |
| Total | $ 33,907 | $ 24,227 |

| Other Non-Current Liabilities: | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Tax liabilities | $ 5,068 | $ 5,407 |
| Other | 86 | 247 |
| Total | $ 5,154 | $ 5,654 |

**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 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 4.50% exchangeable senior notes due February 2023 ("February 2023 Notes") and the 4.50% exchangeable senior notes due October 2023 ("October 2023 Notes", together, 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 had a choice to settle the conversion obligations under the 2023 Notes in cash, shares or any combination of the two. The Company utilized the if-converted method to reflect the impact of the conversion of the 2023 Notes, unless the result was anti-dilutive. This method assumed the conversion of the 2023 Notes into shares of the Company's ordinary shares and reflected the elimination of the interest expense related to the 2023 Notes. The Company had no 2023 Notes remaining as of December 31, 2023. See *Note 10: Long-term debt* of the audited consolidated financial statements included in our Annual Report on Form 10-K for further details.

The dilutive effect of the stock options, restricted share awards, 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| Net Loss Per Share: | 2024 | 2023 | 2024 | 2023 |
| Net loss | $ (2,625) | $ (36,274) | $ (43,789) | $ (131,490) |
| Weighted average shares: | | | | |
| Basic shares | 96,300 | 89,380 | 94,720 | 76,931 |
| Effect of dilutive securities—employee and director equity awards outstanding, preferred shares and 2023 Notes | — | — | — | — |
| Diluted shares | 96,300 | 89,380 | 94,720 | 76,931 |
| Net loss per share - basic | $ (0.03) | $ (0.41) | $ (0.46) | $ (1.71) |
| Net loss per share - diluted | $ (0.03) | $ (0.41) | $ (0.46) | $ (1.71) |

Potential ordinary shares of 1,437 and 2,509 were excluded from the calculation of weighted average shares for the three months ended September 30, 2024 and 2023, respectively, and 1,168 and 5,336 were excluded from the calculation of weighted average shares for the nine months ended September 30, 2024 and 2023, respectively, because their effect was considered to be anti-dilutive or they were related to shares from performance share unit awards for which the contingent vesting condition had

not been achieved. For the three and nine months ended September 30, 2024 and 2023, 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, net of tax effects:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| **Accumulated Other Comprehensive Loss:** | **2024** | **2023** | **2024** | **2023** |
| Foreign currency translation adjustment: | | | | |
| Beginning balance | $ (24,431) | $ (24,269) | $ (24,121) | $ (24,452) |
| Net other comprehensive income (loss) | 429 | (303) | 119 | (120) |
| Balance at September 30, | $ (24,002) | $ (24,572) | $ (24,002) | $ (24,572) |
| | | | | |
| Unrealized gain (loss) on marketable debt securities, net | | | | |
| Beginning balance | $ 216 | $ (1,674) | $ 954 | $ (1,890) |
| Net other comprehensive (loss) income, net of income tax expense of $0, $0, $0, and $0 respectively | (16) | 295 | (754) | 511 |
| Balance at September 30, | $ 200 | $ (1,379) | $ 200 | $ (1,379) |
| Accumulated other comprehensive loss at September 30, | $ (23,802) | $ (25,951) | $ (23,802) | $ (25,951) |

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 contingent fees and expenses) will be incurred and such costs can be reasonably estimated. At September 30, 2024 and December 31, 2023, 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, which was revised on August 28, 2023. The parties' Second Supplemental Joint Claim Construction Brief was filed on October 10, 2023, and a *Markman* hearing regarding the disputed terms occurred on November 1, 2023. The Court issued its claim construction order on December 15, 2023.

On August 15, 2023, Avadel renewed its request to consolidate this litigation with the litigation described in the Avadel Complaint below. On November 3, 2023, the Court denied that request.

On November 30, 2023, the parties filed cross motions for summary judgment. The parties filed opposition briefs on December 15, 2023. The parties filed reply briefs on December 22, 2023. On February 14, 2024, the Court denied the parties' summary judgment motions. On February 15, 2024, the Court held its Pretrial Conference. Trial was held from February 26, 2024 to March 1, 2024 (the "February Patent Trial"). On March 4, 2024, the jury returned a verdict of no infringement for U.S. Patent No. 10758488 and infringement of U.S. Patent No. 11147782, with damages of $234, which are included in the unaudited condensed consolidated balance sheets in accrued expenses at September 30, 2024.

On March 19, 2024, the Court issued a Supplemental Scheduling Order setting a June 4, 2024 hearing on Jazz's request for a permanent injunction or ongoing royalty. Briefing on Jazz's request closed on May 20, 2024, and the hearing was held June 4, 2024. On August 27, 2024, the Court issued an opinion and order enjoining Avadel from infringing claim 24 of U.S. Patent No. 11147782. That injunction excluded certain categories of conduct, including permitting Avadel to continue making, using and selling LUMRYZ for the treatment of narcolepsy and for use in ongoing clinical trials and studies. The August 27, 2024 opinion and order also granted Jazz's motion for an ongoing royalty, pending additional briefing on the appropriate royalty rate. That briefing closed on September 23, 2024. While a future ongoing royalty is pending briefing and a decision by the Court, the Company recorded an estimated liability for a royalty based on information available as of September 30, 2024. It is reasonably possible that a change in the estimate may occur pending the Court's decision on the appropriate royalty rate. On August 28, 2024, Avadel filed a notice of appeal concerning the August 27, 2024 injunction (the "Patent Appeal"). On September 3, 2024, Avadel moved in District Court to stay the August 27, 2024 injunction pending appeal. Briefing on that motion closed on September 16, 2024. On September 24, 2024, the District Court denied Avadel's motion to stay the injunction pending appeal.

On September 6, 2024, Avadel moved in the U.S. Court of Appeals for the Federal Circuit to stay the injunction pending appeal. Briefing on that motion closed on September 27, 2024. On October 2, 2024, the Federal Circuit granted Avadel's motion in part, staying the injunction with respect to Avadel's initiating new clinical trials or studies.

On September 10, 2024, the Federal Circuit entered a briefing schedule concerning the Patent Appeal. On September 30, 2024, Avadel filed its opening brief. Jazz filed its response brief November 7, 2024. Avadel's reply brief is due November 18, 2024. On October 2, 2024, the Federal Circuit placed the Patent Appeal on the February 2025 oral argument calendar.

*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. On May 24, 2024, the Court denied Jazz's Motions to Dismiss. On June 7, 2024, Jazz filed its Answer to Avadel's Counterclaims.

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 January 23, 2024, the parties submitted a stipulation to extend the case schedule. On January 24, 2024, the Court ordered an extension of the case schedule, including i) completion of fact discovery by June 20, 2024 and ii) a deadline for case dispositive motions by January 31, 2025. On January 24, 2024, the Court issued an order setting a pretrial conference for October 30, 2025 and a 5-day trial to begin on November 3, 2025. On April 22, 2024, the parties submitted a stipulation extending certain pretrial deadlines, including i) extending completion of fact discovery to September 27, 2024 and ii) extending the deadline for case dispositive motions to April 4, 2025.

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 closed on August 10, 2023. On March 13, 2024, Jazz filed a Supplemental Motion to Stay, pending the resolution of the post-trial briefing and any appeals from the February Patent Trial. On May 24, 2024, the Court denied Jazz's Motions to Stay. On June 7, 2024, Jazz filed a Motion for Reargument or in the Alternative to Certify an Appeal. Avadel filed its opposition brief on June 28, 2024. Jazz filed its reply brief on July 12, 2024. On September 25, 2024, Jazz sought leave to file a supplemental brief in support of its Motion to Stay. On October 4, 2024 the Court granted leave to Jazz to file its supplemental brief, which Jazz filed on October 7, 2024. Avadel filed its response on October 21, 2024, and Jazz subsequently filed its reply on October 28, 2024. Jazz's motion remains pending.

*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.

On August 15, 2023, the parties submitted competing proposed scheduling orders, and Avadel requested consolidation with the above First Jazz Complaint litigation. That request for consolidation was denied on November 3, 2023.

On November 17, 2023, the parties submitted an updated joint proposed scheduling order. On January 30, 2024, the parties agreed to a 6-week stay of discovery and submitted a proposed stipulation extending certain case deadlines to accommodate the same. On February 9, 2024, the parties submitted an updated proposed scheduling order consistent with that stipulation, setting the close of fact discovery for August 9, 2024 and a trial date of December 15, 2025. That proposed scheduling order remains pending before the Court as of the date of this Quarterly Report on Form 10-Q.

On March 19, 2024, Jazz filed a Motion to Stay, pending the resolution of the post-trial briefing and any appeals from the February Patent Trial. On May 24, 2024, the Court denied Jazz's Motions to Stay.

On May 10, 2024, the Court issued a scheduling order establishing timing for litigation events including i) completion of fact discovery by August 9, 2024, ii) a deadline for case dispositive motions of May 30, 2025, and iii) a 5-day jury trial beginning December 15, 2025. On June 11, 2024, the Court entered a stipulation by the parties extending certain case deadlines, including i) extending close of fact discovery to November 1, 2024 and ii) dispositive motions to July 18, 2025.

On July 3, 2024, Jazz filed an Amended Answer to the Avadel Complaint. The Amended Answer generally denies the allegations set forth in the Avadel Complaint and includes various affirmative defenses.

On September 6, 2024, Avadel and Jazz stipulated to stay proceedings pending the resolution of the Patent Appeal above, which the Court entered on September 9, 2024.

*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. On August 14, 2023, the DC Court entered a scheduling order establishing timing for litigation events including early summary judgment briefing closing December 22, 2023. On September 22, 2023, Jazz filed its Motion for Summary Judgment. On October 20, 2023, the FDA and Avadel filed their Cross Motions for Summary Judgment. Briefing on the parties' motions closed January 4, 2024. On February 14, 2024, the DC Court set a hearing for oral argument on the parties' motions for February 27, 2024. On February 21, 2024, the DC Court rescheduled the oral argument to April 9, 2024. On April 2, 2024, the DC Court rescheduled the oral argument to May 10, 2024. On May 10, 2024, the DC Court heard oral arguments on the parties' motions. On October 30, 2024, the DC Court granted FDA and Avadel's Motions for Summary Judgment with respect to the sole count in Jazz's complaint and denied Jazz's Motion for Summary Judgment regarding the same.

***Material Commitments***

Other than commitments disclosed in *Note 14: Contingent Liabilities and Commitments* to the Company's consolidated financial statements included in the Annual Report on Form 10-K, there were no other material commitments outside of the normal course of business.

**NOTE 12: Subsequent Events**

LUMRYZ was approved by the FDA for use in the treatment of cataplexy or EDS in the pediatric narcolepsy population seven years and older on October 16, 2024, and was granted ODE through October 16, 2031.

## 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 February 29, 2024 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 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 and in the pediatric narcolepsy population seven years and older.

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 FDA on May 1, 2023 for the treatment of cataplexy or EDS in adults with narcolepsy. The FDA also granted seven years of Orphan Drug Exclusivity ("ODE") 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, the 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. LUMRYZ was approved by the FDA for use in the treatment of cataplexy or EDS in the pediatric narcolepsy population seven years and older on October 16, 2024, and was granted ODE through October 16, 2031.

In approving LUMRYZ, the FDA required a REMS for LUMRYZ to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in adults with narcolepsy outweigh the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion of the drug. Under this REMS, healthcare providers who prescribe the drug must be specially certified; pharmacies that dispense the drug must be specially certified; and the drug must be dispensed only to patients who have enrolled in the LUMRYZ REMS and completed all REMS requirements, including documentation of safe use conditions.

Numerous 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. We currently have numerous Orange Book listed patents.

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. Positive top line data from the REST-ON trial were announced on April 27, 2020.

Additionally, our open-label extension/switch study of LUMRYZ ("RESTORE") examined the long-term safety and maintenance of efficacy of LUMRYZ in patients with narcolepsy who participated in the REST-ON trial, as well as dosing and preference data for patients who switched from twice-nightly sodium oxybate to once-at-bedtime LUMRYZ, regardless of whether they participated in the REST-ON trial. 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 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 switching from twice-nightly oxybate formulations had a stable dose equal to their starting dose. Subsequent interim data showed a preference (94.0%) for the once-at-bedtime dosing regimen. The last patient visit occurred in October 2023.

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 disturbed nocturnal sleep ("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 over twenty years that sodium oxybate has been available.

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 narcolepsy Type 1 ("NT1") and Type 2 ("NT2") were also published, demonstrating consistent improvements regardless of narcolepsy type. A third plain language summary has been published; most recently evaluated the improvements of LUMRYZ on DNS.

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

Avadel has initiated a Phase 3 pivotal trial in Idiopathic Hypersomnia ("IH"), REVITALYZ, which is a double-blind, placebo-controlled, randomized withdrawal, multicenter Phase 3 study designed to evaluate the efficacy and safety of LUMRYZ given as a once-at-bedtime dose, in IH. The study will enroll approximately 150 adults who are diagnosed with IH. On July 31, 2024, we announced that the first patient was dosed in this study.

The primary objective of REVITALYZ is to demonstrate reduction in daytime sleepiness as measured by the primary endpoint, change in total score of the Epworth Sleepiness Scale at Week 14. Secondary endpoints will evaluate the effect of LUMRYZ on additional efficacy parameters including patient and clinician impression of change, idiopathic hypersomnia severity, and a measure of the functional outcomes of sleep.

***Ordinary Shares***

Effective April 15, 2024, our ordinary shares were listed directly on the Nasdaq Stock Market. We caused a mandatory exchange of our ADSs for the underlying ordinary shares on a one-for-one basis. Accordingly, the BNY Mellon, as Depositary for the ADSs, issued a notice of termination of its ADR Program of ADSs to the registered holders of ADSs according to the requirements under the Deposit Agreement among the Company, BNY Mellon and holders of ADSs. The Deposit Agreement terminated on July 15, 2024.

***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. LUMRYZ may face competition from manufacturers of generic twice-nightly sodium oxybate formulations. In January 2023, Hikma Pharmaceuticals plc, announced that it launched an authorized generic version of Jazz Pharmaceuticals plc's ("Jazz") Xyrem (sodium oxybate). In July 2023, Amneal Pharmaceuticals, Inc. announced that it launched an authorized generic version of Jazz's Xyrem (sodium oxybate).

- **Access to and Cost of Capital:** 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:** We have a recent history of generating losses from operations and expect to continue generating losses until revenues from the commercialization of LUMRYZ are sufficient to generate positive cash flow. LUMRYZ is the only commercialized product in our portfolio, and we will incur substantial expenses to continue our commercial launch of LUMRYZ.

***Financial Highlights***

Highlights of our consolidated results for the three and nine months ended September 30, 2024 are as follows:

- Net product revenue was $50,025 and $118,707 during the three and nine months ended September 30, 2024, respectively, compared to net product revenue of $7,014 and $8,510 for the three and nine months ended September 30, 2023. LUMRYZ was approved by the FDA on May 1, 2023 for the treatment of cataplexy or EDS in adults with narcolepsy and we began shipping product to our customers in June 2023.

- Gross profit was $43,870 and $108,242 during the three and nine months ended September 30, 2024, respectively, compared to gross profit of $6,897 and $8,357 for the three and nine months ended September 30, 2023. Cost of products sold increased during the three and nine months ended September 30, 2024 compared to the three and nine months ended September 30, 2023, due to higher sales of LUMRYZ and an estimated ongoing royalty on net product revenue in the current period. Prior period cost of products sold included a greater portion of inventory purchased or produced that was expensed as research and development prior to FDA approval.

- Total operating expense was $44,197 and $147,344 for the three and nine months ended September 30, 2024, respectively, compared to total operating expense of $42,007 and $121,306 for the three and nine months ended September 30, 2023, respectively. Selling, general and administrative expenses increased $1,236 and $26,018 during the three and nine months ended September 30, 2024 compared to the three and nine months ended September 30, 2023, driven by increased headcount and costs associated with the commercial launch of LUMRYZ and higher legal costs. Research and development expenses increased $954 during the three months ended September 30, 2024, compared to the three months ended September 30, 2023 due to new clinical work to evaluate the efficacy and safety of LUMRYZ given as a once-at-bedtime dose in IH, offset by lower pre-commercial related expenses.

- Operating loss was $327 and $39,102 for the three and nine months ended September 30, 2024, respectively, compared to operating loss of $35,110 and $112,949 in the same periods last year, respectively.

- Diluted net loss per share was $0.03 and $0.46 for the three and nine months ended September 30, 2024, respectively, compared to diluted net loss per share of $0.41 and $1.71 in the same periods last year, respectively.

- Cash, cash equivalents and marketable securities decreased to $65,807 at September 30, 2024 from $105,111 at December 31, 2023. The $39,304 decrease in cash, cash equivalents and marketable securities during the nine months ended September 30, 2024 was driven primarily by net cash used in operating activities of $54,780, offset by net proceeds of $9,250 from the sale of ADSs under the ADS Sales Agreement and $5,840 of proceeds from stock option exercises and employee share purchase plan issuances.

**Critical Accounting Estimates**

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

Our significant accounting policies are described in Note 1 of the audited consolidated financial statements included in our Annual Report on Form 10-K. The SEC suggests companies provide additional disclosure on those accounting policies considered most critical. The SEC considers an accounting policy to be critical if it is important to our financial condition and results of operations and requires significant judgments and estimates on the part of management in its application. Our estimates are often based on complex judgments, probabilities and assumptions that management believes to be reasonable, but that are inherently uncertain and unpredictable. It is also possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range of alternative estimated amounts. For a complete discussion of our critical accounting policies, see the "Critical Accounting Estimates" section of the Management's Discussion & Analysis in our Annual Report on Form 10-K filed with the SEC on February 29, 2024.

**Results of Operations**

The following is a summary of our financial results (in thousands, except per share amounts) for the three months ended September 30, 2024 and 2023:

| | Three Months Ended September 30, | | Change 2024 vs. 2023 | |
|---|---|---|---|---|
| **Comparative Statements of Loss** | **2024** | **2023** | **$** | **%** |
| Net product revenue | $ 50,025 | $ 7,014 | $ 43,011 | 613.2 % |
| Cost of products sold | 6,155 | 117 | 6,038 | 5,160.7 % |
| Gross profit | 43,870 | 6,897 | 36,973 | 536.1 % |
| Operating expenses: | | | | |
| Research and development expenses | 3,803 | 2,849 | 954 | 33.5 % |
| Selling, general and administrative expenses | 40,394 | 39,158 | 1,236 | 3.2 % |
| Total operating expense | 44,197 | 42,007 | 2,190 | 5.2 % |
| Operating loss | (327) | (35,110) | 34,783 | (99.1)% |
| Investment and other income, net | 610 | 903 | (293) | (32.4)% |
| Interest expense | (2,820) | (1,978) | (842) | 42.6 % |
| Loss before income taxes | (2,537) | (36,185) | 33,648 | (93.0)% |
| Income tax provision | 88 | 89 | (1) | (1.1)% |
| Net loss | $ (2,625) | $ (36,274) | $ 33,649 | (92.8)% |
| Net loss per share - diluted | $ (0.03) | $ (0.41) | $ 0.38 | (92.7)% |

The following is a summary of our financial results (in thousands, except per share amounts) for the nine months ended September 30, 2024 and 2023:

| | Nine Months Ended September 30, | | Change 2024 vs. 2023 | |
|---|---|---|---|---|
| **Comparative Statements of Loss** | **2024** | **2023** | **$** | **%** |
| Net product revenue | $ 118,707 | $ 8,510 | $ 110,197 | 1,294.9 % |
| Cost of products sold | 10,465 | 153 | 10,312 | 6,739.9 % |
| Gross profit | 108,242 | 8,357 | 99,885 | 1,195.2 % |
| Operating expenses: | | | | |
| Research and development expenses | 10,922 | 10,902 | 20 | 0.2 % |
| Selling, general and administrative expenses | 136,422 | 110,404 | 26,018 | 23.6 % |
| Total operating expense | 147,344 | 121,306 | 26,038 | 21.5 % |
| Operating loss | (39,102) | (112,949) | 73,847 | (65.4)% |
| Investment and other income, net | 3,114 | 1,719 | 1,395 | 81.2 % |
| Interest expense | (8,128) | (7,532) | (596) | 7.9 % |
| Loss on extinguishment of debt | — | (13,129) | 13,129 | (100.0)% |
| Loss before income taxes | (44,116) | (131,891) | 87,775 | (66.6)% |
| Income tax benefit | (327) | (401) | 74 | (18.5)% |
| Net loss | $ (43,789) | $ (131,490) | $ 87,701 | (66.7)% |
| Net loss per share - diluted | $ (0.46) | $ (1.71) | $ 1.25 | (73.1)% |

| | Three Months Ended September 30, | | Change 2024 vs. 2023 | |
|---|---|---|---|---|
| **Gross Profit:** | **2024** | **2023** | **$** | **%** |
| Net product revenue | $ 50,025 | $ 7,014 | $ 43,011 | 613.2 % |
| Cost of products sold | 6,155 | 117 | 6,038 | 5,160.7 % |
| Gross profit | $ 43,870 | $ 6,897 | $ 36,973 | 536.1 % |
| Gross profit as a percentage of net product revenue | 87.7% | 98.3% | | |

Net product revenue increased $43,011 during the three months ended September 30, 2024 as compared to the same period in the prior year. LUMRYZ was approved by the FDA on May 1, 2023 for the treatment of cataplexy or EDS in adults with narcolepsy and we began shipping product to our customers in June 2023. Cost of products sold increased $6,038 during the three months ended September 30, 2024 as compared to the same period in the prior year. The increase in cost of products sold during the period was due to higher sales of LUMRYZ and an estimated ongoing royalty on net product revenue in the current period. Prior period cost of products sold included a greater portion of inventory purchased or produced that was expensed as research and development prior to FDA approval.

| | Nine Months Ended September 30, | | Change 2024 vs. 2023 | |
|---|---|---|---|---|
| **Gross Profit:** | **2024** | **2023** | **$** | **%** |
| Net product revenue | $ 118,707 | $ 8,510 | $ 110,197 | 1,294.9 % |
| Cost of products sold | 10,465 | 153 | 10,312 | 6,739.9 % |
| Gross profit | $ 108,242 | $ 8,357 | $ 99,885 | 1,195.2 % |
| Gross profit as a percentage of net product revenue | 91.2% | 98.2% | | |

Net product revenue increased $110,197 during the nine months ended September 30, 2024 as compared to the same period in the prior year. LUMRYZ was approved by the FDA on May 1, 2023 for the treatment of cataplexy or EDS in adults with narcolepsy and we began shipping product to our customers in June 2023. Cost of products sold increased $10,312 during the nine months ended September 30, 2024 as compared to the same period in the prior year. The increase in cost of products sold during the period was due to higher sales of LUMRYZ and an estimated ongoing royalty on net product revenue in the current period. Prior period cost of products sold included more inventory purchased or produced that was expensed as research and development prior to FDA approval.

| | Three Months Ended September 30, | | Change 2024 vs. 2023 | |
|---|---|---|---|---|
| **Research and Development Expenses:** | **2024** | **2023** | **$** | **%** |
| Research and development expense | $ 3,803 | $ 2,849 | $ 954 | 33.5 % |

Research and development expenses increased $954 or 33.5% during the three months ended September 30, 2024 as compared to the same period in the prior year. This increase was driven by new clinical work during the period of $1,500 and higher compensation costs of $500 due to increased headcount, offset by lower pre-commercial related expenses of $1,000.

| | Three Months Ended September 30, | | Change 2024 vs. 2023 | |
|---|---|---|---|---|
| **Selling, General and Administrative Expenses:** | **2024** | **2023** | **$** | **%** |
| Selling, general and administrative expenses | $ 40,394 | $ 39,158 | $ 1,236 | 3.2 % |

Selling, general and administrative expenses increased $1,236 or 3.2% during the three months ended September 30, 2024 as compared to the same period in the prior year. This increase was driven by higher compensation costs of $2,700 due to increased headcount and higher costs associated with the commercial launch of LUMRYZ of $600, offset by lower legal costs of $2,300.

| | Nine Months Ended September 30, | | Change 2024 vs. 2023 | |
|---|---|---|---|---|
| **Selling, General and Administrative Expenses:** | **2024** | **2023** | **$** | **%** |
| Selling, general and administrative expenses | $ 136,422 | $ 110,404 | $ 26,018 | 23.6 % |

Selling, general and administrative expenses increased $26,018 or 23.6% during the nine months ended September 30, 2024 as compared to the same period in the prior year. This increase was driven by higher compensation costs of $13,200 due to increased headcount and higher costs associated with the commercial launch of LUMRYZ of $9,200, offset by $1,300 of costs related to financing activities incurred in 2023 that did not recur in the current period. The increase in selling, general and administrative expense for the nine months ended September 30, 2024 also includes $5,500 of nonrecurring fees associated with terminating our ADSs.

| | Three and Nine Months Ended September 30, | | Change 2024 vs. 2023 | |
|---|---|---|---|---|
| **Loss on Extinguishment of Debt:** | **2024** | **2023** | **$** | **%** |
| Loss on extinguishment of debt | $ — | $ (13,129) | $ 13,129 | (100.0)% |

Over the course of April 3 and April 4, 2023, we completed an exchange of $96,188 of our $117,375 4.50% exchangeable senior notes due October 2023 (the “October 2023 Notes”) for $106,268 of a new series of 6.0% exchangeable notes due April 2027 (the “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. On June 26, 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. See *Note 10: Long-term debt* of the audited consolidated financial statements included in our Annual Report on Form 10-K for further details.

**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:

| | Nine Months Ended September 30, | | Change 2024 vs. 2023 | |
|---|---|---|---|---|
| **Net cash (used in) provided by:** | **2024** | **2023** | **$** | **%** |
| Operating activities | $ (54,780) | $ (100,482) | $ 45,702 | 45.5 % |
| Investing activities | 36,867 | (78,021) | 114,888 | (147.3)% |
| Financing activities | 15,090 | 156,446 | (141,356) | (90.4)% |

***Operating Activities***

Net cash used in operating activities was $54,780 and $100,482 for the nine months ended September 30, 2024 and 2023, respectively. Net cash used in operating activities for the nine months ended September 30, 2024 was driven by net loss of $43,789 and unfavorable changes in working capital of $28,213, offset by favorable non-cash adjustments of $17,222 driven primarily by share-based compensation expense. For the nine months ended September 30, 2023, net cash used in operating activities was driven by net loss of $131,490, offset by favorable non-cash adjustments of $29,653 due to the loss on extinguishment of debt and share-based compensation expense and favorable changes in working capital of $1,355.

***Investing Activities***

Net cash provided by investing activities was $36,867 for the nine months ended September 30, 2024. Net cash used in investing activities was $78,021 for the nine months ended September 30, 2023. Net cash provided by investing activities for the nine months ended September 30, 2024 was due to net proceeds received from the excess of sales over purchases of marketable securities of $36,867. Net cash used in investing activities for the nine months ended September 30, 2023 was due to net purchases of marketable securities over proceeds received from the excess of sales of $78,021 as a result of investing the proceeds of our financing activities.

***Financing Activities***

Net cash provided by financing activities for the nine months ended September 30, 2024 of $15,090 was a result of net proceeds of $9,250 from the sale of ADSs under the ADS Sales Agreement and $5,840 of proceeds from stock option exercises and employee share purchase plan issuances. Net cash provided by financing activities for the nine months ended September 30, 2023 of $156,446 was a result of net proceeds of $134,149 received in exchange for issuing 12,205 ordinary shares and 4,706 Series B Preferred Shares in the April 3, 2023 public offering, proceeds of $30,000 received for the first tranche of the RPA, and net proceeds from the sale of ADSs under the ADS Sales Agreement of $11,913, offset by payments for the February 2023 Notes of $17,500 and debt issuance costs of $4,357.

***Risk Management***

The adequacy of our cash resources depends on the outcome of certain business conditions including the cost of our ongoing LUMRYZ commercialization activities, 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 February 29, 2024. We will need to commit substantial resources to support the commercialization of LUMRYZ 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 inflation, and rising interest rates, which may have a material adverse impact on our business.

We believe our existing cash, cash equivalents and marketable securities, along with cash anticipated from sales of LUMRYZ, provides sufficient capital to meet our operating, royalty obligation 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 September 30, 2024 and December 31, 2023, 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. 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 September 30, 2024 would have had an immaterial impact on net loss for the three and nine months ended September 30, 2024.

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 unaudited condensed consolidated statements of loss. As of September 30, 2024, 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 nine months ended September 30, 2024.

**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 nine months ended September 30, 2024. 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 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 September 30, 2024, the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to provide reasonable assurance that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on their evaluation, as of the end of the period covered by this Quarterly Report on Form 10-Q, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of September 30, 2024.

***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 September 30, 2024 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, 2023 filed with the SEC on February 29, 2024.

**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 September 30, 2024, 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 |
|---|---|
| 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: November 12, 2024

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

Date: November 12, 2024

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

**Exhibit 31.1**

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

I, Gregory J. Divis, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2024

/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: November 12, 2024

/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 September 30, 2024 (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: November 12, 2024

/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 September 30, 2024 (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: November 12, 2024

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